UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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

DAY 3 - COLLABORATION AND ENGAGEMENT OPPORTUNITIES

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June 9, 2022
1:00 p.m.

Via Zoom Videoconference

Free State Reporting, Inc.
1378 Cape Saint Claire Road
Annapolis, MD 21409
(410) 974-0947

WORKSHOP PARTICIPANTS:

KAUSAR RIAZ AHMED, Ph.D., M.B.A., RAC
Senior Science Health Advisor
Resilient Supply Chain Program (RSCP)
Office of Strategic Partnerships and Technology Innovation
Center for Devices and Radiological Health (CDRH)
U.S. Food and Drug Administration (FDA)

MICHELLE TARVER, M.D., Ph.D.
Deputy Director, Office of Strategic Partnerships and Technology Innovation
Program Director, Patient Science
Digital Health Center of Excellence
Center for Devices and Radiological Health (CDRH)
U.S. Food and Drug Administration (FDA)

PAUL T. CONWAY
Chair, Policy & Global Affairs,
American Association of Kidney Patients (AAKP)

MIKE SCHILLER
Senior Director, Supply Chain
Association for Health Care Resource & Materials Management
American Hospital Association (AHA)

CLAYTON HALL
Executive Vice President, Government Affairs
Medical Device Manufacturers Association (MDMA)

PAUL E. PETERSEN, Pharm.D., M.P.H., CEM
Director, Emergency Preparedness Program
Interim Director, Vaccine-Preventable Diseases and Immunization Program
Communicable and Environmental Diseases and Emergency Preparedness Division
Tennessee Department of Health
Representing the Association of State and Territorial Health Officials (ASTHO)

TAMMY BECKHAM, D.V.M., Ph.D.
Associate Director, Resilient Supply Chain Program (RSCP)
Office of Strategic Partnerships and Technology Innovation
Center for Devices and Radiological Health (CDRH)
U.S. Food and Drug Administration (FDA)

GREG WALDRIP
Breakout Group Facilitator
FDA RSCP- MITRE Support Team

JONATHAN DAVIS
Breakout Group Facilitator
FDA RSCP- MITRE Support Team

JOEL COHEN
Breakout Group Facilitator
FDA RSCP- MITRE Support Team

PAMELA DOUGLAS
Breakout Group Facilitator
FDA RSCP- MITRE Support Team

MELISSA WILSON
Breakout Group Facilitator
FDA RSCP- MITRE Support Team

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M E E T I N G

(1:00 p.m.)

DR. AHMED: Hello, everyone. Welcome and thank you for joining us for Day 3 of the workshop on Building Medical Device Supply Chain Resilience: A Healthcare and Public Health Ecosystem-Wide Collaboration. I'm Kausar Riaz Ahmed, your host for the day. I'm a Senior Science Health Advisor in the Resilient Supply Chain Program in the Center for Devices and Radiological Health, FDA. We had a great day yesterday. In our panel discussion and breakout groups, we explored innovative methods and mechanisms for promoting resilience and mitigating future supply challenges. Next slide, please.

As a reminder, the Center for Devices and Radiological Health is hosting this public workshop to introduce the Resilient Supply Chain Program, bring together participants from across the medical device ecosystem to discuss current health supply chain topics, and explore opportunities to collaborate on enhancing resilience within the medical device ecosystem. Next slide, please.

Our theme for today is Collaboration and Engagement Opportunities. Next slide, please.

Today we will hear a keynote on Overview of Collaboration Mechanisms at FDA from Dr. Michelle Tarver, our panel moderator. Then our panel will discuss opportunities for effective collaboration in the supply chain. Following that, we will take a short break and move into breakout groups for those that are signed up. And then at around 3:25, we will welcome everyone back to hear a report-out of the key takeaways from a selection of the breakout groups. Next slide, please.

Just a quick reminder to send us your questions or comments through the webcast portal using the text bubble located in the webcast window on the bottom right, or through the workshop e-mail address shown here. We will record and transcribe the webcast and

post it to the workshop webpage after the event, and the workshop docket will remain open until July 11. Next slide, please.

Again, here we provide a view of the text bubble that allows you to enter a question or comment during the webcast. We look forward to hearing from you. Next slide, please.

Let's now take a moment to review the key takeaways from yesterday's workshop segment on Building and Sustaining Resilience.

In our discussions we heard building and sustaining resilience across the medical device ecosystem requires collaboration and innovation that would bring together tools and capabilities from across the industry and government. It also requires building on the foundations we developed to address the supply chain challenges over the past few years. This includes continuing to implement the solutions that have worked thus far and build new capabilities to strengthen supply chains; additionally, leveraging available data and analytics to promote data transparency, predict challenges, and provide end-to-end visibility of demand and vulnerabilities. And finally, we need to strategically prioritize investments for domestic industry and domestic manufacturing, advanced technologies, and alternative sources for components and raw materials. Next slide, please.

I'm thrilled to introduce Dr. Michelle Tarver, the moderator of today's panel discussion. Dr. Tarver is the Deputy Director of the Office of Strategic Partnerships and Technology Innovation in CDRH where she provides co-leadership for all scientific, collaborative, and emerging technology related activities. She provides oversight for efforts related to public health emergency preparedness and response activities, digital health, and finally, standards, development, and implementation, partnerships, and patient science and engagement. Under Dr. Tarver's leadership, CDRH is advancing efforts to include underrepresented populations in the evaluation of medical devices, including people living with rare diseases and with diverse age, gender, racial, and ethnic backgrounds. Dr. Tarver

received a B.S. in biochemistry from Spelman College in Atlanta, Georgia, and completed the M.D./Ph.D. program at the Johns Hopkins University School of Medicine and Bloomberg School of Public Health. Following her internal medicine internship, she completed a residency in ophthalmology and fellowship training in ocular inflammation, both at the Wilmer Eye Institute at Johns Hopkins. Board certified in ophthalmology with an epidemiology doctorate, she continues to do research and care for her patients with ocular inflammation. In her spare time, Dr. Tarver provides colorful commentary on the sidelines of girls soccer matches.

Michelle, the floor is yours.

DR. TARVER: Thank you very much, Kausar, for that kind introduction.

Good afternoon, good day, and welcome to the third and final day of our workshop on Building Medical Device Supply Chain Resilience. As you heard from Kausar, the discussions have been thoughtful, fruitful, and expectant, and I've thoroughly enjoyed hearing from our wide array of experts on what resiliency in the supply chain means, as well as innovative methods we may consider to mitigate future challenges. We've heard consistently over the past few days about the importance of collaboration, so it's only fitting that we close out the meeting on this theme.

As I reflect over the past 2 years in our frenetic initial response to the COVID-19 public health emergency, I've been reminded of the words of William Wordsworth. He once said that life is divided into three terms, that which was, which is, and which will be. Let us learn from the past to profit by the present and from the present to live better in the future. Today I have the pleasure of leading our collective imagination on what that future might look like if we intentionally learn from the past and consistently collaborated in the present to foster future resiliency in the supply chain. May I have the next slide, please?

So as you heard, collaboration has been ringing from the rafters of every plenary,

breakout room, and panel. And what's key to every effective collaboration is the inclusion of the key players. By definition, the end-to-end supply chain is cyclical and shaped by multiple stakeholders. It requires knowledge of upstream factors such as the availability of raw materials, transportation, labor factors, as well as downstream factors such as provider purchasing patterns and patient behaviors and outcomes.

So while industry, which includes the suppliers, the manufacturers, the distributors, own the supply chains, hospital systems, providers, and patients are the ones impacted and their purchasing and usage behaviors play a significant role in sustainability of that same supply chain. So to continue effectively addressing shortages and building resilience, we need to develop and sustain inclusive collaboration that fosters trust and reciprocity. Next slide, please.

This is ever more critical with the supply chain complexity that we're seeing in the medical device arena. So let's zoom out to the satellite view of the medical device ecosystem. There are more than 230,000 different types of medical devices on the U.S. market, not individual devices, but different types of devices, and those devices are manufactured by more than 27,000 facilities worldwide. These devices are sent by distributors to more than 6,000 U.S. hospitals and even more clinical practices, as well as ambulatory surgical sites. And durable medical goods suppliers. They are used by more than 9.8 million healthcare practitioners to care for the more than 332 million potential patients and existing patients in the United States.

It is therefore impossible for one individual at that level to have in-depth understanding of the materials needed to make and distribute every single device, its impact on the healthcare providers, and the ultimate effect on patients. And it shouldn't be our goal for all of that knowledge to sit in one individual. Instead, it's important that that information is shared and that we leverage the expertise that exists within that ecosystem

so that we can all learn from one another and bring that expertise to the table. Any supply chain mapping and illumination activities must be clearly and narrowly defined to achieve specific goals and yield meaningful insights. The success of these efforts depends on our ability to collaborate and engage with experts across industry, academia, health professional organizations, as well as patient and consumer groups. Next slide.

So let's start first by better defining the kinds of collaborative efforts we need to build and sustain supply chain resiliency. First and foremost is information sharing which includes data on suppliers and inventory, operational insights, as well as best practices and tools. This sharing, as depicted on the image on the screen, is reciprocal and it's not uni-dimensional or linear, in fact, it's cyclical.

Often when we think of data sharing, we immediately jump to data calls and of course, calls for industry to provide data do serve a purpose and will be needed at some level. But we also recognize that these calls have the potential to be burdensome and could bring additional challenges, as well as all we're getting is a snapshot of the information that's necessary to develop an appropriate response.

Given the scope and the complexity of the medical device ecosystem, information sharing also includes the sharing of expertise that's housed in industry, in healthcare, in the patient experience, as well as some less obvious sources such as the labor markets and transportation channels. This includes information on how the supply chain operates, as well as the best practices and tools for resiliency. This type of information will be critical for any supply chain illumination and mapping activities so that we can identify cross-industry vulnerabilities, as well as opportunities to enhance resilience.

While the goal of the FDA is not to build a supply chain capability of our own, we are committed to designing a program that facilitates bringing industry, academia, providers, patients, and professional organizations, to name a few, together to collaborate on global

supply chain issues, as well as best practices to promote resiliency. And shared information helps to fuel thoughtful, coordinated actions and that's the second critical element that's needed to sustain supply chain resiliency.

You heard earlier in the week about the unintended consequences resulting from lack of coordinating and inclusion of the critical stakeholders. When there is an active or anticipated shortage, an effective response requires stakeholders across the supply chain to work together in close coordination with government agencies, as well as end users to address and mitigate the shortage.

So how do we bring stakeholders together across the supply chain to coordinate actions to respond to and prevent shortages? We cannot only think about it when we already have a shortage. Instead, we must think about this before a shortage presents itself. And we can only work well together if we know one another and we trust one another and we have established mechanisms to coordinate those efforts. You heard examples all week about ways outside of a public health emergency, as well as during a public health emergency, such as during natural disasters, where the upstream and the downstream stakeholders have worked together to mitigate shortages.

Similarly, as we identify potential vulnerabilities within the supply chain and seek to proactively address them, effective prevention will require close coordination to adjust behaviors and practices to increase resiliency. Together we can share information on common vulnerabilities and challenges across product categories and then brainstorm to identify opportunities for mitigating those vulnerabilities, thereby building resiliency within the system.

Whether it's manufacturers changing suppliers or using alternative components, group purchasing organizations being more flexible on product specifications and pricing, changes to distribution and usage, or clinical conservation practices, effective prevention

will require engagement across the medical device ecosystem. Information sharing plus coordinated actions have the potential to spark the eternal flame of resilience. Next slide.

CDRH has established and participates in many mechanisms that bring stakeholders together. You've heard about the many public-private partnerships that exist in prior talks, so I won't really spend time discussing those. Instead, I want to briefly share with you how we have identified the imperative of working with certain stakeholders and then adapted mechanisms to help facilitate those partnerships.

On this slide you see listed the Network of Experts and the Patient and Caregiver Connection. We have agreements with professional organizations and patient organizations, respectively, that provide our staff with access to insights about medical conditions from both provider and the patient perspectives, what it's like to use or interface with the device, and the challenges that may be facing that particular healthcare community.

Key elements that I want to highlight are that it's reciprocal, it's born out of and continues due to mutual respect, and it gives us the opportunity to work with one another. These two mechanisms, as a result, have allowed FDA not only to have sustained relationships, but also for us to receive just-in-time input.

The last example I'd like to call to your attention on the slide is Collaborative Communities and this has been one of CDRH's strategic priorities over the past few years. Collaborative Communities are defined as continuing forums where public and private sector members proactively work together to tackle shared challenges, leverage collective opportunities in an environment of trust, respect, empathy, and openness. We don't assert that we're the first entity to use this particular term, but we do know that these grass-root movements really do change the landscape. In fact, there have been models where people have not had a challenge that's been well defined or there's no consensus on how they

might want to define it, where the challenges and outcomes are multidimensional and complex, where there are many partners that are interrelated and then the prior incremental and unilateral efforts they've undertaken to address the challenge has been ineffective. These are the settings where Collaborative Communities are likely to be most beneficial. This is truly an approach that's focused on optimization to prevent duplication and to foster sustained efforts.

Collaborative Communities are convened by the interested stakeholders and appear organically rather than at the direction or the request of the FDA. In essence, FDA, we don't establish, lead, manage or operate them, nor are they intended to advise the FDA. Instead, we, as FDA, participates as any other member working together to build solutions, and we consider adopting those solutions developed by the community if doing so is in the best interest of public health and consistent with the law. These particular communities may exist indefinitely, produce deliverables as needed, and tackle challenges with broad impacts. This mutually beneficial relationship is reinforced by shared responsibility, as well as accountability for achieving results toward common goals. We currently participate in 12 Collaborative Communities and have been asked to participate in a number of other ones. We really do believe that this is the way of the future.

And to paraphrase Barbara Gray, by working collaboratively we have the opportunity for parties who see different aspects of a problem to constructively explore where the differences are and search for solutions that go beyond their own limited vision of what is possible.

And with that, we are going to move to our panel. To help kick off our conversation of how we could make this all possible, I would like to introduce our illustrious panel for the day. We are going to discuss ways to effectively collaborate, what successful collaboration would look like, and how do we build from where we are today to there. So next slide,

please.

I'd like to first introduce you to Paul Conway. Paul Conway is the Chair of Policy and Global Affairs, and the immediate past president of the American Association of Kidney Patients, the nation's largest kidney patient organization. A kidney disease patient of 41 years, he is also the chair of the Food and Drug Administration's Patient Engagement Advisory Committee. His professional background includes health policy and national emergency operations, and he has served under four presidents, three Virginia governors, and in support of five presidential transitions. Welcome, Paul.

I'd like to also introduce you to Mike Schiller. Mike is the Senior Director of Supply Chain for the Association for Health Care Resource & Materials Management of the American Hospital Association. As the organization subject matter expert, he brings over 30 years of healthcare supply chains experience to this role, collaborating with industry leaders from across the healthcare fields on various supply chain, advocacy, and regulatory initiatives.

Working with the American Hospital Association and AHRMM executive and policy leaders, Schiller participates in the development and implementation of the association's strategic direction and initiatives such as the cost, quality, and outcomes movement, clinically integrated supply chain, learning UDI at healthcare learning communities, as well as the association's COVID-19 strategies including the AHRMM vendor vetting program, Supply Chain Resource Council, and the American Hospital Association Dynamic Ventilator Reserve.

Next, we'd like to welcome Clayton Hall, who is the Executive Vice President for Government Affairs for the Medical Device Manufacturers Association, or MDMA. Prior to joining MDMA, Clayton spent 12 years working on Capitol Hill and served as Chief of Staff to three members of the U.S. House of Representatives. Clayton managed a diverse portfolio

of political and policy issues while he was on the Hill, playing a major role in drafting numerous pieces of legislation, including legislation to reform the federal regulatory regime and Medicare payment policies.

And last, but certainly not least, is Dr. Paul Petersen. Paul is the director of the Tennessee Department of Health's emergency preparedness program and the interim director for the Vaccine-Preventable Diseases and Immunization Program. Dr. Petersen serves as lead in Tennessee's response to all public health and medical emergencies. Tennessee has experienced a wide range of threats and public health emergencies requiring decisive action by government staff, healthcare coalitions, and other response partners. Paul also serves on various national preparedness policy committees including work with the National Academy's National Emergency Management Association and the Association of State and Territorial Health Officials. He currently serves as the national chair for the Directors of Public Health Preparedness.

Welcome, everyone.

So we're going to start our panel off with the first question. I'm actually going to direct this to you, Mike. Where have you achieved successful collaboration in supply chain matters or elsewhere, and what challenges have you encountered when collaborating? And how have you facilitated or worked with others to facilitate successful collaborations?

MR. SCHILLER: Thanks, Michelle, and thanks for the opportunity to be here today, it's a real pleasure. So there are a number of initiatives that we engaged in and I'll highlight just a few of those.

To start with, early on in the pandemic we took the hundred million mask campaign that one of our members had initiated, one of the members up in the Northwest had initiated, and we were able to take that program and grow it nationally, and through the program we saw a tremendous collaboration with community businesses, community

partners, companies that were making PPE products, masks, gloves, face shields, and sharing those with hospitals, helping our clinicians, our frontline caregivers care for patients and certainly fill the gap during those early days of the pandemic when PPE was in very, very short and critical supply, to be honest with you.

We also had created the Dynamic Ventilator Reserve program, this was a fantastic program. We started this back in April of 2020 and we worked with 33 health systems and hospitals and had 2800 vents that were pledged to the program. Through this, this collaborative effort with these healthcare organizations, we were able to take ventilators and move them from low-use areas to high-need areas, and over the course of the last 20 months we moved over 260 ventilators to these high-need areas and really made a positive impact in the care of these patients who needed those ventilators, so a great example of collaboration across the healthcare field.

At AHRMM we collaborated with a third-party vendor credentialing company back in March of 2020 when the FDA began releasing their emergency use authorizations and we saw a tremendous outpouring of non-traditional PPE suppliers or gray market suppliers that were entering the U.S. healthcare space and selling their products within the U.S. healthcare supply chain. Our members were inundated with hundreds of calls and e-mails on a daily basis from these vendors who had product to supply.

So what we did is we undertook a program where we began a vetting effort of these vendors, we vetted over a thousand non-traditional PPE suppliers and approved 400. Basically, what we were doing was we were taking the first pass at a vetting program for our members. We hosted those 400 approved vendors on our website and shared those with the healthcare field, letting folks know that hey, you really need to follow your own policies and procedures to approve these vendors, but again, we've taken the first pass and these are the ones that have the lowest risk and we feel comfortable sharing with you, so

very successful, very beneficial.

We also partnered with a couple of other organizations that were doing similar work and we began to build an online repository of PPE that became a necessary tool for hospitals, business leaders, as these businesses began to reopen later in 2020 and had to buy PPE, right, it was something that businesses in the past had not needed to buy, so it was a great industry resource for both healthcare and businesses.

Lastly, back in November, we convened our Supply Chain Resource Council, this council brings together over 60 supply chain leaders from across the healthcare field. Our focus is on the supply chain disruptions, the supply chain shortages, with a focus on solutions, what are some of the strategies, conservation strategies, alternative sourcing strategies that we're seeing the healthcare field engage in to make it through these shortages and disruptions, and that information is shared very broadly with the field and our regulatory agency partners. so some key examples of collaboration in a number of different areas that have proven to be very, very successful and very beneficial.

DR. TARVER: Thanks, Mike.

Well, I need to also ask Paul if you'd like to add a little bit onto that question, the collaborations that you've seen work successfully and what has facilitated that successful collaboration, as well as some challenges you've encountered when collaborating.

MR. CONWAY: Sure, I think probably some of those significant tenets of successful collaborations that we've seen are when, in advance of an issue, people had a very clear understanding of what the unique capacities are that large stakeholder organizations such as ours can bring to bear. And in that spirit, we've worked very aggressively with federal agencies proactively and have had great response back, reaching out to us specifically for our capacities on the side of communications, other relationships that we have, be it on Capitol Hill or with governors' offices or with state agencies, our capacities on media

relations, so that we can be a trusted source of communicating with the media what is fact and what is not fact. We do a lot of that work in the midst of issues like this. And then the other thing that we have is we have the capacity to do pre-substantive analysis of what went right and what did not go right in the event of an emergency or something like that.

And so when you take a look at the involvement of large patient organizations or specialized rare disease organizations, I think it's very important for all of the elements of a collaborative to understand what those capacities are and that in a way, the ability for patient organizations to communicate to patients in large measures, because we have disproportionate credibility, we're a known brand, people trust us as a source, and if we seek to correct something or put out timely information, it will be recognized.

The other thing that has been helpful is the recognition of our capacities, not just AAKP, with other organizations for both quantitative and qualitative data on a quick turnaround basis for what's actually happening in the field. For us, that's through our patient ambassador program where we have ambassadors in every metropolitan area in the United States and in every state where they monitor social media, they can give social media insights about what's happening in certain areas so you can see trends and impacts.

And then the other thing that we have the ability to do is put a group of patients very quickly on a phone or on a video chat with officials or with other collaborative partners to hear firsthand what they're seeing at either a retail location or what they're hearing from a medical practice or from a hospital in terms of their access or limits to certain types of care or product. And I think in that spirit, those are the types of elements that have made things successful, not just during COVID but also during natural disasters. I hope that's responsive to you, Doc.

DR. TARVER: No, it's wonderful. And I think you've highlighted the importance of bringing the patients to the table as part of the conversation.

Dr. Petersen, could you also comment on successful collaborations, what's worked and hasn't worked in a public health emergency as well as outside of that emergency, from your experience?

DR. PETERSEN: Great. Thank you, Michelle.

So working at the state public health level, I get to work a lot in the kind of intersection of both healthcare, public health, and emergency management. One of the big findings that we see over time is the need to be scalable, we have to have scalability of resources, especially during times of fiscal plenty and famine. There are different opportunities for us to strategically invest in smart resources that can last a long period of time and really help us with both public and private sector engagement, but then also sustainability. So some of the stuff we really are focused on.

One of the things that we kind of highlighted as a successful collaboration during our COVID-19 response in Tennessee was there was a huge need for ventilators. So I think each state kind of did some of this on their own in addition to what Mike was talking about at AHA. So we bought a good number of ventilators and IV pumps and PAPRs and other things, and one of the things that we knew we did not have the capability of was to basically be able to maintain those resources so again, back to sustainability, how do we support that.

So one of the strategies that we employed was to develop a biomedical equipment company contract, and what that kind of enabled us to do was to empower this contracted entity to both maintain and deploy resources when needed across the state. Again, whether that was ventilators, IV pumps, or PAPRs, a lot of those procurements came about because of the need to both facilitate healthcare facilities and hospitals, but also some of our alternate care site hospital planning that we did to develop basically additional search capacity. It was really a great partnership between emergency management and the

Department of Health because really what this allowed us to do was to support healthcare partners to be able to surge with resources that they cannot maintain themselves. And so we were able to basically bring together various funding streams to have sustainability over a number of years and develop really prescriptive resource request processes so each of our entities and healthcare entities in the state know how to access that resource using trusted relationships.

And so we have those things in place and a lot of these different processes aren't brand new. So I think there's been other discussion about best practices and things like that. There are other examples of medication and other PPE caches in this space across the country that can be used as a basis for learning and help further this conversation about how do we build a resource that is both shareable but sustainable over time. Thank you.

DR. TARVER: I think that's a great point, the importance of knowledge sharing, how do we build in resiliency, scalability, as well as communicating, because I think that's such a critical element, how do we get the message out and bring in the information.

So I wanted to give Clayton an opportunity, and I don't know if you wanted to comment as well on this question which is the successful collaborations in which you've participated in and what are some of the things or elements of those successful collaborations in supply chain?

MR. HALL: Happily. And again, thanks for convening this workshop.

Early in the pandemic, the early days of the pandemic, of course, were crisis. We had companies who were dealing with business interruptions and stay-at-home orders. Oftentimes those companies were providing products that were needed in response to the pandemic, so working with partners, including the FDA, including the federal government and the White House. It was a bit of a whack-a-mole and thankfully, because of the way the disease progressed, many of the states in the East Coast, as they were pulling together their

stay-at-home orders, they were broad and often the case, shut down medical manufacturing facilities. So we were able to work with a couple of governors in the early stage, develop some model language that allowed for, again, manufacturing sites for key medical products to remain open and then replicate that as the disease spread across the U.S. I think that was really an early success.

And then obviously, we had companies, again, that also manufactured products for critical response that had to flex, and the FDA was very helpful in coordinating those efforts. And then we had companies that, because of the pause of elective surgeries, maybe they had products that weren't needed necessarily in the actual pandemic response and had assets it could bring to bear for all the new entrants in the market, particularly, you saw with the domestic PPE production. And so we were able to do some matchmaking and take regulatory experts that -- I mean, no one had a lot of free time early in the pandemic, but to the extent they had bandwidth and were able to help, you know, maybe more traditional clothing manufacturers, as they started to look at regulatory schemes so they could provide surgical gowns, for example. So those are obviously some early successes and we've learned a lot since then.

DR. TARVER: I think that's a great example of how collaboration sparks creativity, because we really did have to be creative in our approaches.

You all mentioned different types of collaborative efforts, some with clothing manufacturers, some of them with ventilator companies, hospitals, and I wanted to hear a little bit about how did you build trust with those entities? If you didn't have an existing relationship, how did you guys go about fostering that relationship and figuring out who the key stakeholders needed to be in order for us to be most effective in mounting a response? And I will open the floor to anyone who'd like to answer that.

MR. CONWAY: I'll go ahead and jump in. We operate on a set of principles that has

made it very easy for us to collaborate and establish trust. So first what we try to do is diagram different scenarios where we would need relationships and try to work on developing relationships as far in advance as possible. But our core operating principles are number one, the principle of no surprises, so we will always pick up the phone proactively before we talk to anybody in the media or say anything on social media.

Number two, we never assume somebody is doing something for X reason, fill in the blank, without calling up and communicating directly first. Sometimes patients and patient organizations may not be thought of at first, but we need to assume the responsibility of proactively reaching out.

And then the other thing that we are very good at trying to do based on our principles that has made it easy is to be there for the post-event analysis. And I can't emphasize that enough because you must anticipate that mistakes and problems will occur, that's just the nature of any type of an emergency, and instead of casting aspersions, trying to understand what happened, understand what capacities were brought to bear, what might be missing, and who else should be at the table and then being part of a very candid process and confidential to make the next time better.

And for us, that has helped us tremendously with industries in the biologics, in the diagnostics end of the device side, but also with hospitals and with major medical associations and professionals so that we have an ongoing dialogue and oftentimes what we find out is that we've missed an important sector, we didn't map it, we didn't anticipate it, and after COVID we have an extensive set of new relationships that we're working on and that's the positive thing that has come out of it. But really, I think it comes down to how you orient yourself and how you view others in the ecosystem and an openness to engage.

DR. TARVER: Thank you, great.

And I see you're off mute, did you want to --

MR. HALL: Yeah, I would just build on what Paul said, I mean, we are all -- I think everyone on this call, for the most part, are mission-driven organizations, they've developed credibility with a broad group of stakeholders in the regular work that we did before COVID, and those networks and relationships were critical when dealing with kind of spot issues that popped up through the pandemic, and trust is earned and it's earned through, again, relationship.

And I think obviously a challenge, and maybe there's an opportunity to talk about this later in the discussion, but while Zoom is a great platform, it is enabling you to have this workshop, all of us have this workshop and reach a really, really broad audience, it's probably not the best venue to develop meaningful relationships, it's hard to read body language, technical difficulties can certainly be a distraction. Oftentimes when the group gets bigger than maybe five, it can be difficult to have a real collaborative conversation.

And so hopefully we're turning the tide in our own personal experience, we just had our first in-person MDMA event, our annual meeting, brought 200 people to town in April and people really wanted to be back in person. Now, everyone has to make, obviously, assessments on the state of the disease spread and your own medical risk, but I am hopeful with each passing day we're getting closer to something like the return to normal because it really is difficult to develop those sort of meaningful and trusting relationships virtually or even over the phone and frankly, it takes a lot more work than it does to meet someone for a cup of coffee or to catch someone after a presentation as they walk off the stage and kind of share information.

But I would say COVID, by and large, despite the challenges of not being able -- the limits to kind of in-person interaction, it was a unifying event. I mean, I think certainly I can't think of e-mails that were unreturned or phone calls that were unreturned, all of us were certainly in it together and so I think that also played out during the pandemic.

DR. TARVER: Mike, did you have a comment?

MR. SCHILLER: I just want to add to the great comments that Paul and Clayton had shared, that really, there was a renewed sense of goodwill during the course of the pandemic, you know, "we're all in this together" type of mentality which I really think brought a lot of collaboration to the forefront and a lot of trust, I think, right out of the gate to work together; certainly, a lot of different initiatives that came up, a lot of different meetings bringing stakeholders who previously had not come together outside the realm of a pandemic who were now together, which I think also brought together a greater opportunity to network and to build off of those networks and to engage in projects and other initiatives outside of the initial initiative that brought folks together.

So I think that that's really expanded. I know, personally, my own network has grown vastly just over the course of the last 2 years with the number of people who I've now had an opportunity to work with outside of the pandemic, may not have had the opportunity to work with.

So silver lining, and I think that goodwill and that community engagement working with local and community businesses, again, these new relationships that have been established, we continue to build the trust, we continue to collaborate, but I think it's a great model that we can build on and certainly, as we look forward and move ahead to reimagining a new healthcare or more resilient healthcare supply chain, again, I think it's a great model for us to build upon.

DR. TARVER: Paul?

DR. PETERSEN: Yeah, just a bookend to the awesome comments so far. You know, historically, we in states, in Tennessee, and I can talk for other states as well, have really developed relationships and trust over time through a variety of kind of joint activities, whether it's a disease outbreak, a measles outbreak or some type of emergency response,

we have tons of examples of train derailments where we have to deploy medical countermeasures to support a cyanide exposure, to a huge wildfire response, to an influenza search to, of course, COVID, and what that means is each person that is in that response understands the capabilities of others in their community and that ongoing engagement, as Mike said, is critical.

So one of the entities that I really wanted to underscore, and everybody to write it down as a resource in their local community, is a grant-mandated process through HHS Assistant Secretary for Preparedness and Response called Our Healthcare Coalitions. So every state and locality has a footprint of a healthcare coalition that is basically public and private partners, some private partners that work in direct healthcare competition on a daily basis that come together and share information, share resources, and respond effectively as one unit. So these healthcare coalitions are a critical stakeholder in any effective collaboration on both the caching of resources but also deploying of resources and information sharing at the local level in any state.

To ensure a motivated group such as our healthcare coalitions continue to meet, one of the things that we really try to focus on is how do we demonstrate the value add of that collaboration and how do we document through positive impact on the community? So one of the things that I've put in place as a requirement of each of those coalitions is annually they have to create some type of impact story, they have to basically be able to say what the return on investment of these resources are and how they've impacted their community by being able to partner and deploy resources.

And I think one of the other key messages I would say is to ensure that these types of groups at the local level continue to be engaged, it's really critical that they feel like their feedback is heard and that all partners have some type of fingerprint on the outputs of these collaborations so they are vested in the sustainability of those resources but also,

again, really effective sharing and response across the sector. Thanks.

DR. TARVER: That's great. I mean, I think you've highlighted a couple of very important points which is that these relationships cannot be transactional, they need to be relational. And one question that we've gotten in the chat is what kind of information sharing doesn't happen right now, in all the collaborative efforts that you all are undertaking, what kind of information sharing is not happening now and what would help to advance that trust so that that information could be shared that could facilitate response efforts or proactively position us to deal with particular supply chain concerns?

And I'll ask Mike if you want to tackle that first, and then I'll ask Clayton.

MR. SCHILLER: Sure. I think one of the struggles that we still face is true transparency. There's not the visibility that we need, the full transparency across all the different stakeholder groups that comprise the healthcare supply chain continuance, so what we really need to do -- and we're talking about trust here, Michelle, and trust is foundational, right, to taking that next step that allows us to be more transparent with information. There's intellectual property, how is the information going to be used, these are some of the concerns that you hear from different stakeholder groups.

And let's think about this, true transparency and true visibility into supplies, how do we address the human behavior that emptied grocery store shelves of toilet paper? I mean, that's basic, right, basic human nature. So I think that these are some of the challenges that we have to overcome and they can only be overcome, I think, through these public-private task force groups, these coalitions that Paul had talked about, where we maintain that mindset of goodwill and really focus on the patient, right? I mean, at the end of the day, it's the patient that is at the center of everything we do and I think that we need to keep that first and foremost in everything.

DR. TARVER: Certainly. More collaborative communities, I'd say that, too, in terms

of a person.

Clayton, did you want to chime in and have a comment for what kind of information?

MR. HALL: Yeah, so good question. I think it will obviously be an area of much attention as the Resilient Supply Chain Program kind of grows. Obviously, you have commercial interests at play and lots of this information is business confidential in our industry and Michelle, as one of your early slides suggested, it's diverse. There are thousands of companies, large and small, offering hundreds of thousands of products for patients and in most cases, really in contrast to other medical products, there are multiple offerings within the same category of medical devices.

So part of one of the real strengths of the medical device industry has been that diversity and the competition within the marketplace and so obviously, there would have to be discussions about data custody and so maybe that's -- I'll table that for maybe a future conversation. But additionally, I would say an area that is a real challenge right now for device makers and also others in the commercial bids market is the opaqueness of the semiconductors markets. You know, chips go in everything and the FDA, your partners at the Department of Commerce have done a great job in helping us kind of raise awareness about the needs for chips for public health, but oftentimes manufacturers have relationships with wholesalers and maybe because of our market size do not have direct relationships with the semiconductor manufacturers.

And I think oftentimes semiconductor manufacturers move their chips through kind of wholesalers and that's created, obviously, a real challenge and I think FDA can continue to play an important role in highlighting our industry's needs as it relates to chips with your interagency partners in the government, but also as a signal to suppliers because oftentimes suppliers say if they had awareness of who the chip was going to, for example, that they would be inclined to prioritize chips for public health. So it is important, again, for

suppliers to understand the public health impact and those considerations as they fulfill orders, so look forward to continuing to work with the FDA on that.

DR. TARVER: I think that's a great point which is some stakeholders that we haven't traditionally talked to, maybe we need to start including so that we can think of the supply chain not just at the finished product stage but really start looking at it more upstream.

We talked a little bit about some of the elements of successful collaboration, some of the collaborative efforts you all have participated in that have been very effective. Let's assume that CDRH is a partner in a collaboration going forward in helping to foster this resilient supply chain. What do you think the goals of that collaboration should be? If we're going to have a sustainable relationship, what would success look like to you all? And I'd like to start first with you, Clayton, since you're --

MR. HALL: Right.

DR. TARVER: -- center screen right now.

MR. HALL: Of course.

DR. TARVER: What would success look like?

MR. HALL: So I mean, I think going back to the goal, the shared goal continues to be to strengthen the public health supply chain in the U.S. and ensure that our patients have continuous access to critical medical products. So on that point we are aligned and obviously, alignment is fundamental on a goal, a shared goal.

You know, in terms of what the program could grow to be, I think as you build it out, success in our view includes creating an open and trusted venue for key stakeholders. In our view, that core group includes, obviously, manufacturers themselves that are representative of the broader industry; as I previously mentioned, we are a very diverse industry, we have very small, also mid-size and also very large international companies, each of which bring their own expertise and perspectives; our partners in the provider

community, including hospitals; certainly, distributors and also the trade associations who represent -- like MDMA, who represent those underlying groups so that we can collaborate on resiliency strategies but also to share information early on, on potential disruptions that maybe one player may see or notice on the horizon so that we can better prepare and kind of avoid shortages.

And as I mentioned, I just want to flag this again because it was mentioned yesterday, but again, the device makers exist in the broader marketplace and so in instances of limited allocations, we often are competing against larger commercial goods manufacturers who have more buying power and so for components like chips and for raw materials. So part of the definition of success really here is continuing to raise general awareness about the public impact of the industry and oftentimes the needs of medical device manufacturers in the broader marketplace.

DR. TARVER: I think it's a very good point.

Paul Conway, I'm going to turn to you to answer this question, as well, because we're increasingly seeing devices that are being used in home settings, so patients are often some of the drivers and shapers of what that demand paradigm looks like in the supply chain. And so could you speak a little bit about what success would look like for you all in terms of the supply chain program's resilience?

MR. CONWAY: Sure. And I appreciate the question because patient/consumers are at the table in so many of these different decisions and now they're really driving, you're correct, the demand for devices, especially that's one of the things that's come out of COVID with telemedicine and other electronically enabled devices, the ability to do things safely in your own environment. So for us what success would look like would be a recognition of our role as an equal partner in the solution of supply chain, to also be able to understand and how other partners understand the complex nature of, for example, kidney

patients. It's not simply kidney disease; usually, these folks have multiple comorbidities that also have to be managed: cardiac issues, bone disease issues, there are supply issues of medical supplies, it's multifaceted. So I think for us, the partnership obviously would have exposure to the other players.

The other thing that I think is very important here to talk about is that successful collaboration for us would be substantive and what I mean by that, is that not only are we on the front end of developing any type of a strategy or a schematic for what it looks like, but we're actually involved in what I would call exercising the plan. So taking the hat that I used to wear at DHS, you have national exercises, you have regional exercises, but it's very important that when you take a look at supply chain-type issues and medical issues, and Dr. Petersen probably knows this well out of Tennessee, is to understand that you involve many different players, but a plan is only as good as you exercise it and you identify over time what the strengths and weaknesses are, and I think that we could bring some unique insights to that and share those with other folks, as well.

But I think the government has many powers, the power to convene is probably the most important and overlooked. And so as you go forward, we appreciate being a part of that and understanding that we also have ongoing relationships with so many other different stakeholders that we might identify some other folks that you might want to consider.

MR. HALL: And Paul, mea culpa, I have some notes I've jotted down and patients were the first in my group and I somehow skipped that, so apologies. They are, obviously, the north star in everything that our companies do in the development of new therapies and treatments and obviously, for the FDA in the delivery of safe and effective devices, so I apologize.

MR. CONWAY: I take it as understood.

MR. HALL: Okay, thank you.

MR. CONWAY: Yeah.

DR. TARVER: I think, Paul, that touches in to your point where you said we pause, we reassess, and we're able to critically evaluate what we do and say, so I think that's really helpful, what we illustrated.

One thing that I also heard is there were some concerns about the information sharing and what kinds of information and what kind of safeguards we need to put in place because we are talking about intellectual property, I think somebody talked a little bit about antitrust considerations on the workshop discussion yesterday. So what mechanisms do you think could be put in place that would allow for us to collaborate and work in that precompetitive space prior to some of that IP, but that would be useful intelligence that could help us mitigate shortages in the supply chain?

And I will ask Mike if you would like to comment.

MR. SCHILLER: Sure, I think one of the strategies really would be to utilize one of the existing tools right now, the unique device identifier. I think if the unique device identifier was broadly adopted throughout the healthcare supply chain continuum, that would help us to better understand utilization, where that utilization is occurring. It would give us additional visibility and transparency, and we talked about further upstream in the supply chain where we really do need that visibility and that transparency, and I think that that will bring about some additional benefits to the entire healthcare organization.

And again, I think it's critically important that we maintain these public-private partnerships, right, these types of initiatives that are bringing all of the stakeholders together. Let's face it, nobody does silos better than healthcare, right, and it's time that we tear down these silos and it's time that we come together in these open environments with the stakeholder groups to better understand. You know, I can't tell you that I fully

understand every facet of distribution and supply manufacturing, I've got a really good idea after 30 years, but nonetheless, manufacturers and distributors may not have as good an idea as they think they do on what takes place in the hospital setting. So a wonderful opportunity for us to learn from one another to utilize the tools that we have at our disposal and utilize them much more effectively than we currently are and that will help us to take the next steps that we all need to take.

DR. TARVER: I think it's a really good point and I think you alluded to the importance of the sustained collaboration, and I'd like you all to speak a little bit about how you see the partnerships, the collaborations that were built in response to public health emergency move forward from here, outside of -- knock on wood -- the public health emergency at some point coming to an end, where we can actually think of what our new steady state looks like.

So I'd like to see Paul Petersen, if you wouldn't mind addressing that, and I'm going to ask, actually, everybody on the panel to provide their insights on that particular question.

DR. PETERSEN: Great, thank you. So I think, to get a better sense of where our next steps are, there are some specific areas that I think have been identified as basically gaps in information. And so one of those things, I know at the state and local level, one of the things that we have dabbled in is trying to develop a standardized supply chain assessment for healthcare facilities, to look within a healthcare coalition, to look within the hospital walls, and to use that to identify vulnerabilities and then once those gaps are known, being able to leverage some of the federal funds that we get through some of these cooperative agreements from CDC and HHS to help patch those holes, but I think the key there is having something standardized so we're all speaking the same language in each state.

Another tool that we have had to use in a few different emergencies, like our Gatlinburg wildfire in east Tennessee was -- there's a tool that CMS has and HHS has called

the emPOWER database and it allows us to gain access to CMS beneficiaries, where they live, and the folks that are on home medical devices so when there is an emergency, we can basically get this list, I kind of have to sign my life away to get it, but I get this list and then we can make strategic decisions about engagement.

So like in Gatlinburg, we had 70 individuals within this area that was completely decimated by fire. We were able to get this tool, go into that community and actually find one individual that was stuck in their home that needed to get to healthcare because we have this list of those that were dependent on medical devices.

So I think incorporating some of these tools are really critical and again, I'd like to underscore that success means using a Babel-tested system with the daily use case. If we don't do that, if we try to create systems on the fly continuously for every disaster it is going to slow us down and we're not going to be kind of a quality improvement learning system and so it's really critical that we do that. So in other words, really having a stable infrastructure that can be effectively leveraged over time is what is needed, and I like to use the term all-hazard preparedness when we think about that and it's really critical. And a lot of really cool practical things are also highlighted in a recent National Academies consensus study on building resiliency in the supply chain that I'd point people to, as well. Thanks.

DR. TARVER: Thank you. Clayton.

MR. HALL: So maybe the conversation is -- maybe I'll answer this in the context of the Resilient Supply Chain Program and kind of, you know, certainly the part of the public launch, although the program has been in place, as of this workshop, I think it's important that stakeholders understand that CDRH does have an open door policy to come to them with issues and that's obviously a message that's been clearly delivered as part of this workshop. Maybe the development of a toolkit that provides kind of key points of contact in the program, identifies their respective roles and responsibilities within the program and

notes what authorities and regulatory flexibility CDRH employs that may help manufacturers mitigate disruptions and that would obviously have value and kind of develop buy-in and you have great toolkits. Michelle, I was looking at your Collaborative Communities toolkits earlier this week and so obviously, there's an expertise in developing these. So there's the collaboration for preparedness and resiliency and that's essential.

But in addition to the work that you're undertaking for resiliency building, there could be opportunities to work with other stakeholders, all of us to some degree have probably worked with the Health Sector Coordinating Council and they are developing their own resources and toolkits to identify and share best practices around resiliency and certainly, I think, could be an important partner in developing some of that with industry participation, broad industry participation as it relates to supply chains and that, again, would be complementary of the work that collectively we're already doing there to develop a list of critical medical devices.

DR. TARVER: Paul Conway, did you have a comment? Thank you.

MR. CONWAY: Yeah, actually I think an important marker for success going forward on this would be the awareness and incorporation of FDA efforts into existing frameworks at the state level. So Dr. Petersen talked about state health councils and that is a part of state governments, but the other critical part, after 9/11, at the state level are the planning mechanisms that governors have in place for all incident response through state homeland security agencies and councils.

Now, oftentimes when those are brought together, they're in reaction to a major event, but the forward planning and understanding of what other tools are available at the federal level, I think, would be important for FDA and also especially for patients to understand that that tool is incorporated, as well as reflected in the ongoing operations of DHS and FEMA, who also have a substantial role in not just response, but response in

rebuilding long term, because if you take a look at some of these issues that can happen at a regional basis in the United States, if it's an earthquake or a severe wildfire or a terror event, you could actually be looking at something that's sustained over time in an entire region and I think that in that way the tools that you folks have developed at FDA are a huge value add and in many cases are clearer in their thinking than a lot of things that have been developed over time but are not as comprehensive now, post-COVID or in the midst of the COVID planning process, they were anticipated 10, 15 years ago, but I think you bring updated thinking to this process that would probably be welcome. It certainly would be beneficial to patients, I think, on the ground.

DR. TARVER: Those are all fantastic comments. I think what I -- and I'm sorry, I'm taking notes, that's what I keep looking down for. You know, I've heard a theme of agility, I've heard the theme of being flexible and adaptable, but the importance of having standardization come to bear so that we're all talking about the same thing at the same time.

Can we talk a little bit -- I think yesterday we heard a little bit about standardization of, you know, what the unit is with the GPOs may differ from the unit in the hospital which may be different from the unit of a particular device from a manufacturer. Where do you all view that standardization may be useful? I think, Paul Petersen, you spoke a little bit about standardizing some of the supply chain assessment tools and what we're talking about, but what are the other things that you think some standardization would be beneficial to help us with as we're looking at supply chain resiliency, things that you think would be best built collaboratively?

(Pause.)

DR. TARVER: And that's an open mike opportunity, so if anybody has an idea. That's one of the questions we actually got from the audience.

MR. SCHILLER: Michelle, I'll go back to my previous comment around the unique device identifier. There is tremendous value, again, across the healthcare supply chain continuum if we're all calling this product by the same name, right? We're identifying it by the same device identifier or DI. When we can have that type of standardization from point of manufacture to point of consumption and then downstream into various patient registries, there's tremendous power in being able to standardize and analyze device performance, what devices perform best in which patient populations. Not only that, but from a hospital cost perspective we're able to identify and standardize on our utilization, and we're able to really get to two things, more of a demand planning environment that we don't currently have. Hospital supply chains are historically based on power levels and power levels are based on purchase order history or AP history, right, what I ordered or what I've received and paid for.

But to move to a true demand planning environment, think of it from a distributor's perspective. It helps them to separate the demand signal, is this a true demand signal or is this a stockpiling or a hoarding demand signal. So how do we begin to separate those signals and utilization at the point of use consumption data that will help us to drive better analytics that become predictive and help us to be much more proactive? Again, when I talk about this, I'm not talking just in a hospital setting, I'm talking the entire continuum.

So I think that, again, UDI is critically important and I think, to be honest, I've been working on the UDI for almost the last 10 years, spearheading a lot of different efforts, working with a lot of different groups. We've taken our eye off the ball a little bit and understandably so, we're in the midst of a pandemic, but as we move into more of a resiliency mindset, what do those next steps look like, I firmly believe that UDI and data standards have to be one of the centerpieces of a resilient supply chain.

DR. TARVER: Definitely agree, the importance of UDI and the opportunities it

provides, I mean, that's how it was envisioned, what you just described.

Anybody else have thoughts --

(Cross-talk.)

MR. HALL: Look, Mike, Mike, I'm going to defer to you as the expert on UDI, I would say UDI obviously has great promise. I think an area of concern that we've heard from our members is obviously there are challenges sometimes, particularly with long-term sole-source contracts into hospitals or systems of hospitals and to the extent UDI can also be used to drive contract compliance, in the opinion of smaller companies that are new entrants that are trying to get into hospitals, you know, that can be a challenge and it could be a real challenge to competition in some areas.

MR. SCHILLER: I don't disagree, there are a lot of hurdles that we have to overcome, but part of resiliency, too, from a hospital perspective is developing a clinically acceptable product substitute list. Sole sourcing, I talked about this yesterday in the breakout group, in the past, supply chain professionals would analyze their inventory or their supply chain based on velocity, right, so you would conduct an ABC analysis. We need to conduct an ABC analysis now around criticality and those items that are most critical, we need to understand those and then we need to assess do we remain sole sourced and if we're currently sole sourced, do we look at multi-source.

I do know, for a fact, that a number of us supply chain leaders are moving to multi-source contracts to mitigate risk in their supply chain. UDI and other tools can help us to identify products in a product category or within a product family so that as we begin to look at what are some of those clinically acceptable products out there, we can bring those in to our physicians and our clinicians. So it's kind of the yin and yang of the UDI, but there's definitely those other side benefits that we haven't really dug into.

MR. HALL: I appreciate those perspectives.

MR. CONWAY: If I could offer one comment on there, Doc, I would encourage that any conversation about standardization involve patients and patient organizations (1) because we can quickly communicate it out. However, in complex patients, if you start -- nomenclature matters and culture matters. And so what we've come to know as certain types of devices and certain types of acceptable procedures and devices that support them, you can get sideways very quickly and without that clarity and engagement, I think you could create a lot of different problems.

But having said that, I do think having common language, actually, is helpful, especially at the point of an emergency when you're trying to get clear information out or to clarify misperception, which is much of what we do in an emergency as a large stakeholder organization, and I think that would then both help the government and other stakeholders like industry to have that kind of insight information up front. Thanks.

DR. TARVER: I was going to say you guys really embody exactly what we're talking about in terms of collaborative -- the importance of including all the stakeholders, right? We heard just in this past exchange how important it is to hear from the healthcare providers, the patients, the manufacturers, and the challenges that each of those communities have.

I will say, there's one other question that I would like for us to talk a little bit about. What are the opportunities that you see, this particular program, the Resilient Supply Chain Program that you've heard about over the past few days, how do you see them adding value to your organization and some of the unique opportunities for your organization to partner with this program?

And I'm going to go with you, Paul Conway, you first, and then we'll go through the line.

MR. CONWAY: Sure. So right off the top, I will tell you this. I think it's very

important for patient/consumers and their families, and caregivers are a big part of any kind of resiliency at the patient level, to understand that they are actually welcomed and valued as a part of the solution. And so accepting that premise, we would very much appreciate any type of opportunity to collaborate with FDA, involve you in our programs to talk about what this means, how patient insights are being incorporated, what the level of substantive engagement is in anticipation of what the future is.

We're all very aware of what has gone on for the past several years in COVID strengths and weaknesses, but to understand that all of that meant something and that is actually going to inform a program on resiliency in the supply chain I think would be very well received and I think that's probably a key priority, and then also to understand that we are constantly updating our capacities for qualitative and quantitative feedback for government and also for private sector partners and other nonprofits and that those insights are available. To us, I think that would be probably the biggest thing, I think you'd find a great reception at the strategic level for our organization.

If we are aware of it and we know that this is moving forward, it also allows us the ability to build it into our strategy, that this is a priority that we are a part of this engagement and this engagement goes beyond a personality, it's now actually part of our plan post-COVID. I think that's something for successive generations of our leadership and other patient organizations and it's very important to get hardwired in now, before we get tired of COVID and we go on to another issue type of thing. Hope that's responsive.

DR. TARVER: Absolutely. And we really appreciated working with the AAKP during the COVID public health emergency where we got insights as to the impacts patients were having at home with dialysis supplies, and thank you all for your contributions.

Clayton, what's your thoughts, how can we be of service and how can we develop this reciprocal relationship?

MR. HALL: Yeah, of course, and thank you for the question, it really is the heart of the matter. Look, you've got, presumably over the past 2 years, you know, anyone that is in the supply chain business has probably got more experience than they have in the past 20 and so you have -- and I'm sure they have the scars to remind you of that, but there is an opportunity right now where, I think, we have -- obviously within our membership we have supply chain experts with decades of experience. That experience can be helpful, obviously, to the FDA as you contemplate policies and guidelines. That experience can be helpful to companies outside of our membership that might be members of other trade associations or other stakeholders on this call like our friends at the hospitals and friends in emergency management.

And so I absolutely see this as an important venue to kind of, again, strengthen these relationships and share best practices and also an opportunity, you know, after an event to do some after-action reporting and talk about lessons learned, what worked, what didn't work, maybe why it didn't work and steps that may be applicable for resilience or to deal with an acute issue in the future, so we look forward to the partnership.

DR. TARVER: Paul Petersen?

DR. PETERSEN: Thank you. So I think, yeah, for this program to be of additional service, I think there's some additional engagement opportunities that are really paramount and I think continuing to engage with HHS ASPR is really important, both on the hospital/healthcare preparedness side, but then also with the Strategic National Stockpile. Both of those entities have kind of a footprint for both caching of resources, but then also providing requirements down to states and to healthcare coalitions on best practice strategies for both device supply chain assessment type stuff, but then also best practices for deployment and cache management and things like that. And then also continuing to engage ASTHO, the Association of State and Territorial Health Officials, I think it's really

important to engage folks, in my role and our state health officials, to make sure that they have a voice and understanding because at the end of the day, we have responsibility for the health and medical response in our states and so we need visibility of what resources are available, how to access them and how to best collaborate, so I would really encourage those ongoing collaborations. Thank you.

DR. TARVER: Mike?

MR. SCHILLER: Thank you, Michelle. I think the biggest -- well, again, I love this focus, this public workshop, the public-private partnerships that have taken place. Paul talked a little bit about hardwiring it into organizational strategies. I think the big hurdle we've got to clear is culture, right, Paul talked about, right, as soon as COVID ends, we're tired of it and we move on to whatever that next shiny object is or that next pandemic or whatever that hurdle is, but culture is -- boy, culture's just the biggest challenge, I think, that we face in healthcare today.

So how do we overcome the current culture, that "let's just slip back into that old comfort zone of how I used to operate," how do we address those, those cultural aspects of supply chain that have been so deeply ingrained, just in time, inventory management, the principles that have been ingrained for decades across the supply chain continuum?

So overcoming the culture, we've got case studies, I think, best practices, leading practices, how we coalesce those, how we make those available, but I always find there's so many different forms that I engage in, I find a tremendous gap between the case studies that are being pooled together and shared and available, and the actual execution of those case studies, of those leading practices. So I think how do we overcome culture, how do we overcome that gap between the case studies and execution in the hospital setting, there are so many competing priorities. So while these groups, these efforts are tremendous and we absolutely need to keep these going moving forward and keep the conversations going, I

think we have to figure out how do we change that culture and how do we take the learnings and actually put those learnings into practice.

DR. TARVER: I think that's a fantastic point. You know, I'm going to borrow a healthcare analogy, is that we have wounds and COVID-19 was a wound and instead of just stitching it right back together, let the tissue remodel, let's build something new, create new efficiencies in the system and I think that's what I'm hearing from the themes that you all have brought out, that this shouldn't be a static thing where we've got a best practice, we put it on the shelf and move on, but how do we test it, try it, put it back in motion and collaboratively do that, understanding there's many other contingencies other than those of us on the phone, that need to be involved in that process.

I know we're almost at time, but I'm going to plant one seed for us to think about and it is that we've talked a lot about the supply chain over the past few days, we've talked a lot about the different stakeholders, but there are folks and sources of information and owners of information that we haven't necessarily talked about. I think, Mike, as you were talking about UDI, maybe think of electronic health records and the vendors of those electronic health records, there are payers that are involved. And what is a driver for healthcare providers to report certain information? There are a lot of different factors in this ecosystem for us to get that information that is critical.

So on that note, I want to thank all of you all for your wonderful contribution to this discussion, for allowing me to share with you about some of the collaborative work we've done, and sharing with us the collaborative work you all have worked on. I believe that we are critically poised to move forward and not stop here, but take the lessons that have been learned and transform them into something that is sustained and actionable as we go forward. So thank you, all.

And I think I will turn it back over to you, Kausar.

MR. SCHILLER: Thank you, Michelle.

DR. PETERSEN: Thank you.

MR. CONWAY: Thanks, Doc.

DR. AHMED: Thank you, Michelle, and thank you to all the panelists. What a fantastic discussion on Day 3, stakeholders could collaborate in a sustainable fashion to strengthen supply chains and advance public health. Agility, scalability, transparency, and bringing all stakeholders to the table, including patients, will certainly go a long way in building resilience. Next slide, please.

Next stop, we will have a quick break before our breakout group discussion. If you signed up for our breakout groups today, you should have received a confirmation e-mail with the link to join. There was tremendous interest in the breakout groups, but unfortunately, we had limited space available in these sessions and so we could only accommodate a limited number of participants.

We will start the breakout groups promptly at 2:35 p.m. For those attending the breakout discussion, please join the breakout session using the link e-mailed to you right now before you go on break, but certainly no later than 2:30 p.m. Please make sure you're using the latest version of Zoom to avoid any technical difficulties. For those of you in general attendance, it's time for a station break. Please return back at 3:25, then we will continue our programming with some key takeaways from the breakout sessions, as well as the day's summary. See you all at 3:25, then.

(Off the record at 2:21 p.m.)

(On the record at 3:25 p.m.)

DR. AHMED: Welcome back, everyone. There was some great discussion in the breakout rooms. Let's start here with the key takeaways from some of the breakout groups.

All right, Greg, let's begin with you, tell us about all the fabulous things you talked about in your group.

l MR. WALDRIP: Good afternoon, everyone. There were several great comments made by our participants. One of those was to talk about bi-directional feedback. So as FDA or other government agencies are asking for information, I think the people sharing the information also want to know how it was used and its value, and also if there's going to be further sharing, how that information may be changed to make better impact.

One of the other things was just clarification of how that information is being protected. As one person said, it only takes one time not getting it right to lose trust, so being able to be clear on information sharing is really important.

Another idea was to talk about less burdensome regulatory reporting and requirements, and one of the ideas was similar to the issue of shortage of baby formula right now where imports of formula from Europe is occurring because the standards are quite similar and importation is being allowed. So being able to do similar things when there are shortages or other types of disruptions can lead to better availability of medical devices.

And then one person said, just in the sense of community, said that we're all struggling with the same things, you know, being able to look at visibility of data, being able to build stronger partnerships, and that we're all united in trying to protect the patient and we can use that sort of viewpoint to be able to unite with common cause, even if it's across competitors.

And one comment, too, was to look at advocacy groups as being the person or group that can really represent that patient perspective and be a uniting force for different collaborations as they occur. That's it for our group.

DR. AHMED: That's wonderful. Those are some wonderful points. Thank you, Greg.

MR. WALDRIP: Sure.

DR. AHMED: Next up, we have Jon Davis. Jon, tell us about the key takeaways from your group.

MR. DAVIS: So we had a fantastic discussion in our group. First of all, one of the things we heard was just how helpful it was to have collaboration vehicles like town halls during the pandemic to really make it easy to engage with the FDA and to have visibility with CDRH, as well as this workshop itself, being a great start to build that sort of collaborative relationship between the U.S. government and the private sector.

We heard a lot of clear opportunities for information sharing, including not just on the supply side but on the demand side, how do we have better visibility into the demand for medical devices and how do we share that across different players within the medical device ecosystem; how do we get better visibility further upstream on raw materials; what are the materials that are going to be potentially limiting and sourced from the same suppliers; where are there opportunities to have better visibility into suitable or pre-cleared substitution components. So if multiple manufacturers are using the same components or different versions of components on their same medical devices, how do we have visibility that the FDA has into those devices, those components, so that when there is a shortage, a manufacturer might be able to use a different component that might already have gone through a regulatory approval process?

Another thing, how do we have better understanding of what stakeholders can contribute, particularly the U.S. government, in terms of data and roles and responsibilities and products? How do we share information about the need for prioritization of supplies needed for medical devices? And finally, how do we have better visibility into where manufacturing is happening and where supplies are coming from, some better idea of what is international or U.S. based?

Ultimately, this group was clear that this is just the beginning, they saw a need for a focus session to first, define a resiliency framework; to figure out what each organization and stakeholder can contribute; and finally, to conduct a multi-stakeholder scenario plan and really going a deeper dive into different scenarios and almost creating a better playbook for what resilience would look like in the face of different trigger events in potential shortage scenarios. So again, robust discussion, thank you to everyone who participated in the breakout sessions.

DR. AHMED: Some of the common themes that we have been hearing about visibility, transparency, and making sure that patients are put right at the forefront and making them a very active and involved partner, as we have in these conversations, those are very critical when we talk about resiliency.

I will now turn to Joel. Joel, were there any other new points discussed in your group?

MR. COHEN: Thanks, Kausar. We had a robust discussion, as well, and touched on several of the points that have already been shared. One that I really wanted to draw attention to is the emphasis on recognizing the value and utility of the relationships and the institutions that already exist, the one-to-one dialogue that happens with pre-submission, and the opportunity to leverage the credibility that CDRH has really developed over the last few years in particular as a trusted coordinator and as a trusted voice.

There was also conversation of the importance of not just collaboration across the industry, but collaboration to produce and deliver a coordinated message when it comes to the importance of prioritization for making sure that scarce resources are available for medical devices over less critical market needs. And the value that the FDA can produce by stepping into that role and inhabiting it fully, as it has. So that was one of the things we discussed, and just the value of the conversations we've been having over the past few

days, over the past several months, the value of these qualitative discussions where people can come together and share their perspective from within their offices, from the work that they're doing, and recognizing that there's a lot of collaboration going on and that more of it is valuable and desirable, and there are a lot of opportunities to keep working along the relationships that have been so expanded and so important over the last few years, to keep facing these challenges and working on our solutions as we go forward.

DR. AHMED: I couldn't agree with you more there, Joel. Thank you very much.

We will next turn to Pam. What were the highlights from your group, Pam?

MS. DOUGLAS: Thanks, Kausar. Yes, just like the other groups have mentioned, we had a really deep and energetic conversation, and some of the things that came up that haven't been discussed were better ways that smaller regional players can get engaged so that we have access to the same information and opportunities as maybe the larger national groups.

We also talked about how the U.S. government might be able to coordinate with agencies beyond the FDA to do -- you know, have more of a whole of government visibility and coordinating in that way, the U.S. government could help pay attention to the impacts of what they're doing and how it might impact device manufacturers, for example, if they're going to change the size of a product in order to not have wastage, it might actually have a manufacturing challenge because there may not be the capacity to make that type of a vial.

And so we also had a good conversation about use of Collaborative Communities, including the success of a Case for Quality, which is a CDRH-led collaborative community and how that was a great example for how the organizations could come together to try to tackle these problems, and we identified a couple areas where they might be able to come and work together, including we were talking about raw materials and the raw material outlook and that this was something that both a collaborative community and maybe the

U.S. government might be able to help provide some insights to because it's something that's easier to see at a large level than it is to see a as small manufacturer, as a small organization. So we had a very good conversation, especially including some ideas about how the U.S. government might be able to maybe work collaboratively with industry to get their perspectives in advance, maybe having a standing community that they could access in order to understand any impact of current or future policy regarding the supply chain so that they could just reach out now and that way, there wouldn't be any unintended effects of a change to address one issue. So that's all we have.

DR. AHMED: Very interesting points. Thank you, Pam.

Our final reporter for the day is Melissa Wilson. Melissa, how did the discussion go in your group?

MS. WILSON: Thanks, Kausar. We also had a really energetic discussion in our group. I think one thing to highlight that maybe hasn't been said maybe today, I think it came up yesterday, and it's really around the unique role that the FDA can play around data and data transparency, it was a really big topic for us today. And not only just the ability to share data, but then to use that data to drive some resilience in categories that are known to be problematic and constrained, and so really getting ideas on how not only owning the data and sharing the data, but really how can we make action out of that data to build resilience in places that we know it needs it desperately. So that was probably one that I'd highlight, it was a little different maybe than some of the others today. So thank you.

DR. AHMED: Thank you, Melissa. So to the group in general, to the reporters in general, as you were talking about collaborations and engagement and making sure we build trusted relationships and build end-to-end supply chain visibility, were there certain aspects of or characteristics of successful collaborations, did they come up, that would potentially promote resilience? So were there certain -- what were the characteristics of a

successful collaboration community? What should a collaborative community strive for? When I say collaborative community, I don't mean one specific type of collaboration, I'm talking about collaborations in general.

MR. WALDRIP: This is Greg. One thing I would say I've heard throughout is trust, right, there has to be people coming with no hidden agendas, they have to actually take a risk in order to gain trust. So being able to step forward to share information, to show vulnerabilities is a great way to get others to trust you because you're willing to take that step forward. So I think being able to be vulnerable and step forward and take that risk, that leads to greater trust amongst all the people during collaboration.

DR. AHMED: That's fantastic. Any comments from others?

MS. WILSON: Yeah, I was going to say in addition to trust, something that came up in our group, and I think it was highlighted during the plenary session before, was really the need to make sure that it's a representative group, large and small, whether that's manufacturers, providers, healthcare systems, but to really make sure that the table is large and includes a diverse group of key stakeholders was a topic of our conversation, as well.

MR. DAVIS: And just to add to that, you know, I would say that I think we had a fairly robust conversation about just how big of a problem it is for us to think about and to scope and to size appropriately. So making sure that we're having the right conversations, the right collaborative conversations, even to just plan the answer to that question, which is what should this look like, I think is really important and something that was a key takeaway from our group.

DR. AHMED: For sure, for sure. So when they talked about these collaborations, were any examples shared or were principles brought up on what these collaborations would look like during a supply chain disruption or some kind of an emergency, and how would these move and change shape once you have dealt with that emergency or the

disruption? This time why don't we start with you, Joel?

MR. COHEN: So that's really a great question. One of the issues that we were talking about is sort of the endurance of these challenges and as we've discussed, I think, every day of this workshop, the example of resin is a challenge that everyone faces and that frankly, not an issue that was created by the pandemic and that that's an issue that is likely to endure, and that these collaborations have to be durable and they have to be sustainable and it sort of speaks to the challenge of moving from the crisis response of the last 2 years, and it's something that I know we've talked about, how to move from that crisis orientation to a steady state of collaboration and candid conversation of this and honest feedback and maybe regulatory flexibility to accommodate changes in the face of exogenous supply shocks.

And this came up in my discussion yesterday, as well, that the return to normal isn't a return, it is a pursuit of whatever our new state is going to be and that the centrality of establishing trust because we're going to need it, and working along the relationships and the institutions that we have because they have proven their worth and what we need to do is keep doing and keep collaborating and keep those relationships and those efforts moving forward with really sustained momentum as a real priority for weathering the current shocks and preparing for the next.

DR. AHMED: That's very true, sustained momentum would be very important as we prepare ourselves for normal supply chain operations unless we're dealing with any kind of emergencies that come up.

Pam, were there any discussions along these lines in your group?

MS. DOUGLAS: I think a few additional points we heard is the importance of transparency and I guess I'd say that from the perspective that an organization may or may not have the view where they could sort of see the demand or see the forecast that's

coming in, but it would be extremely helpful if they could have a little more insight into that because a company could scale up to deploy and be ready to go but it also needs to know that that product is needed. And so to the extent that the collaborations that are formed can help send an early demand signal, I think that would be beneficial.

DR. AHMED: Completely agree. Any other last comments from the reporters for today?

MR. WALDRIP: Just one thing I'd offer that I heard that kind of ties into what was just said is somehow the conversation has to change between a supplier and a consumer, especially if that supplier serves as multiple industries. So if we look at resin, if we look at semiconductors, the conversation can't just be about volume, it can't be a transactional discussion because a medical device purchaser is probably going to lose out in the volume if it comes to something like semiconductors. But if we're talking about value and value to society, value to the citizens of this country, then the conversation changes and maybe the availability of those commodities changes as the conversation changes. So it has to change away from necessarily a monetary discussion to a value discussion.

DR. AHMED: That's true. It can't be a transactional discussion, it has to be a collaborative discussion where we are all coming together to what is one common call here.

With that, I want to thank all the reporters, as well as the breakout group participants for your insightful comments and for the discussion. I will now turn it over to Dr. Tammy Beckham for closing remarks.

DR. BECKHAM: Thank you, Kausar. I want to take the opportunity today to just thank everyone who attended the workshop this week. A special thank you to our speakers, to our panelists, to our moderators, to our reporters, every afternoon the discussion was incredibly rich.

I think we heard some common themes, some that were wrapped up in the last

session as we brought this 3-day workshop to a close. I think there was just incredible input on the value this program can bring and the value proposition for moving forward. We heard a lot of really good feedback about opportunities for this program to provide value back.

Today's theme was all about collaboration and even though we focused on it today, I think we heard it throughout all 3 days and the importance of it. You know, we did hear today relationships should be just that, relational and not transactional, and couldn't absolutely agree more to that, is that trust is a key to building resilience for everybody across the ecosystem working together and for this program, as we work with our partners, trust is key. We heard areas where this program can provide value back, convening, helping build resilience, and forming uncommon vulnerabilities and alternatives.

We also heard about making sure that we're working with our stakeholders to provide a least burdensome regulatory approach and then that was key.

Also, we heard transparency was key, that oftentimes when we do requests for data, it's nice for you all to understand what we do with that, how it's used and being able to share that back and help build that trust.

The program having an opportunity to bring people together to share best practices and tools and that collaboration is an inclusive term and that communication should be bi-directional, those were all great points brought up, not just today, but over the course of the 3 days.

We also heard that, you know, what was just talked about, that we need to leverage some lessons learned over the last several years and not only leverage those lessons, but build and sustain on them. And one of the key things was sustainment, how do we continue to sustain those partnerships, how do we continue to maintain them, because the best preparedness and planning is to make sure that we have those relationships prior to the

next emergency.

We need to also come together and contemplate what worked and what didn't work, a hot wash taking into account the learnings into the future.

And we also heard during the panel earlier this afternoon the need, and it was shown brightly during that panel, to have a multi-sector participation at the table when we're talking about potential solutions because every sector is going to have a different perspective and the pros and cons can be critical to coming together collectively to determine what some of those solutions are to build resiliency. And I do think those are key activities and key places that this program can help and will help moving forward to play a role.

Obviously, we heard patients, and they are, they are the north star, so remaining focused on the fact that patients is what brings us all together so that we can tackle through issues to ensure that our patients and providers have that access to critical medical devices. And we need to recognize their role in the solution and involve patient groups early on and throughout the process and ensure that they have substantive input into solutions that we're talking about.

So the 3 days that we spent together have been very rich and I thank you for your comments. I also was very pleased to hear early on in the wrap-up here that folks saw in the breakout sessions that this should just be the beginning of the conversation because it should be the beginning of us continuing these novel ways and conversations together to find solutions to build resiliency. And so we agree and we look forward to many more interactions so that we can come together collectively to look at sustaining what we've built, continuing to develop those relationships and that trust and continuing to enhance that moving forward.

So as a reminder, I just want to say that the public docket is open through July the

11th, you know, comments to that, very much appreciate it and those contributions are going to continue to help us implement our program. Continued public engagement obviously is going to further enrich our program as we move forward and bring the most value add to our stakeholders. And we are very fortunate to have engaged partners and we want to ensure you that while we're wrapping up this workshop we're going to continue our interactions and our engagements and we're very appreciative of your input these past 3 days.

So thank you so much, everyone, for attending. Thanks again to all our speakers, panelists, moderators, and reporters and we look forward to the multiple interactions we'll have going forward. Thank you and have a nice week.

(Whereupon, at 3:48 p.m., the meeting was adjourned.)

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C E R T I F I C A T E

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

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

June 9, 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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TOM BOWMAN

Official Reporter

Free State Reporting, Inc.
1378 Cape Saint Claire Road
Annapolis, MD 21409
(410) 974-0947