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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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

DAY 2 - BUILDING AND SUSTAINING RESILIENCE

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M E E T I N G

(1:00 p.m.)

DR. BLOCK: Good afternoon, supply chainers, and welcome to Day 2 of the Building Medical Device Supply Chain Resilience Public Workshop. I'm your host for the day, Frank Block. I'm with the All-Hazards Readiness, Response and Cybersecurity Team here at CDRH. We've been working very closely with the Resilient Supply Chain Program on medical device availability issues during the pandemic.

We had a great day yesterday. In our panel discussions and breakout groups, we explored the meaning of resilience in medical device supply chain, in addition to discussing potential opportunities to measure resilience. As a reminder, the Center for Devices and Radiological Health is hosting this public workshop to introduce the Resilient Supply Chain Program. Next slide, please.

The goal of this public workshop is to bring together participants from across the medical device ecosystem and discuss critical supply chain topics, as well as to explore opportunities to collaborate and enhance resilience within the medical device ecosystem. Next slide.

Here's a quick overview of the themes for this 3-day workshop. Yesterday we discussed the definition of resilience and how best to measure it. Today's theme is on building and sustaining medical device supply chain resilience. And on Thursday we'll explore mechanisms and vehicles to facilitate collaboration between the Resilient Supply Chain Program and the private sector. Next slide, please.

In today's program, we'll hear remarks from Tim Manning, the former COVID-19 supply coordinator for the White House, and we'll continue it in the afternoon with a panel discussion on innovative methods for mitigating future supply chain challenges. After the panel discussion, Dr. Tammy Beckham will provide our keynote on CDRH's Resilient Supply

Chain Program. Then some of us will take a short break and those signed up for breakout sessions will move into their breakout groups. At around 3:30 we'll welcome everyone back to hear a report-out of the key takeaways from the breakout discussions. Next slide, please.

Just a few reminders. Please send us your questions and comments using the webcast portal text bubble located on the bottom right, or through the workshop e-mail address shown here. We'll record and transcribe this webcast and the workshop docket will remain open for public comment until June 11th. Next slide, please.

This is a view of the text bubble that allows you to enter a question or comment during the webcast. Feel free to click on it and ask your question. Next slide.

Looking back to yesterday's key takeaways from our discussions on defining and measuring resilience, resilience means getting the right items to the right place with minimal time impact to patients and providers. Resilient supply chains need to adapt and recover from any challenges. They must tailor their characteristics uniquely to the specific material needs of the device.

Another takeaway of note is the need to prioritize and invest in existing relationships throughout the supply chain. Resilient supply chains must show flexibility and adaptability, as well as strong public-private collaboration through active and transparent communication. We'll be sure to continue the great discussion today as we focus on building and sustaining medical device supply chain resilience.

Next up, I'd like to turn it over to Dr. Tammy Beckham to introduce our next speaker.

Tammy.

DR. BECKHAM: Good afternoon. And thank you, Frank, for that. Next slide, please.

Today I'm going to introduce Dr. Tim Manning. Tim has worked on the front lines and at the senior-most levels of crisis and emergency management, homeland security and

resilience for nearly 30 years, most recently as the White House COVID-19 supply coordinator, helping to lead the U.S. government's response to the pandemic. In this role he helped to support the global industrial base and resolve supply chain challenges and logistics for the essential tools needed to respond to the pandemic. While at the White House Tim worked with major global manufacturers, NGOs, and partner governments around the world to further efforts to produce vaccines, therapeutics, medical devices, testing and diagnostics, PPE, and other supply chain challenges. He also led an effort in the space of 2 weeks to create covidtest.gov, a multibillion dollar operation of multiple U.S. government agencies offering home test delivery.

Tim previously served the entirety of the Obama administration as the Deputy Administrator of the Federal Emergency Management Agency for protection and national preparedness. Over his nearly 3-decade career, Tim has helped coordinate the response to countless emergencies and disasters throughout the United States and worked with partners around the globe. I am absolutely thrilled he is here today to share some thoughts with us and discuss advancing critical medical device supply chain resiliency, and please join me in welcoming Mr. Manning to the workshop today.

MR. MANNING: Thank you, Tammy. It's really wonderful to be with you and be with you all today. It's really just an honor to be able to spend some time talking about this really critical topic, you know, the theme of the overall effort here to foster resilience in the medical supply chain, medical device supply chain, in particular. You all attending here understand more than anyone else the criticality of building resilience into our healthcare supply chains.

And I want to take just a pause on that word here as we start today, on resilience, because we often also talk a lot about securing our supply chains or strengthening supply chains or, in other verbs, to modify our activities. But resilience is an important concept

here and goes further than any of those others and I think a much more thoughtful, much more visionary approach and I think fundamentally required going into the 21st century. Really, I think it's our only path forward because the world is unsettled, I think, much more than we give credit to on the day-to-day.

So there's a NOAA facility, a laboratory and observation facility on the top of Mauna Loa in Hawaii, on Big Island, and they measure carbon dioxide in the atmosphere every day, multiple times a day. And so today it was 421 parts per million. That is a record in the history that we have any record of over the last 300,000 years, that is the most we've seen at any time in 800,000 years and it is growing exponentially. I have a sample here that I got from there about 10 years ago and it was in the late -- kind of the upper 300s and I'm afraid it will never get back there. The five hottest years in our history that we have record for were in the last 5 years. The hottest 10 years in our history that we have record for were across the last 15.

And so with this shifting climate pattern come all kinds of other ways that the world shifting in a way that we are not expecting or accustomed to. That's going to cause shifting animal migration patterns, it's going to cause shifting human migration patterns, encroaching human settlements on permafrost; there's a wide range of things that are going to be changing in our world aside from all of the experiences that we've been dealing with over the last few years with the COVID response. And with this shifting and growing population, that population has an extraordinary level of mobility beyond anything we've seen in human history, as well.

And so while we've always had emerging novel diseases and we always will, we have a greater potential now for the intersection with animal populations that humans haven't interacted with in a very long time, if ever. We have an opportunity for humanity to move around more rapidly and more widespread than ever before. And so you put all that

together and I think my big concern here is that what we think of as our understanding of our world isn't exactly right because our base rate is wrong. You know, we look at flood zone mapping, we look at -- when we talk about climate, there's an old adage that climate is what you expect and weather is what you get. That understanding of what we expect is based on our experiences, based on the data that we have over the last 10, 50, 100, 150, 200, in some cases thousands of years of records.

But the world is changing so rapidly that that base rate is not necessarily representative of what the future is going to look like and we know that because we see a dramatic increase in shocks, global shocks, COVID-19 being probably the most severe in any of our lifetimes and certainly the most severe pandemic in over a hundred years, but we see other shocks on a regular basis and what we need -- and we can predict some going forward.

So what we really need to do in building a resilient healthcare community is build that resilience into our supply chains, into our industrial base, into our manufacturing capacity and kind of across our whole society, the ability to withstand those shocks, to be able to adapt and rebound and recover from them more quickly, because I think what we've seen through the COVID-19 pandemic, what's laid bare for us is that as we optimize for efficiency, we create brittle systems, we create systems that are extraordinarily efficient at reducing storage costs or reducing transportation costs or reducing manufacturing costs, but they build in single points of failure, they build in concentrations, geographic and geopolitical concentration of efforts that with minor disruptions cause massive ripples across our production capacities.

And so from the healthcare specific challenges that we've dealt with every day, you know, when I saw this every day working with all of you, we had in the disruption of the supply chain things specific into the healthcare industry, like single-use products for vaccine

manufacturing. But we also saw economy-wide impacts, things like thermoplastic resins for the manufacture of basic products as well as kind of some further through the supply chain and, of course, now semiconductors. These are things that move across the entire economy, not just in the healthcare space. And these shortages, as you have all experienced, have a wide range of proximal causes. We lump them all together as disruptions in the COVID-19 response, but the reality is those thermoplastic resin disruptions were largely a cause of weather events last year.

Now, the semiconductor shortages are largely a result of shifting economic patterns over the past many decades, certainly predating the COVID-19 response, and shifting consumer buying patterns.

So we have to look across the entire economy and we've got to look across the entire spectrum of potential shocks and think these things through as we build our 21st century approach to resilience in providing the essential critical tools to those who need them and to do this, we need all of society to buy in.

Now, we've made great progress across the COVID-19 response, the work that you've all done coming together to solve these problems, resolve these challenges and get the tools in the hands of the healthcare professionals that need them, really will be the stuff of legend for many decades to come. But we need to continue that progress and to continue that progress, we need everybody's buy-in.

There is going to be a requirement, a need for a shifting business model going forward, where there's an understanding that some things might cost a little bit more in order to account for that resilience to prevent those disruptions, to be able to continue to hold market share, to be able to continue to supply your products to customers and the response. You know, I think there's a great example in the Joplin tornados where there was a high level of planning on the part of one large retailer than another and that one large

retailer was open in days after that tornado where the other took a significant time to recover and get back into market, and that disruption caused a significant shift in the market share in that community, of course, for a long period of time. But another probably even better example is that we all buy insurance, fire insurance or disruption insurance, whether or not we have a fire, as a risk mitigation strategy.

And so we need to contextualize, kind of going forward, what the 21st century is going to look like for potential shocks and disruptions and that as a risk mitigation strategy, sometimes we may have to bear additional costs into more resilient supply chains, even if there's a more optimized way to continue forward from a cost perspective, as a risk mitigation perspective, to continue to the success of our lines of effort.

So these disruptions are going to continue, we've got geopolitical issues that are causing challenges to all of us every day and we've got geographical conditions, climate challenges we just discussed, public health responses, economic responses, all of these things pointing towards the need, the critical need, to think through the resiliency in everything it is that we do.

So with that, I'm going to pass it back over to Tammy and the panel, and thank you to FDA for launching this really critical effort and for all of you for participating in the sessions over these few days, and I really look forward to hearing from some spectacular panel members coming up here next in the session with their really amazing success stories over the past couple years and their thoughts about the future. So with that, back over to all of you. Thank you for having me, it's been a great pleasure and I look forward to the success of your work. Thank you.

DR. BLOCK: Thanks so much for your remarks, Tim.

Next up, we have our panel discussion and I'm thrilled to introduce Linda Ricci, the director of my team's division, the Division of All-Hazards Response, Science and Strategic

Partnerships, who will lead our panel discussion this afternoon. Ms. Ricci loves to work at the forefront of new technology. She began her career doing early AI computational modeling for control systems in military aircraft. During this work, she taught a course in neural networks in which the class formed a human-backed propagation network with a classmate serving the components of the network. From there, she went on to work as a software engineer in the medical device industry in Seattle before joining FDA. At FDA, she has several roles including branch chief within the Division of Cardiovascular Devices, and the Associate Director for Digital Health within the Office of Device Evaluation.

Ever the adrenaline junkie, Ms. Ricci is an avid snowmobiler and loves to drive her snowmobile very quickly on frozen lakes in Western Maryland. She's also a scuba diver and is planning to do some diving in Guadalupe to see some great white sharks, a trip that our office director, Dr. Schwartz, would highly recommend.

While at FDA, Ms. Ricci completed her M.P.H. and especially enjoyed her course work in epidemiology. Currently, she's the Director of the Division of All-Hazards Response, Science and Strategic Partnerships within the Center for Devices and Radiological Health, and has been working very closely on FDA's response to supply chain challenges experienced during the COVID-19 pandemic. Please join me in welcoming Linda Ricci.

Linda.

MS. RICCI: Thank you, Frank. And thanks to all of you for being here today and continuing our discussion on resilient supply chain. Especially a thank you to Tim for your excellent comments, we really appreciate you spending time with us today to discuss your experiences and get your perspective. During today's panel, we want to build off of our discussions that we had yesterday, as well as Tim's comments today, and today we really want to take time to explore methods for mitigating future challenges. Next slide, please.

So I would like to take this time to introduce the panelists. First, we have

Paige Ezernack. Among many roles, she is the chief of the newly established Defense Production Act Emergency Response Authorities Office, the DPA ERA, and that leads the DPA program at HHS. She also leads the HHS use of emergency response authorities including public health emergency declarations, the Public Readiness and Emergency Preparedness Act, and DPA-related authorities such as the scarce material designation and importing restrictions list. She is the senior subject matter expert on DPA for ASPR and a senior advisor to HHS Secretary's office on her past priority rating requests for which she has been instrumental to the COVID response.

Next, we have Anoush Frankian. She is a Senior Manager of Regulatory Affairs at Fujifilm Sonosite, where she is responsible for leading and managing regulatory strategy, compliance, and global submissions. In her 7 years at Fujifilm, she has supported operations and supply chain process development through regulatory intelligence and guidance. She also has been active with the Medical Imaging and Technology Alliance, or MITA, through her company's membership for the past 4 years.

Next, we have Dr. Monica Gorman. She is the Deputy Assistant Secretary for Manufacturing in which she directs the U.S. Department of Commerce's efforts to advance the global competitiveness of manufacturing industries through international trade and investment policies and promotion strategies. Dr. Gorman oversees the Office of Transportation and Machinery, the Office of Energy and Environmental Industries, and the Office of Health and Information Technology.

Next, we have Deb Kramer. Deb was appointed the Acting Assistant Under-Secretary for Health for Support in March of 2020. In this role, she serves as a principal advisor to the Under-Secretary for Health in the Department of Veterans Affairs. She is responsible for leading several programs within the nation's largest integrated healthcare system, the Veterans Health Administration, including healthcare environment and facilities,

procurement and logistics, healthcare technology management, Veterans Canteen Service, and the VA Logistics Redesign.

Next, we have Heather Mallinckrodt. She is the Associate Vice President for Contract and Program Services at Vizient. In her role within the medical, surgical, lab, and distribution team, Heather is responsible for the strategy and execution of national agreements which deliver significant value and operational improvement for products purchased by Vizient members. Heather led embedded contracting efforts for over 13 years before taking this role. The team she has led featured deep expertise in supply chain operations and development and fostered aggregated contracting.

Next, we have Abby Pratt. Abby is the Senior Vice President for Global Strategy and Analysis and the COVID-19 supply chain lead for AdvaMed. Abby leads AdvaMed's work in several global markets and since 2020, in March, has led the association's COVID-19 supply chain support for the med tech industry's efforts to navigate the critical supply shortages and transport disruptions to ramp up production. Previously, Abby served as an international trade specialist at the U.S. Department of Commerce with responsibilities for the medical device and pharmaceutical industries in China, Western Europe, and India, and spent several years in Japan working in international relations and trade policy.

Please join me in welcoming the panel to this discussion.

Much like the format that we used yesterday, there are a number of questions which will be directed to panel members for responses and in addition, if time allows, we will take questions from the audience. So please, as Frank has identified, feel free to ask questions as you hear the discussion that's ongoing.

So our first question for the panel. What processes and procedures or methods have you put in place to enhance resilience in your supply chain?

First, I would like to ask Anoush to address this question.

Anoush.

MS. FRANKIAN: Sure. And thank you, Linda, for introducing the panel members.

So I'll briefly touch on our responsibilities as medical device manufacturers and then move into providing a few examples of what my company is doing to enhance resilience within its supply chain.

So as medical device manufacturers, we are required to establish and maintain a quality management system which includes the company's policies, procedures, and work instructions for its various activities. This also includes planning and implementing purchasing controls and of course, establishing a framework for your supply chain management.

When working to enhance our supply chain processes, my company first works to identify stakeholders within its own supply chain, then the tools that are being used and the necessary steps required to either repurpose assets or adapt processes in response to an anticipated supply shortage or even competitive shift.

It is important to note that processes developed by manufacturers for their activities are subject to both internal and external audits, as well as inspections.

And regardless of how accurate a manufacturer's forecasting tools are, assessing and identifying risk through a risk management system is essential for enhancing resilience in supply chains. This means that, as OEMs, we already have innate incentives to control and mitigate supply chain challenges through risk management.

In addition to risk management, we are already identifying critical subcontractors, crucial suppliers, we are maintaining scorecards for all of our approved suppliers, and we are even qualifying alternate vendors for critical components and parts that are used in our system.

I'll wrap up by mentioning that we do need requirements from the regulators that

are least burdensome, and any new requirement or program should give manufacturers flexibilities and have a clear value proposition.

MS. RICCI: Thank you very much. Next, I'd like to turn it over to Abby to add additional comments.

MS. PRATT: Thanks so much, Linda. And also, just thank you to Tammy and the team for hosting this wonderful workshop, and also thanks to Tim for his excellent remarks to set the stage for today and for all of his support as the White House COVID-19 supply chain coordinator. His service and his value has been immense and I just want to thank him and we really miss him, along with you all at FDA.

You were able to hear from Anoush, one of our members, about what companies individually -- you know, great examples of what an individual company does to promote resilience and be well situated to address these kinds of challenges. But I wanted to talk a little bit about what AdvaMed, as an association, does, which is obviously very different as a membership and association than an individual company.

You know, what we really try to do, especially over the past couple years, is figure out how can we support our members to navigate these supply chain challenges and then ultimately, how do we ensure through that support that there's no disruption in the delivery of health care, because I think that's the real concern with all these different challenges that Tim articulated so well, that just layer upon another, is how do we adjust ourselves to these new dynamics and how do we stay nimble and agile.

So one thing we did as AdvaMed, at the start of the pandemic, is we created a supply chain task force that was comprised of experts from our member companies with responsibility for supply chain logistics and sourcing. We did not have a dedicated work stream prior to the pandemic. And so this was a critical group to sort of gather companies to compare notes and share best practices and then look at broadly across the industry

what's happening and how can we help our members navigate not only the pandemic response but all the impacts of the pandemic, and then other things that were layered upon. And I think one of the first things we did, and I think it's critical even to this day, is working with our members to navigate the Defense Production Act, first thinking about how it can be deployed effectively to ensure that continuity of patient care, to ensure that those resources and products are searched in the right way. But also, we worked very closely with our members in the government to ensure that there was no unintended consequences and that if there were ripple effects from rated orders, for example, that the government was aware of it, it could step in and tweak the DPA accordingly. So that was one critical partnership early on that continues to this day.

A couple other things that we do as a supply chain task force is constantly monitoring those critical shortages that Tim talked about and you'll hear from others, whether it's semiconductor chips, resins, paper, pulp, critical gases, we've been looking at and monitoring those shortages. And also on the transportation side, both domestically and globally, looking at all those backlogs, delays, and impacts of the container shortages, the congestion at the ports, the COVID outbreaks in China and Asia, and then also looking at the impact of geopolitical events such as the war with Ukraine and how is that going to impact the delivery of health care. So you know, looking at all these different elements, we've been able to put in place some key partnerships to address these challenges in a new and different way.

So for example, on the transportation side, we were able, as an association with our members, to work with the White House port envoy, with the Federal Maritime Commission, key port authorities and terminal operators, to figure out specific tools and mechanisms to expedite containers containing medical supplies and equipment. So we worked closely with the Port of LA, Long Beach, Oakland, and also on the East Coast, a

couple of the key ports there, to flag those containers and make sure that they were getting through the system as efficiently as possible amidst massive delays and backlogs. So that was just one example of a partnership that has sprung up in the past year or so.

And then on the shortages side, I mentioned we're not just monitoring and discussing and comparing notes, we're actively reaching out to the government and this team, in particular, to alert the federal government about potential upstream shortages that we're seeing. And I think the value in doing it through an association is it's not just one or two companies here or there, we're really able to sort of cast a wide net, hear from a broad range of companies, large and small, domestic, global, to get a sense of what are just sort of little warning signals versus what is a potential tsunami. And I would say semiconductor chips, in particular, has become a massive crisis for the med tech industry and has real implications for the delivery of patient care, and so just those partnerships of alerting and figuring out how can we work together that there are no delays, how can we work with suppliers to prioritize healthcare.

And I guess one theme I would just like to highlight, and then I'll pause and let the next person go, is that whether it's the transportation issues or the supply shortages, what we've seen consistently is, is that health care and the delivery of health care is a small piece. When it's transport, we can't compete with the Walmarts of the world. We're just a small amount of product, you know, floating around the world, coming into major ports. And the same thing when the supply shortages, the amount of chips that we need is just a drop in the bucket compared to the auto industry or other key sectors.

So even though health care is a small sliver of the more vast ecosystems, we're a small sector, we're obviously critical, critical to taking care of patients, critical to making sure hospitals and ambulances and nursing homes have what they need. So I think our true hope is that these partnerships lead to an awareness of the criticality of making sure that

health care is prioritized and that ultimately, the medical applications and the medical needs are prioritized amidst these challenges, whether they're transport or shortages or otherwise, as we build more resilience across the board.

So with that, Linda, maybe I'll pause and let others weigh in on this topic.

MS. RICCI: Thank you very much for your comments, Abby. We definitely, at the FDA, have appreciated working with all of the organizations, MITA, AdvaMed; you've been great partners.

Now I would like to turn to Heather and get her remarks on this first question.

Heather.

MS. MALLINCKRODT: Yes, thank you, Linda. Well, both Anoush and Abby brought some great points forward and great examples of things that have happened in the last 3 years and I just want to expand on some of those.

Healthcare supply chain, as you know, is a very dynamic environment and at Vizient, being a services-wide, data-enabled organization working closely with over 5,000 providers of all different sizes and geographic locations, we're continually evaluating how to best meet the provider needs and developing a resilient supply chain, developing a very robust supply chain, takes visibility, transparency, redundancy, resiliency, some of the topics that both of you have also touched on.

But one of the things that Vizient is doing, and we've really bucketed those in four different areas, providing supply chain insight, so including market insight to providers, arming providers with information needed to effectively navigate prior to challenges occurring, partnering with organizations like supply risk solutions to gather pedigree information to understand the true risk so the provider can determine their risk mitigation strategy. And then we saw, particularly during the pandemic, that when critical medical supplies are sourced, manufactured, packaged, labeled or even sterilized in a single

location, whether domestic or overseas or any combination, then a disruption at any point in the sequence could upend the entirety of the supply chain, so that visibility is very important, and then working on the development of a supplier scorecard in partnership with our suppliers that provide product to the members.

Second, a very well-wired source and process. We work in partnership with our suppliers and our manufacturers for further insight into upstream availability and alignment, also adjusting contracting expectations so that we work again with those partners, with those suppliers, those manufacturers, to get that earlier visibility, that earlier notification.

The third is actionable how-to's, so determining best practices. We've put together critical supply profiles for determining which categories not just are of issue today but may be of issue in the future, and making sure that we have a repository of readily available cross-reference for product. We understand where the raw materials are coming from, we understand which products may be of most concern.

And finally, Vizient partners, really, with a number of different industry organizations to collaborate, including different government agencies, as well, to provide information and to really help providers to navigate and to really create that robust supply chain.

MS. RICCI: Thank you, and I thank all three of you for those very thoughtful responses to that question, much appreciated.

Now moving on to Question 2. This goes along with looking at the totality of the ecosystem in supply chain, you know, in building off of Tim's remarks about we all need to be involved. So we have heard from the manufacturers, the trade organizations, and the distributors. Now we really want to take a look about, for the second question, about how do you work with organizations or the government to improve resilience.

Paige, can I ask you to lead us off there?

MS. EZERNACK: Sure, I'd be happy to. Thank you so much. And I'm looking forward to today's discussion, as well.

You know, I think following the COVID-19 pandemic and issuance of several executive orders, HHS was tasked for and expanded its role in supply monitoring. Our office has worked to establish open lines of communication with several interagency partners and private industry to really monitor and better understand pinch points and bottlenecks in the supply chain. I think prior to COVID, we had very limited visibility in that area, especially as we looked to leverage DPA authorities to help ensure that we had the supplies and materials that we needed to respond to any public health emergency, whether manmade or naturally occurring.

I think the DPA office has consistently communicated with the administration and relevant interagency partners, so within HHS and across the inter-agencies, departments like Defense and Commerce and DHS, Homeland Security, FEMA. They have very active DPA offices working with those groups to ensure that any effort to prioritize resources for HHS didn't conflict or contradict orders that were already priority rated through other departments. I think we leverage these relationships to really address vulnerabilities in the domestic and medical resource marketplace, and that meets the threshold of necessary and appropriate to support national defense.

We often hear DPA is the answer for just about any constraint or supply chain issue. However, there are very limited uses for priority rating or Defense Production Act authorities. In the Act, we're very limited to certain types of national defense needs and certain types of resources and HHS, of course, is health resources. But in order to maintain those open lines of communication, we established a resource mailbox at HHS so you could easily reach out to contact us. Today we primarily use those authorities to support a robust response to COVID-19 and address, most recently, the infant formula shortage.

So we work with FEMA to ensure that we also are executing the DPA authorities under Title VII, which is voluntary agreements, we wanted to create those agreements with private industry that we could leverage in order to better respond and better prepare to respond to public health events. These voluntary agreements allow the U.S. government to consult with private industry and that also lets us create associated plans and actions in which participants are granted leave from specific anti-trust laws. So these specific voluntary agreements have promoted public health supply chain resilience through increased communication between federal agencies and private industry and greater visibility into the available supply and current projected demand of critical PPE and medical resources to respond to COVID.

Moving forward, we intend to leverage all DPA authorities to open additional lines of communication with the private sector and to better understand current and future supply chain constraints that may be impacting the public health industrial base. Thank you.

MS. RICCI: Thank you. Yes, I know you all have been very busy during COVID and we definitely appreciate all of your efforts to help with the medical device supply chain constraints that we have seen.

Now I'd like to turn to Deb. I'd like to hear your response to this question, coming from the VA.

MS. KRAMER: Yeah. In terms of improving resilience, what I'd like to focus on is our work with the White House and our interagency partners to implement the National Strategy for a Resilient Public Health Supply Chain. That was released last July. That strategy aims to design, build, and sustain a long-term capability in the United States to manufacture supplies for future pandemics and other biological threats. It has three strategic goals: building a diverse, agile public health supply chain and sustaining long-term U.S. manufacturing capability; transforming the U.S. government's ability to monitor and

manage the public health supply chain through stockpiles, visibility and engagement with all of our partners in the private sector and the public sector; and establishing standard systems in governance to manage the supply chain and ensure the fair, equitable, and effective allocation of scarce resources.

The work over the last two and a half years, since last July, in working and developing the strategy and now implementing it, and the 29 actions required by that strategy and the work over the last two and a half years for COVID response has really gone far in building stronger working relationships among the interagency federal partners, Homeland Security, DoD, VA, and HHS in particular. And that's going to pay off in big dividends later on, especially as we go through and formalize these relationships so that the folks that follow behind us with the pandemic that comes in another 10 or 15 years don't have to reinvent the wheel.

Back to you, Linda.

MS. RICCI: Thank you very much, very thoughtful comments, really appreciate that and I appreciate your perspective from the VA.

Next, I'd like to move on to Question 3. Where do you see opportunities to increase supply chain visibility and improve demand forecasting?

I would like to lead this off with Monica from the Department of Commerce. Monica.

DR. GORMAN: Great, thank you so much, Linda. I have really appreciated hearing from all of the different panelists to such important perspectives on this topic and I think, just as everybody has said, COVID-19 really has highlighted just these critical economic and national security issues that are present in so many of our supply chains and it's not an overstatement to say that they are among some of our most urgent challenges. So very timely panel today.

I do want to take a step back for a moment and just note, I think, as we've heard from Paige and from Deb, the Biden-Harris administration is taking a whole-of-government approach and having me here from Commerce, as well, just adds to that. It is crucial that we have a whole-of-government approach to address these challenges. And our work is being guided, first and foremost, by Executive Order 14017 on America's supplies chains that the President issued in February '21, just after taking office. That order stresses the need for the United States to build resilient, diverse, and secure supply chains.

Under that order, last June, just about a year ago exactly, we released 400-day reviews on semiconductors, batteries, critical minerals, and pharmaceuticals. Those are available on the White House website. I would encourage anybody who hasn't had a chance to please take a look at them. Commerce and my team, in particular, led the report on semiconductors and I'll talk about that more in a minute.

And then this past February there were six 1-year industrial-based assessments also published by each of the agencies that led them. Commerce, again, co-led with DHS the report on the information and communications technology sector. All of these reports offer an assessment of the risk and then a roadmap to how we're going to address them.

So we've certainly seen, and it's been mentioned by others, the impacts of the semiconductor shortages, in particular, have had a significant impact on the medical technology industry. The semiconductors are essential either to the manufacture and functioning of these technologies or they're crucial in overall health therapies.

So one of the reports recommends -- there's a number of different aspects that we're pursuing right now. First and foremost is investment in our domestic manufacturing base that is absolutely truly in semiconductors where there is legislation right now on the Hill that we're hoping to see passed that will invest in semiconductor manufacturing here. But it's also strengthening our leadership in research and development, it's ensuring that

we have the workforce of tomorrow to build the products that we need here, and it's really increasing our information sharing and coordination with our international partners. We know that we can't do this alone, we can't do it alone as a government in the United States, we also cannot do it alone just as the United States, we need to work with our partners.

So we know that the private sector is going to take the lead on building transparency and security into their supply chains. I think we got some great examples from Anoush earlier as to how they're doing it, and then Abby talked a bit about this, as well, from the AdvaMed perspective. But we know that the government also has a role and the Department of Commerce, in particular, is focused on a few aspects to increase supply chain visibility.

So the first way in which we're doing that is working with our international partners. So the United States is not alone and our allies and partners are facing many of the same supply chain challenges that we are, so we need to work together. We can work to diversify the medical technology and semiconductor manufacturing base, we can work together to develop standards that both promote diversification but also enhance security, and we also need to strengthen trade mechanisms that counteract their practices.

One example of this, a very current example is the United States-European Union Trade and Technology Council. There is a dedicated working group on supply chain resiliency and within that working group we are very focused on semiconductors, including the med tech concerns that have been raised, so a very live example of how we are starting to bring this to life.

We're also focused at Commerce on the workforce side of this as we look to have more manufacturing here, how can we ensure that we have the workforce ready. We're doing this in a number of ways, whether it's the Good Jobs Challenge, the STEM Talent Challenge, so on and so forth, lots of different incentives there.

And then Commerce is also getting involved where we're seeing trade restrictions, particularly in the medical space. Certainly, early in the pandemic we saw cases where exports were being restricted or supplies were just being limited due to lockdowns and Commerce worked with the state department and others to try to have some of those resolved and get the goods flowing again.

I'll just note again the importance here of working together, both across the government and together with the private sector, this is not going to be solved by any of us working in isolation, but it's going to be solved by us bringing together our best ideas and working collectively to address the problem.

Back to you, Linda.

MS. RICCI: Thanks, Monica, I really appreciate all those comments and I know that our working relationship between FDA and the Department of Commerce, along with our ASPR colleagues, has been very beneficial in understanding the challenges associated particularly with the semiconductor shortage. So our partnership definitely has, I think, been a benefit to both of our sides and to your point that we are not, any of us, able to do this in isolation and we need to work with the ecosystem.

Heather, can I ask you to also comment on this question?

MS. MALLINCKRODT: Thank you, yes. I appreciate Monica talking about the whole-of-government approach and some of the work that is occurring to really help mitigate a lot of the risks. Your know, as we see it, and I had mentioned this earlier, key to ensuring that all of the stakeholders in the healthcare supply chain are able to mitigate these risks, and we talked a little bit, you touched on it, Monica, as well, the transparency, understanding the location of each of the critical steps. And I think accentuated during the pandemic, we saw that Vizient alone vetted over 10,000 suppliers to sell to providers, many of which were brokers selling from the same factory location. So understanding where products are

coming from are critically important.

In addition to that, holding additional inventory. Vizient also worked on a program with suppliers to hold additional inventory for providers so that they can ensure product is available when needed.

And finally, the domestic manufacturing, which also was touched on, partnering with suppliers that are domestic manufacturing so that the providers can determine the risk to select a product that is domestically produced or near shore, as well, where appropriate.

So those are really the areas that I think will help providers to increase the visibility as well as understanding supply availability and mitigating those risks.

MS. RICCI: Thank you, Heather, those are great points and I'm really glad you brought those up.

Paige, can I ask you to jump in this conversation?

MS. EZERNACK: Sure, I'd be happy to. Thank you so much. And I appreciate the thoughtful comments that everyone has shared so far. I agree wholeheartedly in the cases that there are a lot of opportunities that we need to leverage moving forward.

I think extending external surveillance capabilities to monitor the health and medical resource marketplace, identify potential vulnerabilities, is a key area that we want to invest in. You know, we have an ability now to fully visualize the broader health and medical resource marketplace and it is reliant on supply chain insights and data that we review as a result of these public and private partnerships. So these are areas that we intend to invest in moving forward by cultivating and maintaining the federal and industrial relationship established as a result of COVID-19, and these were forged through the fire of responding to COVID-19 over the last couple of years. We expect to continue to work with both industry and federal colleagues to promote resilience and ensure robust preparedness efforts.

I think prior to COVID-19, HHS had very rarely used priority rating authority or DPA authorities in general. I think there was hesitancy to do that because we had very little or very limited visibility into the health resource and medical supply chain to marketplace, and I think we understood that every use of DPA authorities will have an impact, big or small, on the supply chain. And so without that visibility that we really need to best understand what the impacts are of every action, there was very little desire to use those authorities.

I think one thing COVID has forced us to do is to build those relationships to have that visibility, to invest time and effort into understanding the supply chain, building relationships with suppliers and manufacturers and across the interagency led by Mr. Manning at one point for the administration, and most of the people on this panel participated in that interagency working group. I think we really built a coalition, a public-private-government coalition that allowed us to leverage the experience, the knowledge and capabilities across the medical resource manufacturing marketplace to best respond, to be better able to respond to COVID. And I am hopeful that those partnerships will continue and we can continue working together to address some of these challenges.

Back to you, Linda.

MS. RICCI: Thank you so much, I really appreciate those sentiments. We definitely don't want to lose the ground that we have gained during COVID and maintain our relationships and take advantage of the opportunities that we have created for ourselves and moving forward with this. So thank you very much for reminding us of that.

I do want to take this opportunity also to remind the audience that we should have time during this session to address your questions to the panel, so please make sure that you are sending your questions forward.

Now for our next question. What are some innovative and novel methods for building a resilient supply chain?

Deb, can I ask you to kick us off here?

MS. KRAMER: Yeah, I'd be happy to. Thanks, Linda.

One thing I'd like us to consider is that hospitals and hospital systems are not the customers of the supply chain, but are part of the supply chain. If you live in a hurricane-prone area, you keep extra water on hand and batteries and other supplies to get you through whatever would hit when that hurricane comes through your area until help can reach you. That's what hospitals and hospital systems need, to start thinking about that in the same way. How are you going to take care of yourself in the interim if we face something like we did in 2020, until the entire national effort can come to bear to start to bring resources where they're needed? So if we could start to change that mindset, that would be really helpful.

In VA, we are kind of lucky, our size is our advantage. We've got about 380,000 employees, 170 hospitals, 1200 outpatient sites of care, and that gives us the capacity to be able to flex a little bit when something like this happens. We have a healthcare operations center and in 2020 we met twice a day, 7 days a week, all of our senior leaders out of VA and the Veterans Health Administration, to include our Secretary, as well as the senior executives who run our 18 regional veteran integrated service networks. Each of these, they're located around the country, Puerto Rico, the Virgin Islands, and what we did in real time was solve problems and share situational awareness of what was going on across the country as we learned more about what COVID was doing to our systems.

We also changed our mindset from one where the stuff that you acquired from the commercial sector belonged to the hospital that bought it, to the fact that everything that we buy is an enterprise asset. And then that allowed us to be able to cross-level supplies, equipment, and staff from an area where COVID wasn't as bad, say the upper Midwest, in early 2020, down to someplace like New Orleans or New York or New Jersey who were

being hit really hard by the first wave of COVID, and that made sure, that ensured we did not run out of material. We operated at the contingency level, but we were never forced to reuse material.

And then the other thing we did was established regional readiness centers. What we've done with that is we're going to hold about 120 days of supply based on our biggest demand level during the COVID pandemic, and that material actually builds resiliency into VHA's internal supply chain. So if a commercial sector partner can't provide PPE, as required, because of an international incident, China closes a port or a manufacturer goes down because of an environmental event in their area, we still have the capacity to support health care until the commercial sector can come in.

Now, not every hospital or healthcare system has that size advantage and that's why I'd like to suggest that if you're a healthcare system out there, we might consider how we can apply the proven practices that the U.S. electric utility sector uses for national disasters. I don't know about you, I'm in the Northeast, Pennsylvania is where I live, I work in D.C.. It's not uncommon, starting about this time of year until the middle of November, where I see utility trucks lined up in a convoy ready to go south to support somewhere where they've been hit by a hurricane and the power has been wiped out.

These mutual aid agreements, there's a national one linking about 1100 utility companies. There are also regional mutual assistant groups that help each other in times of need and the idea here is strength in numbers. They share supplies, they share equipment like power poles, transformers, utility trucks, staff, as well as data and information. Those proven practices and the methods they did to establish regional and national agreements, mutual assistance agreements, is something I think the U.S. healthcare system could apply for events like COVID or other bio-events.

Over to you, Linda.

MS. RICCI: Thanks, Deb, that's a great analogy and example from the energy sector. A great idea.

Anoush, can I ask you to further comment on this?

MS. FRANKIAN: Sure, absolutely. So building a resilient supply chain for imaging device manufacturers really means that it includes having the ability to continuously sense changes and obviously pivot or adapt to those changes. This relies on the strengths of our company's capacity to first plan and of course, the ability to adapt or respond dynamically to both internal and external changes. So to sense and pivot requires better communication outside of a regulatory scheme, and I really want to emphasize that communication here and reporting needs to be distinguished where the former allows for companies to place preventative measures in place for their activities, while the latter is a reactive approach.

So our company is improving accuracy for supplier classification, data, manufacturing location, at a product-by-product level and this all starts in the early design phase of your development process where you are including your suppliers and involving them in order to design resilience in your product and, of course, your overall supply chain.

Another thing that we're doing differently is making direct phone calls and going deeper and deeper into our supply chain to foster visibility. So these activities require greater allocation of resources in terms of head count and, of course, time on behalf of the organization.

I think it was mentioned earlier, as well, that it's really important to think about how materials and components critical to various products out there can be prioritized for the medical device industry and, of course, public health. In these cases, we have supply chain team members trying different things where they are having conversations with vendors, explaining the need of the component and its criticality and, of course, how it will be used

in an end item that is potentially lifesaving or life-sustaining. So those are some different things that we are doing and they're definitely new to our organization.

MS. RICCI: Thank you very much, really appreciate hearing directly from a manufacturer about what you are doing and how you are working to build resilience. Very helpful.

I'd like to move on to our next question. What are the most important actions the government can facilitate to build resilience?

Abby, I'd like to ask you to lead off with that one.

MS. PRATT: Yeah, thanks, Linda.

I mean, I think we already heard like a lot of great examples already of initiatives taken by the government-public-private partnerships, you know, informal, formal, the FEMA voluntary agreement. I mean, I think it's hard to -- you know, particularly what Paige said, to me, resonates: that we've stood up all these partnerships and work streams in like almost real-time communication and assessment. And so I think it's critical that we preserve and build upon those work streams because it really -- it comes to a new level and I think just that communication is so critical to get ahead of any crisis and we know, listening to Tim, and we all know in our everyday lives that things are only likely getting more challenging because we're in a new world where there's so many impacts.

So I think just, again, I couldn't stress enough the importance of these communications, these partnerships, these real-time collaborations, and I think it builds trust and goodwill and then I think we all ultimately want to serve patients at the end of the day.

You know, another thing obviously on the regulatory side, and I think others have alluded to this, but figuring out ways when companies have to be nimble, when they have to pivot, how do we maintain regulatory flexibility and efficiencies so that they can qualify

new suppliers, if they have to redesign products to accommodate these shortages, these upstream shortages, if they have to -- I mean, I'm working with companies that have to shift suppliers from Russia to Ukraine or to Poland right now. So those kinds of changes where companies have to quickly react and pivot, making sure there's that regulatory flexibility and efficiency.

And then I think also, and Monica alluded to this, but on the trade and commerce side, how do we work together to ensure that healthcare goods and their inputs are moving around the globe efficiently, how do we minimize things like export controls which we ourselves, the U.S., was guilty of as -- you know, the proliferation across the globe. But I think we learned that those things just make it harder and interrupt global supply chains of healthcare products and impact resiliency. So I think that's another area.

And just last but not least, if I'm thinking of actions that the government can take, I'll just restate what I said earlier, but just ensuring that the delivery of healthcare in this country is a priority as we compete, if you will, with other sectors that are trying to move their goods and products and get to that last mile of it. You know, we have to just be mindful of how important that delivery of health care and the end user is. So I would just conclude with that.

MS. RICCI: Thank you, Abby, great points. I think it's important to emphasize that. So we need to continue to be nimble, you know, manufacturers as well as government as well as hospitals, and if we don't do that together and in the same direction, then it won't be as effective. So really appreciate you bringing up those points.

Monica, can I ask you to comment on this, as well?

DR. GORMAN: Sure. Thanks, Linda. And I know we're coming up on time, so I'll keep my remarks brief.

But I can't emphasize how much we are thinking about this and I'd say there are

three buckets in which we are looking at these actions. One is around how do we increase visibility and transparency into the supply chain from a government standpoint? How do we promote information sharing both between the private sector and government, but also government to government? And then how do we increase our coordination and collaboration with our allies?

And through COVID we have taken a number of different steps to do this. I would point to the request for information that Commerce issued around the transparency side, really seeking to understand which industries, such as medical technologies, were feeling the shortage of the semiconductors and to understand not just semiconductors at large, but specifically which nodes, which types of chips were in shortage, so that we could then target our actions.

Similarly, around information sharing, Commerce set up this microelectronics early alert system complementary to a lot of the work that FDA is doing, and that is a way for companies to alert us when they know of a disruption happening in the semiconductor space, to let us know, we can then bring the full force of the U.S. government to bear to try to address it in real time with the hope of mitigating the negative impact of that shortage.

And then on the collaboration side, I already mentioned the U.S.-EU Trade and Technology Council. We are also having deep discussions with Japan, with Korea, specifically on the semiconductor issue, noting that it is such a critical industry to med tech especially, as well as others, and we have to get this right.

So those are a number of different examples of actions, sort of innovative actions that we've taken, but I would stress that the challenge ahead of us now is how we do we institutionalize this going forward? How do we learn from what COVID has taught us and start to build mechanisms that will live beyond this moment and help us hopefully be more nimble going forward?

Just a couple of examples that I would point out. I already mentioned the chips legislation that is currently on the Hill. It is landmark legislation, it will invest in expanding the capacity of semiconductor manufacturing and it will do so here in the United States. So we're certainly very hopeful that that will pass, it will set up our marker in the ground that we need.

There is a legislation pending before Congress that would create a supply chain resiliency program within the commerce department to really monitor these issues in more real time, as well as work more closely with the private sector and be able to provide more support, including for small and medium-sized firms that are crucial, particularly in the upstream parts of the supply chain. So those are just a couple of ideas that are out there that would start to institutionalize us, institutionalize these challenges that we have and hopefully create a way for us to be ready, be more nimble, and be able to take these lessons and take them forward into the next crisis.

Back to you, Linda.

MS. RICCI: Thank you very much. Definitely appreciate all of those comments.

We have just a few minutes left. I would like to pose to the panel a question from the audience. So this first question is how do we get companies to share manufacturing, sourcing, and other elements with providers to provide an objective qualification of the risks associated with the end products?

So I don't know if Heather, Abby, or Anoush would like to kick us off with that one.

MS. MALLINCKRODT: I'll go ahead and kick us off. You know, there were two comments as I saw this question, two comments throughout the panel that I kind of wanted to highlight. The first one is we talked about partnership, partnership across all stakeholders and that's what's really important here as we approach this question. The second comment that was made, that Abby made, actually, was about unintended

consequences. As we approach transparency, further transparency, we have to be very cautious about unintended consequences and potentially creating a failure to provide product as opposed to helping to mitigate it.

So how do we get companies to share manufacturing? Like I said, I think this is a partnership where it is between providers and manufacturers and sourcing to help understand so that the provider can determine their risk mitigation strategy, so they can understand what their true risk is, and it becomes a part of doing business, understanding what your risk is when you're purchasing a certain product. I think that's when it needs to be counted as a value proposition in order for providers to purchase a particular product.

MS. RICCI: Thank you very much for that, really appreciate those comments.

We have about a minute left, so Anoush or Abby, would you also like to comment on this very quickly and then I'll wrap it up?

(Pause.)

MS. RICCI: And if not --

MS. PRATT: Sure.

MS. RICCI: Oh, go ahead.

MS. PRATT: Happy to step in. Yeah, I tend to agree that the partnerships and information sharing -- and I think it will evolve over time the kind of information that gets shared. I would caution, I think there is this sense that end-to-end supply chain mapping is the panacea for supply chain disruptions and I think we just have to think about in the context of how complex supply chains are and how much they change. And so sometimes, once a company has a product and they have mapped the supply chain, there might be an innovation that changes, so we want to make sure that any information that is collected is actually useful and reflects the reality of that supply chain. So I think there's the ideal concept there and also the reality of how you go about mapping the supply chain.

MS. RICCI: Great point, great point. We definitely want information to be actionable information and not just information for information's sake, for sure.

So I want to thank all of the panelists, this has been a very rich discussion and I really enjoyed interacting with all of you and hearing all of your perspectives on this very important topic. I really feel like all of us have lived through this COVID experience and demonstrated how collaborations and partnerships for each part that we have in this ecosystem has helped to -- certainly helped with the COVID response, but also with the specific elements for the supply chain and making sure that the end patient, which is always the goal, the most important part of the ecosystem is the end patient, that they have what they need, that we are all working to make sure that the patient is at the forefront.

So thank you again and thank you, Tammy, for putting this workshop together and I'll turn it back over to you, Frank.

DR. BLOCK: Thanks so much to you, Linda. And thanks, as well, to all the panelists for a great discussion this afternoon. It was quite fascinating to follow along during today's discussion and learn all about the ways of transportation partnership. Partnerships help to relieve supply chain constraints as well as some of the innovative methods for mitigating future supply chain stock.

It's now my pleasure to introduce Dr. Tammy Beckham. Dr. Beckham is the Associate Director of the Resilient Supply Chain Program here at FDA/CDRH. Before pursuing her career in the sciences, she played both the piano and the French horn professionally, and holds an M.S. in music from the Cincinnati Conservatory of Music. But she ended up selling her French horn to help pay for veterinary school and then joined the Army, which kicked off her career in research and diagnostics, working specifically on the Ebola and Marburg viruses in a BSL-4 research lab. Dr. Beckham currently lives in College Station in Texas, which she and her family would consider home. In one of her previous

roles in College Station, Dr. Beckham worked for Texas A&M running four vet labs, two BSL-3 labs, as well as the infectious disease center for the Department of Homeland Security. Most recently, Tammy served as the director of the Department of Health and Human Services Office of Infectious Disease and HIV/AIDS Policy, where she received the Secretary's award for distinguished service for her work leading the kidney health working group and again, for her work leading the COVID-19 testing and diagnostics working group. So join me in welcoming Dr. Tammy Beckham.

Tammy.

DR. BECKHAM: Thank you, Frank. And thanks, everyone who was on the panel this afternoon. It's really good to be here with you today, it's such a pleasure to have the opportunity to chat with you. Today I have the honor of introducing the new Resilient Supply Chain Program. But before I get started today, I want to thank all the CDRH staff that have worked tirelessly over the last couple of years, not only addressing supply chain issues but also helping to vision and build the foundation for the program I'm going to talk about today. In addition, I want to thank the many stakeholders and attendees of the workshop whose feedback prior to the workshop and during the workshop and into the future is going to help ensure that this program offers maximum value to entities across the medical device ecosystem. Next slide.

So I'm going to start by saying that, obviously, I don't need to tell everyone in this room about the complexity of medical device supply chains or the variety of events that could lead to a shortage of critical medical devices for our patients. Over the last few years we've all witnesses how natural disasters like Hurricane Maria, Winter Storm Uri, recalls, and the COVID public health emergency have led to shortages of critical devices. These shortages, unfortunately, have most often had the greatest impact on our most vulnerable populations. FDA/CDRH, like many of you, has largely been in a reactive posture, hearing

about shortages after they occurred or when they're imminent. Responding to signals of ongoing shortages, we've been able to work with healthcare providers, manufacturers, suppliers, and our interagency partners to help mitigate and reduce some of the impacts of these events. But reducing the impacts is not enough. We collectively have an opportunity now and into the future to build on our lessons learned. We know that by taking proactive measures and identifying and addressing vulnerabilities and risks in supply chains of our most critical devices, we cannot only promote resiliency, but we can protect our patients, our healthcare workers, and the U.S. public from these disruptions. Next slide.

Over the last 2 years CDRH has worked to implement processes and procedures to manually collect information required to evaluate and assess supply chain shortage signals. We have worked with our stakeholders to address a wide range of critical medical devices like PPE, gowns, gloves, ventilators, testing agents and supplies, pediatric trach tubes, IV bags, and blood collection tubes and those are just a few.

And in addition, we have coordinated outreach efforts with our stakeholders to better understand supply chain shortage implications to our patients. We've performed comprehensive patient impact assessments and these have resulted in working with our partners in evidence-based regulatory and non-regulatory mitigations such as immediately put in effect guidances, emergency use authorization, priority ratings you heard about earlier, expediting 510(k)s and conservation strategies, and those are a few. Each one of these mitigations resulted in additional medical devices available to our patients.

And as mentioned yesterday, the shortages that we see today, as opposed to the beginning of the pandemic, are very different. We are now seeing more systemic supply chain issues caused often by events that have occurred independently of the COVID public health emergency. Paper for labeling, packaging, semiconductors, and resins. These systemic issues are ongoing and evolving and impacting a broad set of medical devices.

In fact, resins -- next slide, please -- is a perfect example of a systemic supply chain challenge that has had impact and is still having impact across a large number of manufacturers and medical device types. To date, the supply chain issue, which was caused by Winter Storm Uri and hurricanes back in late 2020 and early 2021, has impacted over 30 manufacturers and 180 device types. And I caution that these numbers are probably a little bit conservative because the situation is ongoing still today.

Since 2021, FDA has worked across the interagency and with our partners so that we had a greater understanding of resins, how they're used in manufacturing. We performed supply chain eliminations and analysis and assessments, and our activities working across the interagency and with our partners and our stakeholders have resulted in increased allocations and when needed, priority ratings for the med tech sector.

However, we've been largely reactive, only learning about shortages for particular resins as they are occurring. And this supply chain issue, like others, has also had a disproportionate impact on our underserved and vulnerable populations. One only needs to look at the recent impact to a device used to compound total prenatal malnutrition for critically ill neonates to see the ongoing impacts to our most vulnerable populations.

Over the past 2 years we've been able, collectively, to capture lessons learned and although we have been reactive in nature, we have been working to develop innovative processes that we've heard about today and yesterday, collaborations and partnerships, and we have built the foundation for the future program that I'm going to talk about today. We are now poised to leverage those collective efforts and fully implement a more proactive permanent program at CDRH that supports supply chain resiliency. Next slide.

The Resilient Supply Chain Program will be housed in the Office of Strategic Partnerships and Technology Innovation. This program is intended to be proactive in nature and have strong effective partnerships and collaborations with the multiple representatives

across the medical device supply chain. Next slide.

The mission of the Resilient Supply Chain Program is to strengthen public health supply chains by proactively monitoring, assessing, and communicating vulnerabilities and risks to prevent shortages of medical devices. But our successes will be measured not only against some of the outcomes that you see envisioned on this slide for our program, but also how you, the stakeholders, view our program and its value. And although I'm presenting today on where we, CDRH, see our program and its vision, I want to reiterate again that we are here this week to hear from you and gather your input on where this program can be a value to our stakeholders, our patients, and our healthcare workers. Next slide.

The CDRH Resilient Supply Chain Program is going to be structured across four primary focus areas: resilience building, shortage assessments, product authentication, and research and innovation. No one focus area will function in a silo but rather, this program is going to be highly matrixed. Our staff will function as interdisciplinary teams of health scientists, medical device experts, and data scientists designed to proactively monitor and assess supply chains for critical medical devices. The program will work collaboratively within CDRH, across FDA and the United States government, and with our stakeholders, and key to its success is efficient and effective partnerships.

The foundation of this program will be a robust data analytics and modeling capability. We will harness information from internal, public, and commercially available datasets and information provided by the industry through our new CARES Act authority to enable visibility of the supply chain from raw materials all the way to the device at the patient level. This program will be focused on monitoring and strengthening supply chains for critical devices, those that are life sustaining or life supporting and required to have on hand at all times for patient care. This program is not intended to rule the action, but

rather be appropriately scoped so that it brings the greatest impact and efficiently utilizes its resources to bring maximum value. The resilience building and shortage assessment focus areas, we'll work with our partners across the medical device ecosystem to look at innovative ways to build resilience and when needed, assess and navigate shortages. We will use advanced data analytics and modeling capabilities to help identify vulnerabilities and risks and interdependencies in the supply chain. And the information that is gleaned from these activities can be used to inform actions that we, collectively, can take to assess impacts from potential mitigations or the impacts of an imminent shortage.

Similarly, we're going to harness the breadth of data and analytical capabilities to protect patients and providers from counterfeit and fraudulent devices. Using our analytics, we can prevent them proactively from entering the marketplace.

And last but not least, we will invest in research and innovation so that we can improve our abilities to better forecast demand, explore potential impacts of novel regulatory mechanisms that we can explore together, and other opportunities to strengthen resiliency. Next slide.

And although we've made substantial progress over the last few years, working with many of you day to day to address challenges and respond to shortage signals, our processes are still manual and laborious. We do not yet have access to the right data at the right time so that we can identify and prevent supply chain disruptions before they occur, but we're getting there.

As we move forward, our vision is to maximize prevention and enable resiliency. We are currently in the early phases of transitioning some of our more manual processes to automated capabilities. We're also working to evaluate and integrate data sources and supply chain information that can be utilized to perform vulnerability and risk assessments, do that demand forecasting that we so critically needed during COVID. And also disruption

modeling. Once fully developed, these capabilities will enable us to better support our stakeholders, our private partners, and our USG partners with evidence-based data for mitigations and solutions.

A good example of the work the program is informing right now is the ongoing challenges that we have with medical device sterilization. CDRH has been working with our stakeholders to gather data required so that we can understand potential impacts to availability of critical devices, given some of the current geopolitical and environmental concerns. And as you know, the FDA has two master file pilots and one under consideration that was just announced yesterday.

We are performing assessments that are needed to better understand potential supply chain issues with critical medical devices, given those implications. We are using the information and working with our industry to promote least burdensome regulatory approaches so that if we need to change modalities and that's warranted, we can. These efforts are critical for supporting supply chain resiliency. Next slide.

Of course, we can't do this alone, and we had a great panel talking about all the interagency relationships and the public-private partnerships that we developed during COVID, and we need to continue to have effective and efficient partnerships with our private partners to achieve our goals because, as we've seen during COVID, together we are stronger.

And to this end, after the workshop, we are going to continue to enhance and grow our stakeholder engagement and our partnerships, and tomorrow's session is entirely focused on collaboration. I encourage you to attend, I encourage you to provide feedback and input on opportunities and concrete mechanisms for us working together moving forward so that we can do what folks had just talked about, we just sustain and build on the capabilities that we've developed. Next slide.

As we hear your feedback during the week, I want to leave you with a few thoughts about this program and the value proposition to patients and the medical device community. FDA/CDRH has a very unique role in medical device supply chains. By the very nature of our mission, we have not only the medical device expertise, we have relationships with stakeholders across the ecosystem, healthcare providers, patients, distributors. We understand how a device is used in a clinical setting. We can look at potential alternatives. And this unique vantage point gives us an opportunity to really utilize all of this expertise and capabilities so that we can provide and help work with you collaboratively to enhance resiliency and protect our patients.

As we move forward, this program will continue to enhance our role as an essential coordinator on supply chain issues within the USG, just like we've done over the last few years, providing industry, patients, and healthcare workers with a single point of entry to coordinate on medical device supply chain issues.

Our program has been and will continue to be the source of evidence-based data to support both regulatory and non-regulatory supply chain mitigations. We will expand our focus and role in prevention moving forward. And as we've heard today about sustaining our relationships with the private sector and with the our USG partners, our coordination and collaboration will become more formalized and we will enhance our ability to provide this evidence-based information that can then inform strategies for prevention, resiliency and, when needed, mitigations. Next slide.

And lastly, I just want to also leave with a few words saying that together, we can work collaboratively to ensure that we keep our focus on our patients, our healthcare workers, our vulnerable populations, our underserved communities and the U.S. public health as a whole. Keeping our focus on health care and patients, we can work collaboratively to strengthen the supply chain, reduce our dependency on foreign sources

and strengthen our national security, all while keeping at the center of everything we do, our patients, ensuring that they have access to safe and effective medical devices when needed.

I want to thank you for joining us today, thank you for listening to me. We value your input and we really look forward to hearing from you and our future partnerships and collaborations. Thank you.

DR. BLOCK: Thanks, Tammy. And thanks so much for your presentation today. I especially enjoyed your slide reiterating that all shortage response activities are all ultimately focused on the patients and their need to access medical products.

Next up, we have a few minutes before our breakout groups begin. If you signed up for our breakout groups today, you should've received an e-mail with a link to join. There was tremendous interest in the breakout groups but unfortunately, we had limited space available in these sessions. For those attending the breakout groups, please join your breakout group session using the link you received in your RSCP workshop confirmation e-mail. We'll start in about 10 minutes at 2:40 p.m., but please, go ahead and join your breakout group early before taking your 10-minute break. You never know, Zoom may just have to do an urgent update.

But for those of you in general attendance, it's time for a station break. Please return back at 3:30 when we'll continue our programming with some key takeaways from the breakout session, as well as today's summary. Note that 3:30 Eastern is a different time than yesterday. Hopefully all that was Atlantic enough, I'm not sure I could be more Pacific. Thanks all, talk to you soon.

(Off the record at 2:33 p.m.)

(On the record at 3:34 p.m.)

DR. BLOCK: Hello and welcome back, everyone. Thanks, all, for the fascinating

breakout discussions. Now, let's turn to some of the breakout group leaders for a quick rundown on some of the key takeaways from their breakout group session.

First up, Melissa Wilson. Melissa.

MS. WILSON: Thank you, Frank. Good afternoon, everyone.

We had a really robust discussion in our breakout room this afternoon, just like we heard yesterday, and a lot of the key takeaways actually build on some of the things we heard yesterday, continuing to leverage the relationships and positive impacts that those have had as the government and private sector have come together to respond to the public health emergency.

Some of our key takeaways from this afternoon's discussion include the need for further demand for testing down to the provider level so that industry has the ability to respond to that information and can predict their needs in a much longer-term way.

Another piece that came up was the role that the public health emergency flexibilities have given to hospitals and health systems and the care that they deliver, and continuing again to leverage those flexibilities which have driven resilience in the healthcare segment.

Some of the great comments that came out were leveraging the HHS supply chain control tower, so we've built that capability, how do we continue to use that data and information and how can it be leveraged to drive change in the public -- excuse me, in the private sector, so our manufacturers and distributors. And then how can we provide more accurate data to our healthcare providers around availability of key products and information, so really continuing to grow that information and leverage it for multiple uses beyond what it's being used right now.

Another sort of "aha" that came out was, is there a role for government to play as a critical marketplace for key items like semiconductors and resins, the things we've spoken

about, is there a way that government can connect those suppliers who might have availability with the manufacturers who are so desperately looking for those products?

And then again, information sharing continued to be a theme. Is there an opportunity or a way for FDA to continue, as they've done during the public health emergency, the expanded use authorities and those kinds of things and make sure that that information really gets to the front line, to those reviewers, so that as the Resilient Supply Chain Program is making changes and working with manufacturers to drive that resilience, that we're communicating that very broadly across FDA so those reviewers who are really on the front lines have all the information that they need to employ and make sure we're taking advantage of those resilient opportunities.

And then the last comment that came up, and I think we heard about this, this morning in the plenary session, was building resilience has a cost and there's an opportunity for us to continue dialogue on how that cost might be absorbed and where the government might have a role to play in that.

And I think that was about it from our Breakout Group Number 1, thank you.

DR. BLOCK: Excellent. Thanks so much, Melissa.

Next up, let's hear from Jerome Cordts. Jerome, were there any key takeaways from your breakout group session?

MR. CORDTS: Yeah, we had a great breakout and we did have a few highlights, I would say, from our group. So the first one, we talked a bit about the risk-based approaches and there seemed to be some good consensus on the use of risk-based methods to help inform where investments are needed. The just-in-time manufacturing came up, it presents certain challenges and that needs to be factored into an overall risk approach for the country.

Another one, we talked about proprietary information and challenges associated

with sharing that type of information. We talked earlier in the plenary about having more transparency and with that transparency comes, you know, more information sharing and some of that information can come with caveats about how it's used, whether it needs to be aggregated and how far you can go with the sharing. So ways to protect proprietary information is really important and methods to do that are critical.

We also talked about incentives and the incentives both to share information and incentives, as well, to maintain extra inventory. And so we can talk about monetary incentives, financial incentives, some kind of other business incentives, but we need to be as creative as possible when it comes to considering alternatives to promote this resiliency, not within a single organization, but across the whole country. And so how that filters from an individual provider to our national public health resiliency is an important factor.

And then the fourth one that came up today, and we had some interesting -- I would say there wasn't full agreement on this, but we talked about reliance on single-use devices, how we tend to be very disposable in many of our dealings and that's the way it is, it helps to protect patient safety, for example. But there is a balance, there's a balance if you think about it from a holistic standpoint, there's a balance between single use and reusability, and the group started to get into some good dialogue on that and then time ran out. So I'll stop there, thank you very much.

DR. BLOCK: Thanks so much, Jerome.

Next up, let's hear from Eduardo Rocca. Were there any key takeaways from your breakout group session?

MR. ROCCA: Yeah, absolutely. We had a great session and we had representation from the industry supply side and manufacturing and also from the healthcare organizations, so it was a very dynamic conversation. I would say the key theme was transparency and communication, and I'll expand a little bit. On transparency, the idea of

really understanding the role of health of a critical product through the whole life cycle, whether it's the raw materials to use, the eventual disposal, really understanding domestic and overseas markets and providers, parts and pieces, etc.. And also that transparency could be able to forecast demand, potential manufacturing risks and mitigation strategies that come with that.

On the communication side, you know, really expanding the communication channels between government and industry, really, the government facilitating communication among industry, but also at the same time understanding the realm of what is and is not possible. The word jurisdiction was talked about, who owns what within the supply chain, within the government and within industry or associations, to be able to understand how to facilitate that communication and also what can be legally done in case of the need.

Another part of the communication that is critical is education around multiple acts that we have, you know, for example, it could be the defense act or the national stockpile, people really wanting to have better education and better understanding of government acts or governance.

One of the other key themes that we had was innovation to help with an infection process. There was an example given of -- within industry, that they were able to step up their help to be able to -- they knew earlier on that there was this need, so they were able to create better techniques and better tools to produce a new space and manufacture masks at a massive capacity. So a brand-new technology that didn't exist before, so being able to speed up that process, whether it's through not only the technology, but also being able to use those masks, right, to be certified and so forth after.

And we talked a little bit of communication where you could have suppliers and the reserves, per se, where smaller businesses, whether domestic or overseas, that can be

certified ahead of time through the process in case they need to step up and communicate -- so not certifying people during the emergency but to have those pre-certified ahead of time.

And with that, I think that was a fantastic session and I thank all the panelists that attended and that's what we have for the talk.

DR. BLOCK: Wonderful. Thanks so much, Eduardo. Something really jumped out, the comment being meeting accurate demand forecasting really could be a key piece in all of this.

Next up, let's hear from Laila Handoo. Laila, can you share some key takeaways from our breakout session this afternoon?

MS. HANDOO: Absolutely, happy to. Thank you to everyone participating in the session. We learned some very interesting key takeaways. Similar to others, there was a theme on increased transparency and in particular, what was very interesting is there was a dialogue on increased transparency with regards to what devices, products, are most critical and more transparency on the guidance and direction around who would receive those devices first, so getting a sense of the limited supply and prioritization. Very interesting point.

Additionally, there was a focus on expansions with partnerships between industry, associations, and enhanced collaboration.

And also similarly, we heard a great point on enhanced data sharing and really interesting to understand regulations regarding that and enhancing that for those involved in industry and government.

So with that, thank you.

DR. BLOCK: Excellent. Thanks so much, Laila.

Next up, let's turn to Taylor Wilkerson. Taylor, are there any key takeaways that you

gathered from your breakout discussion this afternoon?

MR. WILKERSON: Thank you, Frank. And I think, like everyone else, we had a really good discussion, a really energetic discussion around this topic. In addition to some of the themes that others have already mentioned, you know, a couple things that came out in our group, one was around data analytics and the government's ability to be able to collect data on supply chain and provide information to industry by collecting data, doing the analysis on it, and helping industry understand what's going on in the environment.

Another piece, and Eduardo's team, it sounded like they touched on this a little bit as well, is the importance of the whole government approach to this, that this is not just about devices being safe and effective, this is about getting those devices to move around the country, around the globe, and that need to bring in the transportation policy, the trade policy, all that together to really discuss how to make supply chains more resilient.

And the last one was a really interesting point around just getting better awareness outside of the supply chain community of what everyone in the supply chain does to make these devices available, that part of the problem is the people who are making policies and the public and the clinicians, etc., don't really have a good understanding of what all happens in the supply chain and therefore don't really have a good understanding of what things might help the most in terms of creating more resilience or how some other actions might actually hinder resilience because they don't understand how that impacts the overall system. So again, a lot of great discussion and a lot of great ideas coming out.

DR. BLOCK: Very interesting. Yes, agreed. Thanks so much, Taylor.

Next up, let's hear from Jon Davis. Jon, are there any key highlights you'd like to share?

(No response.)

DR. BLOCK: Jon's having technical difficulties right now. But for some of the

breakout group leaders overall, are there any key highlights from your discussion on mechanisms or approaches that can enhance end-to-end supply chain visibility?

MR. WILKERSON: So Frank, this is Taylor, I can jump in and offer a little bit of what we discussed. You know, one thing that came out and that was discussed in our group is the fact that, overall, the software tools that are available to folks, whether it's providers or manufacturers, to really capture visibility and process the information around visibility, have really gotten to a much better maturity point. It's something that used to not be something that the healthcare sector had a lot of access to and now it's getting to the point where there is that access and there are tools that are tailored for health care and that's a big point of getting the visibility and then again, the discussion I just mentioned about the government's ability to be able to provide visibility back to the industry based on the data and analytics that they're able to capture.

DR. BLOCK: Very interesting, thanks so much. It looks like Jon was able to rejoin us here.

Jon, any key takeaways from your breakout group that you'd like to share?

MR. DAVIS: Yeah, thank you so much. So we heard a lot from a variety of different participants across the medical device ecosystem about how they're currently investing time and money to improve their data tracking and their transparency, their risk identification, and the tools that they're building in house to get a better handle on their supply chain and how they're being impacted. But largely, these are happening independently, so there was definitely an opportunity for the U.S. government to promote standardization across, not just in terms of data sharing, but also with product names and identification, the very basics of being able to get towards something like interoperability.

Another common thing that came across, one of the most important elements for resilience is having a well-trained supply chain team who speaks the same vernacular and

the same language and has proficiency with supply chain terminology. How do we promote that through a program like this so that we have a better and more effective supply chain team across different elements of the medical device ecosystem?

We definitely had some discussion around premarket actions and opportunities, including the opportunity of could we reduce the burden of proof for secondary suppliers versus a primary supplier, make it a little easier for replacements and substitutions to happen when there is a potential issue.

There was some good discussion at the end around transparency and data sharing being critical, but also being mindful to balance that against the burden and cost that comes with that because ultimately, if the burden becomes too high, then ultimately that could undermine resiliency goals as it pushes and forces others out of the market.

So a really, really good, robust discussion in my breakout group. Thank you to the participants who provided their input.

DR. BLOCK: Excellent. Thanks so much, Jon. And thanks, all, and thanks especially to all of our breakout group leaders.

I see Jerome has his hand up. Jerome.

MR. CORDTS: I just wanted to add to your prior question, Frank, that there were two particular data points that were perceived as valuable. One is where there are single-source products is a data point that others might want to know about. And the second one was on the awareness of shortages. So the fact that there may be drug shortage notifications or device shortage notifications, those are important data points that many, including all the way to the public, may be interested in knowing. So having the ability to do that legally and administratively and realistically would be helpful.

DR. BLOCK: No, understood. Thanks so much, Jerome. So thanks, all, and a special thanks to all of our breakout group leaders.

So this concludes our breakout group discussion, as well as Day 2 of the Building Medical Device Supply Chain Resilience Public Workshop. Please join us again tomorrow for Day 3, where we are going to explore mechanisms and vehicles to facilitate collaboration between the Resilient Supply Chain Program and the private sector. But until then, be well and have a good rest of your afternoon.

(Whereupon, at 3:53 p.m., the meeting was adjourned, to be continued the following day, Thursday, June 9, 2022 at 1:00 p.m.)

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 8, 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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