11978091
FDA Roundtable: Strengthening the Supply Chain for Blood Manufacturing
September 29, 2026

CONFIDENTIAL ROUGHLY EDITED REALTIME FILE
Compliments of Birnbaum Interpreting Services

****

This file was created in real time by a Realtime Captioner. Communication Access Realtime Translation (CART) is provided in order to facilitate communication accessibility and may not be a totally verbatim record of the proceedings. A consumer should check with the presenter for any clarification of the presentation.

****

>> Anne Eder: Hello and welcome to FDA's roundtable. We've brought together experts in the industry, manufacturing and Federal Government to discuss strengthening the supply chain for manufacturing blood components. I'm your guide for the day, Anne Eder, the Director OBRR.

Today the roundtable will discuss, in session one, the current state where blood establishments report disruptions or potential disruptions to FDA for OBRR and blood establishments to manage.

This is a reactive strategy by the end user and this is not sustainable and very stressful for everybody involved. We need prevention. We need to understand the challenges and gaps and opportunities to strengthen the supply chain for blood manufacturing. In session two, the manufacturers will discuss their supply chains for critical supplies in blood manufacturing. And finally to wrap up the day, our speakers from the Health and Human Services will share their agency's and department's activities in supply chain, whether directly involved in blood manufacturing today or whether it can be applied to blood manufacturing in the future.

The roundtable will not address, or at least will not address directly. blood shortages. We're discussing the material supply chain, not the human in the supply chain, that is, not the blood donor.

FDA expects licensed blood centers to provide a safe and adequate blood supply to meet the needs of patients. We need blood every day of the year. And licensed blood establishments do meet patients' needs very effectively and very efficiently. But there are challenges. This past summer, just an ordinary August, the largest blood supplier of about 40% of the blood supply, the nation's blood supply, announced that their distributable inventory, that is the blood they had on the shelf to distribute to patients, was at its lowest in years. We need to talk about that. Because in every disaster to date, every mass shooting, every natural or man-made disaster that

requires massive transfusion and hundreds of units of blood, it's the blood on the shelf that can be moved around the country that's immediately available that saves lives.

So we need to talk about that. We need to talk about preparedness. We need to talk about next summer. We need to talk about platelet shortages. So we're planning another roundtable to focus on the blood supply. That is for another day. Today we're focused on the critical supplies in blood manufacturing. We're not going to talk about materials in the supply chain that are covered by other efforts, that is, sample tubes, personal protective equipment and gloves. Although the Office of Blood Research and Review, OBRR, has gotten involved when those shortages have happened in blood establishments. But today we're going to focus on critical supplies that are unique to blood establishments and source plasma establishments. And we're not going to discuss development and approval of innovative blood components, such as dried plasma. Although OBRR does review those regulatory applications and facilitate that development of those innovative products as we recently did for the first freeze dried plasma product. And you can read about it at this link. So the Office of Blood Research and Review primarily is involved in regulatory review, inspections and compliance, policy development, and mission-related research. Today, we're focusing on our activities in blood manufacturing supply chain. And this includes, donor screening, including confirmatory or supplemental testing, collection sets, that is, blood bags, anticoagulants, immunohematology reagents, and blood establishment computer systems, which we regulate.

In 2020, the U.S. Food and Drug Administration identified a list of essential medicines, medical countermeasures and critical inputs. Essential medicines are those considered medically necessary to have available at all times in an amount adequate to serve patient needs and in appropriate dosage forms.

Each year, the approximately 70 blood collection license holders at about a thousand centers, collect about 12 million donations each year to meet the needs for life-saving blood in the United States.

For source plasma, the 28 source plasma license holders collect over 50 million liters in about 1200 establishments across the U.S., and provide over 70% of the global supply of plasma, the worldwide supply of plasma, for plasma derivatives.

Now, if I had a unit of blood up here from one licensed blood establishment and another unit of blood from a different establishment, it would look about the same. Because we have standard labeling, the bag looks about the same. But this really belies the complexity of the supply chain as shown in this slide. So the blood bags can differ in respect to the anticoagulant, the additive solution, the filter, the number of bags in the configuration, the needle, and other factors.

Now, one manufacturer provides about 70% of bags to the licensed blood collectors in the U.S. And you'll hear from manufacturers today. For collection apheresis devices, shown on this slide, of course the devices are different, the disposables are different. And for the testing platforms a serological platforms is shown on the left. These are just examples. I couldn't possibly illustrate all of the complexity in the supply chains. A serologic platform is shown on the left and these two are NAT platforms; each one is different. Each one has a complicated supply chain.

Now, blood manufacturing supply chains can become disrupted for any one of a number of reasons. And we will be discussing some of those reasons and some actual examples that we've had to manage through, and that we're managing today.

Contributing factors and causes of supply chain disruptions include relying on one manufacturer because when that one manufacturer makes decisions or is dealing with a natural disaster, cybersecurity issue, it affects, it can affect a substantial proportion of the U.S. blood supply. Quality and compliance issues, business decisions to discontinue a product that the blood supply relies on. Natural disasters and cybersecurity incidents.

When the actual cause of a shortages may not be apparent to blood establishments, and this happens frequently. So when the, when blood establishments ask for a solution, it may not be appropriate. That is, releasing a product if there's a quality issue that affected safety.

And the short-term solutions don't fix the root causes. So for example, FDA can consider extending an outdate of a compliant or non-compliant product if that decision is supported by a risk assessment on the safety and effectiveness of the product. FDA can consider exercising enforcement discretion and take no regulatory action in face of noncompliance, again if it's supported by a risk assessment. But that doesn't fix the problem upstream.

Some real-world examples you'll hear presented today by the Deputy of the Office of Blood Research and Review, Orieji Illoh, are the ones we're managing. And unfortunately we're dealing with several today involving blood bags because of quality and compliance issues, manufacturing decisions to discontinue. Anticoagulant solutions for the same reasons. The field is very aware of the decision to discontinue, glycerolyte which is the solution relied on to freeze red cells. And you know, an industry shouldn't depend on one solution to freeze red cells. So that situation needs to be addressed so that we have continuity and more than one solution for freezing red cells.

And the device needed to deglycerolize those frozen red cells. And an interesting unexpected solution where raw material that's not regulated by FDA that's used in licensed immunohematology reagents is in short supply because the supplier is discontinuing the manufacture of raw material. Back in 2013, some of you may remember, the anti-HCV recombinant immunoblot was discontinued and FDA issued recommendations on how to conduct further testing when donors had a reactive anti-HCV screening test.

So the objectives for today are to describe the supply chain for blood manufacturing and identify what supplies and equipment are essential to manufacturing blood and blood components. To discuss current challenges and how blood collectors respond to shortages in the supply chain. To identify the root cause of shortages in the supply chain and propose solutions to prevent such shortages and discuss the role of various federal agencies in strengthening the supply chain for blood manufacturing.

Session one will discuss the current state. Our moderator is Leah Mendelsohn Stone who is the Vice President of Public Affairs and Policy at AABB. And she'll lead our speakers. She'll introduce the speakers and lead a panel in a moderated discussion. And then we'll have a short

break. And when we return from the break, Mary Homer from BARDA will lead a discussion of our manufacturers and how they build resilient supply chain and lead our panel in a moderated discussion. We'll have another break until 1:30. And I hope you'll all return to hear session three where CAPT John Oguntomilade from HHS, the Office of the Assistant Secretary will lead, will listen to our speakers and he will lead a panel discussion. And then we'll have our open public comment session where we have some speakers provide important perspectives on the supply chain for blood manufacturing. And then I'll come back in the end and summarize some key take home points that we heard and wrap up the day.

So presenters, I want to remind you that, if you do have technical difficulty each speaker is going to share their slides. If you run into difficulty, we have back up and we can pull up the slides. All you have to do is ask. We ask you to stay within your time limit to be fair to the other speakers. Moderators will give you a warning if it looks like you're going to run over. Please mute during the speaking, during the presentation section if you're not speaking. But unmute when it is your time to speak and turn your camera on when you're presenting and during the panel.

Participants, we're not able to use the chat feature and we won't be responding to questions during the roundtable. However, we were able to accommodate many in the open public comment session. However we did have to limit because of time constraints, and we did get requests a little too late to accommodate. We apologize for that. If you submit feedback, please do submit feedback after the roundtable. We will respond to you to answer your question, and we will consider posting FAQs after the roundtable.

So thank you and let's get started.

I would like to introduce our first moderator, Leah Mendelsohn Stone who is going to lead our first panel. The floor is yours, Thank You.

>> Leah Mendelsohn Stone: Thank you so much. And thank you FDA for hosting an important roundtable. It's my pleasure to moderate the first session. I am going to share my, the slides. And while I am doing so, I'm going to ask John Hagins to get ready to present his slides. Our objectives on this session is to describe the supply chain for blood manufacturing and discuss current challenges and help blood collectors to respond to the shortages in the supply chain. We have four speakers that Dr. Eder mentioned. First, John Hagins who is the Chair of AABB interorganizational task force also the President and CEO at the Community Blood Center in Appleton, Wisconsin. Our second speaker is Bill Block who is the President and CEO for the Blood Centers of America. The third speaker will be Dr. James Knowles who is the Vice President of Global and Regulatory Policy and Scientific Affairs at the PPTA. And then Dr. Orieji Illoh is the Deputy Director the at OBRR and CBER. John, I'm going to stop sharing my screen and turn it over to you to begin.

>> John Hagins: Thank you so much, Leah. I think you should be able to see my screen. All right. Good.

Good morning, everyone. As Leah and Dr. Eder mentioned, I'm John Hagins. And for today, more importantly the Chair of the AABB Interorganizational Disaster Task Force on Domestic Disasters and Acts of Terrorism. For the sake of time, I'll shorten that to disaster task force.

A little bit of background about the AABB. Many of you are familiar, is an international not-for-profit association representing individuals and constitutions in the fields of transfusion medicine and biotherapies. Mission is to improve lives by making transfusion medicine and biotherapies safe, available, and effective worldwide.

The disaster task force was established in January of 2002 with three main focal points. Disaster task force came out of the post review from the terrorist attacks of September 11. And as many of you may remember or at least know, there was an incredible response from the public to donate blood as a way of doing something cathartic during a really difficult time. Over the course of the few weeks afterwards, there were many, many blood donations, more than what was certainly needed and more than what the system would normally collect and distribute. And unfortunately, that six weeks later a number of units, began to expire. In the aftermath of that, and in the review of the situation, one of the areas that was identified was, there was no coordinated messaging coming from the blood community to the public about the need for, or there was no need for blood donation.

So in January of 2002, the task force was established with the three main phases in mind. Help ensure that the other blood collection efforts resulting from domestic disasters and acts of terrorism are managed properly. Two, is deliver clear and consistent messages to the public regarding the status of America’s blood supply, and three, identify infrastructure challenges and coordinate the transport of blood.

The fourth definitions of what would include disaster in any domestic disaster act of terrorism where there is suddenly a larger need of blood or there's a temporary restriction or elimination of blood collectors ability to collect, test, process, or distribute. Or temporarily restricts the local population from donating blood or creates a sudden influx of blood donors requiring accelerated drawing of blood to meet an emergent need elsewhere. The composition of the task force at the center is the coordinating body which is the AABB. And there's the critical event assessment group. This group meets within the first hour of identifying a potential disaster did includes members from America's Blood Center, American Red Cross, Blood Centers of America and liaisons with the Armed Services Blood Program and the Office of OASH. Additional members if there's a full task force association include the American Hospital Association, College of American Pathologists, AdvaMed, National Marrow Donor Program, Plasma Protein Therapeutics Association and the liaisons with CDC and FDA.

These are a few of the disasters that the task force has responded to over the years since its formation in 2002 through 2025.

So those triggering conditions can either come internally from a blood center or a hospital and that's concerned about the blood supply. In all cases they go through the blood collectors and the AABB and the organizational disaster task force is notified of the situation.

So what happens during that emergency chain of events, AABB immediately convenes a meeting of the CEAG to assess the environment. The local blood centers are involved, estimate blood needs, assess the blood supply and identify infrastructure-related issues and communicate that information to the IDTF. The CEAG determines the strategy and coordinates the effort, including coordinating a broad message in conjunction with HHS transporting and coordinating needed blood supplies and identifying priorities. They communicate the CEAG to other members of the task force.

This is one that addresses something that Anne mentioned that affects the system, and in this anatomy of a disaster, there are five phases. Pre-event vulnerabilities, warning signs, trigger events, cascading impact and response and recovery. In Phase 5, activate back-up systems, initiate IDTF coordination are the activities that I'll focus on as part of a review of a more recent activation. So this was a ransomware event. On day zero there was a CEAG alert. Once alerted the disaster task force can be in a call with the critical assessment group within the hour. Evaluation began of the blood center's product, logical needs, operational capacity and possibility of activating the full task force.

On day one, activation and coordination, we had communication set up, 9:00AM daily call, to streamline communications. We alerted the full IDTF and began to develop the PR subgroup to meet and prepare public donation messaging as needed. Operational support and recovery in days one through nine. There is shipment coordination in addressing Blood Center's immediate product needs, particularly for type O positive and negative O blood cells and platelets. Create capacity monitoring process throughout the recovery process. The blood center experienced various levels of functionality. And they were working closely with the blood center as they address multiple challenges. Continuing through days one through nine there was a process to do demand forecasting with the blood center providing forecast of future needs. And then the task force was able to plan and allocate resources accordingly. At the same time all of this happened there was pending hurricane process that was impacting the area. So the disaster task force began to monitor the path of an approaching tropical storm, which later developed into a named hurricane and had potential impact on the same region. Preparations were made to make sure continued support for the event.

that lasted ten full days. The interest center operations began to return to near normal levels and all critical systems were restored and the disaster task force gradually reduced active levels of support. They further no supply requests and IDTF active involvement ended on day ten. Teams from America's Blood Centers, American Red Cross, and Blood Centers of America did a fantastic job of making sure resources were rallied around from the various blood centers throughout the U.S. and funneled into the impacted center .

By day 13, under final monitoring and deactivation, the IDTF was monitoring the hurricane and the impact along with any residual needs from the ransomware event. The deactivation happened on day 13. Once confirmed that no critical needs existed the total product support that was coordinated included 3700 LRBCs, and 1400 SDPs. Just to note at the bottom almost 250 red cells and 126 SDPs were shipped to cover other resource needs in the hurricane and other hospital requests in the area. That's one example of a disaster task force activation and how we

respond when there is a threat whether natural or man-made. One of the other items that the disaster task force is involved in is planning blood needs in the events during a large-scale event, like the FIFA World Cup and the planning around that activity. There was a distribution of guidance for blood facilities and preparing for the FIFA World Cup and for planning purposes they treated all U.S. base matches and locations as a national security event. That means a report was issued from the disaster task force that covered matches through the following week. The report elements included host city primary and back up blood centers and all the trauma centers, current daily and weekly national blood supply inventory. What each blood center had as a response strategy and pertinent contact information. At the same time, the PR subgroup of the task force. Prepared communication plans that if there was something that happened we were prepared with our communication plans at that point in time.

So each week, in addition to planning for large scale events, monitoring natural and possible manmade disasters, the disaster task force also creates a weekly summary of the blood supply which we send to our hospital partners in HHS and others. I'll finish up with resources. They include the task force website, handbook, planning for the FIFA World Cup. There's a cybersecurity and biotherapies resource there and resource by Dr. Ramsey and Frank Berry, An Interorganizational Task Force for Disasters Affecting U.S. Blood Supply published in 2025. With that, I'll conclude my official comments and stop sharing. And so the question period.

>> Leah Mendelsohn Stone: Next we're going to hear from Bill Block the Chief Executive Officer for Blood Centers of America. Bill, if you come off mute and start sharing your screen.

>> Bill Block: Thanks, Leah. Thank you, Anne for the invitation to present. As Anne mentioned, I'm the President and CEO of Blood Centers of America and I'll walk you through the challenges we've had. I thought this was an interesting quote that was in one of the NIH publications early on. It just happened right after the pandemic. But obviously we didn't come out of the pandemic necessarily stronger. We did learn a lot from the pandemic. And I think we've become more resourceful because of it, but helped us identify gaps where there are gaps.

Let me talk about some of those. In, just this year, for the first eight or nine months we had quite a few. This is not atypical. We faced supply chain disruptions every year.

But Anne alluded to regulatory holds that were in place for two of our blood bank manufacturers. And this could have impacted in a significant way, fortunately one of them was short lived, six days. The other one is still ongoing relative basis but is not a highly used bag. Anne also mentioned the glycerolyte discontinuation notification. That obviously is critical for rare donor programs across blood centers. We also got the word that the COBE-2991, which is a deglycing machine, will discontinue in about three years. We really have to find another solution for that altogether. And then we had notification of a bag that's pretty critical for our pre-hospital use, the 35 days CPDA-1, discontinued sometime mid ‘27. They're trying to prepare for alternatives there. But in the interest of time, I'll press on.

Some people are not aware that Blood Centers of America supports 60% of the country's blood supply. They're all independent blood centers across the country and there's about-- 150 sites.

And we thought we've done a lot to strengthen and harden our defenses around preparedness for events that occur. But it's never enough.

So you can never let down your guard. So we very focused, John mentioned the IDTF, we're a member of that, our risk mitigation strategies and participate in resource sharing which means we move blood to where it's necessary across the country and normal basis moving blood where it's necessary.

I wanted to talk briefly about what's going on with innovation. This is an example of one innovation that is being brought to help us really mitigate labor cost which is a significant cost. The average, you know, cost per unit collected is about 50% labor. So this particular automation helps us reduce that. And we have many centers adopting it. The reason I share it with you, the quicker that can get out, the quicker we can produce more platelets and mitigate platelet shortages which you heard from Anne earlier did take place and have already this year. I do think this type of automation is critical for the industry to embrace and others as necessary to continue keep a robust supply of blood products. We appreciate the suppliers driving the innovations forward because it's critical for our blood centers.

I did want to talk about, Blood Centers of America, we established post COVID what's called a third party logistics. It's really a critical resource for our blood centers across the country should there be a gap in supply. And we keep about 30 to 45 days of supply on hand there through a very strong partner in this space. Their name is HemaSource. Keeping 30 to 45 days of critical supplies in a consignment basis in their centers and shipping them on a vendor managed inventory program in automated way to our centers if necessary. It gives us breathing room if there's a disruption to supply. 30 days is not much if you ask us to ramp up capacity by more than 10%. There's not a lot of inventory in the system. Inventory costs money and takes up space to areas that are hard to come by with our blood centers.

This is a very efficient way to mitigate that.

I did want to give you a picture of where manufacturing occurs for the blood bags in particular. As Anne alluded to there's a major manufacturer that makes most of the blood bags in the country. Their particular sites are in Puerto Rico. They make the whole blood bag there and gotten license about a year ago in the Czech Republic for U.S. codes to make blood bags which is a great development because it mitigates risk in Puerto Rico which has a tendency to be vulnerable to hurricanes, the power structure there, difficult to bring back online quickly. We're very, you know, glad and also pushed hard for Fresenius Kabi to develop this other licensed plant in the Czech Republic. That gives you on the idea on the blood bag manufacturing there is a filter we use for leukoreduction made in Bologna. It's earthquake-prone that area, they built a facility that has a lot of mitigating structure to it with regards to earthquakes but you never know. And it's the only one that makes that filter across the country. So we're very reliant on that not being disrupted. There's risk. And they're doing something about that risk but it takes time and money.

I did want to talk briefly about the low-titer or O whole blood bag, used predominantly, used by the military and used by our blood centers significantly for pre-hospital and EMS care. The

reason they want 35 days is it gives them a longer shelf life. And it gives them logistics flexibility so that, if they have to move it back to a trauma center, they have more time to do that.

So we found out that this particular bag is being discontinued by the primary manufacturer today which is Fresenius Kabi. It is a low SKU volume. I think Eddie Kubo will talk about this later on the manufacturing side. But we identified a short-term solution to it. And we also think that, longer term, there's a possibility that another potential manufacturer or manufacturers, knowing that there is an opportunity here will be able to serve this critical space. So today we have a short-term solution identified. But it does require validation of centers and work. But we're prepared to do that.

And then I kind of talked a little bit about, you know, what Fresenius Kabi has done with glycerolyte and we've identified another product, made by a company called SALF in Italy. They are in good communication with the FDA. I know Anne and her team started to talk to them about potentially the pathway that they would have from a regulatory standpoint to bring that Glycerolyte product to the U.S. If they do that, that will give us an alternative to Glycerolyte but we can't control that. We're looking for different technologies that might be better longer term both companies that have technology that could be used-- one is a non-DMSO freezing methodology that could be used to freeze red cells and platelets. You already heard about the freeze drying of plasma. It's similar in the platelet and red cell category. So this would be a good long-term opportunity because it gives us the ability to stockpile blood products for emergency purposes much more significantly than we can do today.

And then just a couple final points before I turnover to James to talk more in the plasma side, I just wanted to say that, you know, when we look at what do we need to do to be prepared for the gaps in the supply chain, we know there's one main manufacturer doing that. One of the ways that we have worked with them and they've worked to invest in their business to mitigate risk is that they now have two license plants, one this the Czech Republic which was October of last year got licensed for U.S. manufacturing which is great. We've also worked with them closely to mitigate other areas of manufacturing, for instance, they make the leukoreduction filter. And they have dedicated and well prepared to make that in another plant that they have identified in our building a plant to support. So we're happy that there won't just be one plant manufacturing that critical filter.

The other piece that we think we really need help with, I mentioned earlier that inventory costs money and takes up space. We have found a great solution in a third party provider called HemaSource. We want to load more inventory to we can respond to critical events across the country and military as a continuing supplier of blood. What we need is more than 90 to 120 days of inventory. We would love to work with government stakeholders to help fund that. And we have found a way to rotate that through on a first in, first out basis. It's a one-time funding exercise that we would then manage the inventory going forward. It would give us flexibility because, what we found is during emergencies, we're able to bring in the donor and the donors show up. If we don't have the consumables on the shelf we won't be able to support a huge ramp up. And we feel like that's a gap that we've identified. We have a plan both in the short-term to bring in more inventory. In the long-term, we believe that vertical integration is necessary. So

considerations for either reshoring or other plants making these products or in different places would all mitigate this risk that we currently have.

So I wanted to address that here and certainly we can talk more about it on the panel. Thank you for your time and turn if back over to Leah who is going to introduce James. Thank you very much.

>> Leah Mendelsohn Stone: Thanks, Bill. Next we are going to hear from James Knowles who is the Vice President of Global and Regulatory Policy and Scientific Affairs at PPTA.

>> James Knowles: Thanks, Leah. I think you should be able to see my screen as this comes up. Yeah, and thank you to the FDA for including source plasma in this conversation. I will spend time explaining to everybody what is different to the blood collection world and ultimately the finished product. I'll start with, since this is about the supply chain, I will talk through similarly to what AABB does, we have emergency preparedness task force. And also give three case studies going back to the pandemic, lessons learned in plasma collected for hyperimmune globulin. And impacts of the industry specifically for saline and anticoagulant due to Hurricane Helene. And touch on the Glycerolyte and the anti-D plasma collection which is used for RH immunoglobulin.

Since this is the plasma supply chain, I want to gather everybody who our members are. Ultimately our largest global members whether they have plasma collections and manufacturing and biologics based in the U.S. who has vertical integration.

These are most of our plasma collection members. And this, because it's a global supply chain and global industry, we have both Canadian, U.S., European plasma, Egypt plasma center. This is about the supply chain, you can see many of these familiar associate members we have. They are the supplies, equipment, partners, provide valuable technology resources and testing resources throughout the industry.

So before I get into focusing on plasma, the FDA asked me to focus on plasma collection. I'm going to focus to say in the orange box, the donor and moving through the plasma for fractionation. This highlights the complexity why all our collectors collect plasma. It's for plasma derived medicinal products which moves through the fractionation process and distributed globally. There are many external and internal factors that impact every part of the supply chain.

I want to focus on the plasma collection chain. These areas are not necessarily in order but these are all important areas of our supply chain that can have impact whether it's from a regulatory perspective, whether it's storage and testing whether it's the impact of testing supplies, reagents, impacts of cyber attacks and focus on the supplies and equipment. Without that we cannot collect donors. Without any of that, we need donors in the first place. And alluded to what we'll be talking about donors, but they are an important part of our journey along this supply chain.

So where are most of supplies from? Most of the supplies, and it's similar but dissimilar to the blood world. Majority collect our plasma in plasma bottles as opposed to bags, although many of the manufacturers purchase recovered plasma from many of the companies including the Red

Cross, et cetera. That's really important. But we really focus on these areas because these are probably the most critical ones as you can see both from the Americas as well as the Asia Pacific area.

A minute to talk about the emergency preparedness priorities. Obviously, we have members part of our emergency preparedness both from the collection, fractionation, testing, supply, distribution perspective. When we have a need to convene this emergency preparedness task force; we have holistic and very complete supply chain understanding of where the strains are, the opportunities are, and that helps us when we think about our ongoing activity and our priorities.

So as I said, we partner with a lot of the supplies. We're able to coordinate if there are, for example, pandemic situations or viral situations we're able to partner with pathogen safety working group. And we're also able to focus on the engagement because we are a global level we have to have the engagement with the EMA, EDQM as well in terms of how material and plasma moves from the U.S. to Europe.

These are some of the member identified priorities that have come up over the years in conversations. Again these are holistic high level, personnel obviously is a big piece whether that's a pandemic, whether that is a hurricane, another natural disaster. Obviously we have to address shortages, we have it's an important piece. Logistics the testing and the contracted services, everything that goes into maintaining, a plasma collection center and ensuring the center remains available and open in the event of any kind of emergency or supply chain disruption. And obviously I think communication and emergency flexibility with regulators is a commonality between the blood collection world and the plasma collection world.

This is a heavy slide. I want to focus on these. We have done a number of in-depth surveys with all our members and because of that highlight really in-depth areas that we wanted to focus on in our organizations. I'll focus really on, you can think about everything from risk planning all the way through to the impacts and influence that we can have on local and state government considerations. Obviously in our situation, I'll come to that in the next slide, we are looking at medicine production in certain supply chain disruptions in emergencies. The four I highlighted focus down on the end-to-end supply chain of plasma collection including the communication between regulators, public relations, the staff considerations, the donor considerations, all the supply chain considerations you can see in terms of vendor management, facilities for distribution, critical supply shortages and identification and alignment on the critical supplies, reliance on for supplies not manufactured in the U.S., transportation, for example, moving in areas of confinement or impacted by war for example, and product shortage management, how do we get a big part of this?

One of the significant differences to understand in our supply chain is we may not see, we may see an impact to plasma collection as a result of a supply being unavailable or disruption for emergency, we may not see that because of the length of manufacturing time typically from collection to release of product because of the complex manufacturing steps it can take seven to 12 months. You won't see the impact to the medicine availability for that period of time. So it's

important for us to see into the future to be able to offset any inventory that the companies are built into plasma.

I want to focus on the case study on the pandemic again. I think everybody can write a thesis about their experience during the pandemic and the blood in the biologics world. One of the things we were asked or charged with was the development of hyperimmunes for, immunoglobulin for COVID. That starts with the collection of convalescent plasma. What happened, we were able to put together something called the COVID alliance, where we were able to work with government agencies that increased the communication, the regulatory flexibility, the financial support, the research and development, et cetera that were able, PPTA was in the middle of this and move the process along. And I think it went relatively well. There were shortfalls. I think that's part of the conversation perhaps when we talk about the end-state medicine.

Where we did struggle, I think the changing restrictions. No one had gone through this. There were supply interruptions that affected both collection of normal source plasma which was necessary to continue the availability of existing medicines as well as convalescent plasma that we were trying to pull in for the development of novel hyperimmune globulins for COVID before the vaccine was available. Obviously the testing capacity ability for reagents assay performance, that can impact donor qualification.

We saw transport delays and shortage constraints throughout. And had to improvise in many cases, many of the companies that we have as members had never collected plasma in bags before. We had to make big changes to computer systems. We had to validate how to transport bags versus the plasma units which is a rigid plastic and all this took time to move through. Throughout this, everything had to be followed to using the procedures.

Let me go to Hurricane Helene. As part of the plasma process, plasma and whole blood is taken out of the donor, plasma is centrifuged out. Collected and red blood cells are returned to the donor. Each time it happens we have to add anticoagulant to make sure there's no clot. That cycle happens two or three times. At the end of that we supply the donors with saline which obviously was impacted, both impacted by Hurricane Helene. The site in North Carolina supplied 40 to 50%, used by the plasma center. I recall talking to the manufacturer, trying to do risk assessment to see what was the critical industry and obviously hospital held seven days or less of industry. Their focus was supply. What we had to do is pivot. Thankfully Bill mentioned HemaSource. They were in the center of the storm and already had lessons learned in terms of the pandemic, building resilience. They had 74 days of saline, 95 days of anticoagulant. The inventory was sat across different warehouses. And manufacturing was able to increase production in their manufacturing facility in Mexico.

And in addition to that, we were able to keep the anticoagulant supply, remained stable. Without anticoagulant we cannot collect plasma. That's a safety issue. Saline inventory was more finite. But our IQPP which is the PPTA standards allows for temporary oral hydration. While this is not a permanent fix, we were able to supplement lack of saline infusion with gatorade, except for

minimize impact. That combined measures prevented an industry shut down. Lessons learned that came from the pandemic we're able to transfer.

The third one I think Glycerolyte this is used to store blood cells. Collected from blood donors that have high-- once confirmed to be sterile and free, inoculated to plasma donors that is used to manufacture anti-D immune globulin.

It's clear the FDA working closely to provide the provider, additional provider is alluded to. This is one current and working through the different situation of that.

While we don't have a median at this department shortage, as we remember thinking about the timeframe, we need to think about the future product availability today in order to have no shortage.

So high level, lessons for the broader collection supply. First lines of defense, hold higher inventory, qualify more than one SKU supplier. Distribute across warehouse location. Maintain purchase history so you know how much people need when people are asking for more product, you need to balance that across the industry. And obviously assess geographic concentration and the import. Strengthening, confirm back up. Prioritize-- and dedicate resources and funding to the resilience. I think it's really in everybody's company's value to put funding, procedural guidance for supply management and emergency preparedness. And these are pieces that would apply to plasma collection and blood supply. It's also included an essential activity. Prioritize access to constrained supplies. Ease transport export restrictions. I think for the supplies and materials, if we can find additional regulatory flexibilities for accelerating the qualification, not to compromise the quality and safety, of course. But I think that's an opportunity for my conversations with our members. And obviously as we can see faster use of license inactive facility, streamline validation and coordination early with FDA. They've been working on moving that from a manufacturing that a CDER and CBER perspective. Plasma is an essential raw material, an important piece to recognize. I think our industry is to focus of contact, understanding time limit and flexibilities that the industry and government can activate quickly. Acknowledge those, formalize those that way there is less misunderstanding as we move forward. With that, I want to thank you all. If you have questions, feel free to get in touch with PPTA and myself. Back to you, Leah.

>> Leah Mendelsohn Stone: Thank you so much. Our fourth and final speaker on this panel is Dr. Orieji Illoh Deputy Director of OBRR at CBER. Dr. Illoh. Come off of mute and check. Great, Thanks.

>> Dr. Orieji Illoh: So good morning. Thank you, Leah for the introduction and thank you to our industry partners for their presentations.

They have made my presentation easier because they provided a lot of detail that I might be repeating again.

So my goal here is to give an overview of FDA's experience with the current state of the supply chain and I'll also be providing examples.

For the outline of my talk, I will be talking about products regulated by OBRR, some of which you heard from Anne earlier, OBRR's experience with causes of supply chain disruption as it applies to the blood manufacturing supply chain, issues and examples.

We all are aware that OBRR regulates blood establishments that manufacture blood components and source plasma. But in addition, we also regulate the products that are used to manufacture blood and source plasma. I have examples listed on the slide including apheresis devices for red cells, plasma, or platelet collection, blood collection containers anticoagulants, and additive solutions, Pathogen reductions devices, blood donor screening tests for relevant transfusion transmitted infections, such as HIV, HBV,-- immunohematology reagents and compatibility tests, hemoglobin measurement devices and blood establishment computer software.

These systems or these products typically have different regulatory pathways for review including BLAs, NDAs, PMAs, 510ks, and when applicable if investigative, INDs and IDEs. I want to note that, is that the manufacturers of products for blood collection are really small. You can probably count them on your hands. And sometimes that's part of the issues with our supply chain when it's interrupted.

I want to mention, one of our major manufacturers of blood bags, manufactures about 70 to 80% of the blood bags.

My next slide here just shows an example and it's not all inclusive. But the manufactured of products used in the U.S. supply chain is global. While most of our manufacturers you can find within the U.S., we have manufacturing of either finished products or components that as you see in this map here, all over the globe.

And so once again, when there are disruptions, this becomes an issue in our supply chain. Now I'll share with you our regulatory requirements for shortage reporting related to the blood supply chain. It depends on the product. If it's a drug or biologic, section 506C of the FD&C Act which is the Food, Drug, and Cosmetic Act, requires notification of FDA six months before permanent discontinuance or temporary manufacturing interruption that may cause a meaningful supply disruption. For devices the regulation is a little different. Section 506J of the FD&C Act requires notification of FDA of an interruption or permanent discontinuance of manufacturing during or in advance of a pandemic.

Within CBER, our Office of Compliance directs the CBER-regulated product shortage program. I've included a link that provides a lot of information about reporting shortages, existing shortages and guidance documents that describe these two regulations that I've talked about.

So now, how does OBRR become aware of supply chain disruptions? As Anne mentioned earlier, unfortunately a lot of times when we hear about this supply chain disruptions, it's pretty late. And a lot of times we can only end up offering short-term solutions.

So I really hope that by the time we're done with this roundtable today, we can come up with more long-term solutions to some of the events and get across that it is important that we become aware of potential supply chain disruptions.

Iin terms of how we become notified, very often the manufacturer will notify FDA either because a regulatory requirement or voluntarily. —On occasion we here from the end user, and it comes in different forms, the FDA, you know, my supplier is not providing the number of bags I need or they're not able to meet my typical number of products that I need. Or they inform FDA that a manufacturer might have informed them that they're going to discontinue manufacturing.

We also hear from our blood organizations such as AABB, PPTA, BCA and ABC. And on occasion FDA will communicate with the manufacturer, for example, following a natural disaster or following compliance actions. For example, recently there was a water crisis in Puerto Rico. FDA reached out to the manufacturer of blood bags located in that country to make sure they were still able to continue manufacturing to meet consignee needs.

From our experience, I have here summarized some of the causes of supply chain disruption. Like we have mentioned, one of our major manufacturers is located outside the U.S. And that geographic concentration has related vulnerabilities. We also hear about environmental factors and logistics, typically, for example, natural disasters such as hurricanes which we heard about from other speakers and I'll also expand upon. And related logistics are transportation, communication, and so forth. We also hear issues of manufacturing and quality issues either that there's a manufacturing defect that is noticed in the manufacturing facility or there are quality issues or compliance issues following an FDA inspection, for example. Business decisions are something we hear about. Demand fluctuations may occur and you also heard about the COVID-19 pandemic which I won't expand on because that's a different conversation to have.

I'll go into some examples of supply chain issues and FDA actions. Under environmental factors we recall in 2024 Hurricanes Helene that affected North Carolina and the FDA products not only CBER but CDER regulated products as well, including normal saline and our products sodium citrate anticoagulant, which is used in the collection of source plasma.

In this case, with available data from the sponsor, FDA was able to authorize expiration dating extension of existing lots of sodium citrate anticoagulant. This action was taken for other products, too, including normal saline. This helped to mitigate potential shortages.

And then we'll all recall, Hurricane Maria that affected Puerto Rico in 2017 and affected multiple facilities that manufacture products regulated by FDA. There was loss of power, communication, transportation, staffing issues and many other logistic complications.

In this case, together with many government agencies, FDA worked with companies to prevent or mitigate shortages. In our case, as an offshoot of the event, FDA subsequently approved a blood bag system manufactured at an alternate facility by one of our manufacturers.

Like I mentioned earlier, other speakers have talked about business decisions. So one example which Bill expanded on is Glycerolyte. So the issue here is the sole manufacturer for the US market we only have one manufacturer. The manufacturer notified both consignees and FDA that they will discontinue manufacturing this year. Glycerolyte is used to freeze red blood cells

and support our military blood program, rare blood donor units and also you heard also and the source plasma world for red cell immunizations.

So what are we doing? I think Bill explained on this a lot. FDA is exploring alternatives at this point to make sure we continue to have Glycerolyte for our red cell products.

Another example of a business decision is that in 2024 one of the manufacturers of blood bags notified FDA that they were going to sell their manufacturing to another buyer. Now, this happened but time was needed to reestablish manufacturing by the buyer leading to insufficient supply of products. We heard about this through our end users, the consignee saying we're not getting enough of what they needed. We established frequent communications and updates with this buyer who is, I think relatively new to our side in OBRR and we got frequent updates from them to make sure they were able to supply the needs of their consignees.

And for some of you that have been in this business for quite a while you might remember the HCV recombinant immunoblot, RIBA supplemental test. The manufacturer of this product discontinued manufacturing in February 2013. So this led to FDA having to communicate with blood centers about alternatives for supplemental testing for HCV. FDA posted information for assisted blood establishments in managing donations that are repeatedly reactive on an anti-HCV screening test and subsequently drafted guidance.

Another common thing we see that we have to work with our manufacturers, sometimes pretty quickly, is when there's a change in raw material or components of a finished product.

This could be an alternate or new supplier, e.g. for filters for blood bags, plastics, we've had cases of adenine for solutions and bovine serum albumin used for our immunohematology reagents.

When the changes occur, it might be a major manufacturing change or moderate manufacturing change for which the manufacturer has to submit submission to FDA to get approved. In those cases, we are able to work with the manufacturers to expedite reviews if applicable. This is one area where we would want to get away from, rushing to complete reviews to mitigate a potential shortage or a shortage.

I noticed that in some cases, maybe our industry partners can talk more about this, is for example, for raw material needed for manufacturing a product , some manufacturers don't have alternate suppliers in place. So there's a time taken to identify an alternate supplier when there's a sudden shortage.

And then manufacturing or quality issues. This is one of the problematic areas for us on occasion. I have examples here because a lot of times it ends up causing recalls which obviously could affect the supply chain.

So in 2016, for example, blood establishments once again, were the ones who notified us of issues because they were noticing an increase leukoreduction failures. This turned out to be due to manufacturing defects or manufacturing on the blood bag side and this led to recalls of multiple lots of their bags. And so FDA had to work with blood establishments to establish an

alternate way to determine whether the units they had collected were actually leukoreduced and some instances somehow to implement the use of alternate bags.

And then the second example I have here is recalls following blood bags and solutions because of inspectional findings or compliance issues which could compromise donor or patient safety. I have examples here, particulates and solutions and sterility issues. These are areas that Anne mentioned earlier we work with sponsors or blood establishments to explore alternatives but is not sustainable and not always the right approach to use especially if there's risk involved in terms of patient safety and donor safety.

What does FDA or OBRR do to strengthen the supply chain? As I mentioned earlier we already have our reporting requirements and have our CBER shortage program that keeps up with shortages. We also encourage development of alternate products. I hope many of you are aware of our recent guidance regarding buffy coat bags. And this guidance is to manufacturers of such bags and provides information on what will be needed for submission. We're open to discuss with the manufacturers of such bags. We provide regulatory advice and oversee the development of novel products. We welcome discussions with sponsors who want to talk about alternate products and we retain communication with others in FDA, stakeholders and other government entities as needed.

So, in summary I hope I've demonstrated that the supply chain for the U.S. blood manufacturing is complex and global. There are multiple reasons for supply chain disruptions. And often unfortunately our interventions are short-term. Hopefully we can get to a better place. FDA encourages manufacturers to notify the agency of supply chain issues early. Advanced notification allows FDA to collaborate with manufacturers to prevent or mitigate potential shortages. So thank you and I'll hand it back over to Leah.

>> Leah Mendelsohn Stone: Thank you so much. So we are moving into the facilitated discussion part of this panel. I will ask all of the speakers to come off mute and rejoin. And the first question for this session is what are the critical supplies for the manufacturer of blood and blood components? And for that question, I will start with Bill to ask you.

>> Bill Block: Thanks, Leah. Well, obviously blood bags we spend a lot of time only those. And you now we also collect platelets and those medical plastics are the most critical. But we have others, ancillary products, for instance, you know, a lot of people use ChloraPrep, that's probably the main product used to prep the needle area before you're taking blood and drawing blood. That's actually had a recall. And there's been things like that, that also are very critical. So maybe your other question is part of this, is what are you doing about it? We're trying to add inventory of these critical components to give us breathing room and trying to identify other alternative manufacturers. So that would be my answer.

>> Leah Mendelsohn Stone: Thank you. James, I would love your perspective on this question as well.

>> James Knowles: Absolutely. I think as I alluded to in my presentation, we obviously depend a lot on the apheresis plasma bottles and the connecting tube. That's one of the most critical

pieces. There are several manufacturers of that, but every company has business preferences. It does take time to move over especially if there's an associated piece of equipment that is from the same manufacturer.

You know, I also talked about Hurricane Helene, anticoagulant is quite unique this this sector in the sense that is an absolute most in order to continue plasma collection.

And I think saline, this is something that the industry's implemented many years ago in the interest of donor safety. Clearly we have a short-term temporary opportunity or let me say, options in terms of using an oral hydration which is in our PPTA standards. But I think from a medical perspective, the saline is the preference.

So they are the main three that we would want to highlight. Obviously everything is connected. But those are the three that would impact day-to-day plasma collection.

>> Leah Mendelsohn Stone: Great. And John, do you have in addition to what James and Bill highlighted?

>> John Hagins: I would add, also in the critical supply chain are the BECS providers as critical infrastructure and providers, the software that run most of our blood centers are one of those critical items and one susceptible to bad actors in many cases and not just a natural devolution of some sort.

>> Leah Mendelsohn Stone: Great thank you. The second question, how does your organization monitor for and respond to supply chain disruptions and shortages involving critical supplies for the manufacture of blood and blood components. John, why don't we start with you?

>> John Hagins: Sure. One of the things that the AABB IDTF does and alluded to is monitor the status of the blood supply in the U.S. and report that to all of our partners. Hopefully it provides early warning signal that, if things are going in the wrong direction, we can take action. We have been fortunate except for some regional shortages, we do green, yellow and red report every week. Over the last year we've been in a generally green status although we had regional issues that have popped up from time to time. But that's done on a weekly basis and reported.

There's also some reporting that's done on a daily basis in order to supplement our weekly report.

>> Leah Mendelsohn Stone: Great. And James?

>> James Knowles: We rely on equipment manufacturers, suppliers of the manufacturers and suppliers, the distributor as well as the not just in the plasma collection but throughout our fractionation, we rely on that in PPTA, similar to AABB to reciprocate that information out. We rely a lot on what the FDA puts out either through MedWatch or through other shortage notifications. I think that's important. And I think also again similar to AABB, one of my colleagues is on the disaster task force. And I think it's important that AABB and PPTA continue these conversations. While there are slightly different supplies, fundamentally the reasons and therefore the solutions can be a combined effort. So I think the power in numbers, the communication through interindustry as well as within inter-companies through the associations is really valuable.

>> Leah Mendelsohn Stone: Bill?

>> Bill Block: Yeah, the only thing I would add is that we do monitor the drug shortage list, too. It's been helpful from the FDA to put products on there that we can continue to use during shortages that do occur, for instance, GVS is on that list today. We can continue to order.

The other thing I would add is we try to give our interest centers a couple of alternatives and make sure they're validated on the alternatives on the products so that, if there's a shortage, we can shift to an alternative. Not always easy because not a lot of alternatives. Where we can, we try to do that.

>>Leah Mendelsohn Stone: Great. And I know Orieji, you spoke about this issue during your presentation. Do you have anything else to add?

>> Orieji Illoh: I think there were two things we were able to do depending on the issue. For example, I mentioned the RIBA test where we're able to offer alternatives. I see it two ways, either work on offering alternatives or we work with the sponsor on whatever is the cause of the supply chain disruption or potential disruption is. We also have requirements of reporting. So that's how we sometimes become aware of a potential shortage. In Bill's presentation, for example, he mentioned ChloraPrep. When that happened we worked with blood establishments to explore alternatives in terms of disinfecting the arms for blood draws or on other occasions we might have to work with sponsors to approve alternatives for their products.

>> Leah Mendelsohn Stone: Thank you. Moving onto the next question. How have shortages of critical supplies for the manufacturer of blood and blood components affected blood center's ability to meet demands and require to maintain an adequate blood supply? John?

>> John Hagins: From the disaster task force perspective, one of the features I think of our system is it's the fact that it's decentralized. If there are issues that impacted a blood center in one portion of the country, we have been able to draw resources from others. And they've been available. In addition, the communications that have surrounded those situations have built the confidence in the fact that, if there is a situation, blood donors will respond in order to backfill the blood supply that's being moved into the areas of concern. So one of the key components of the disaster task force is one, of course, responding and meeting the resource demands. The other is the communication piece to make sure any inventory that's been expended in a certain area can be backfilled from-- in the areas that are shipping it.

>> Leah Mendelsohn Stone: Thank you. Bill?

>> Bill Block: Yeah. I think on this one, what we've tried to do is, because there have been shortages and because we know that supply chain is fragile, we have tried to identify the critical products that need to go to our three PL strategic partner at HemaSource and put those in inventory as much as we can so we can mitigate risk. The other area would be as John knows, within BCA we have independent blood centers that have inventory of finished good products on the shelf for emergency response. So they actually make sure they are available. Gives us a bit of buffer during emergencies. There are about 35 centers that participate in that program. So I think it helps.

>> Leah Mendelsohn Stone: And James?

>> James Knowles: Yeah, I say definitely over the last 10, 15 years, they mentioned the HCV, RIBA shortage where the industry had to pivot. In recent years we had a test tube shortage of a certain volume. The industry had to think about alternatives, alternate volumes for testing that required obviously internal validation by every company. I think that's one piece.

The industry as a whole is a lot better as understanding that our thought process is more fragmented whether it's testing, collection or even plasma for fractionation, the impact and availability of the finished product. As you continue to think about your own portfolio of how you respond to supplies, you have to think holistically about the entire chain. Because there are key areas, that have an impact there. And testing whether it is HCV or test tube shortage several years ago, is another example.

>> Leah Mendelsohn Stone: Great. So the next question. Is what are the challenges and gaps in anticipating and responding to supply chain disruptions and shortages? And for this one, why don't we start with John?

>> John Hagins: Sure. Bill alluded to this earlier. When there is a challenge that comes up, most of the situations, when we're dealing with it from a disaster task force perspective, the need is emergent at that point. One of the gaps is how to fill in the first 24 hours emergency when it's needed. This is when Bill alluded to the blood emergency readiness core which is about a group of 35 blood centers that have reserve in any given week about 50 type O red cell products that can be shipped without question within 24 hours of an emergency. A responsive tactic in order to respond to gaps that maze come up from time to time whether that is again manmade or natural disasters as it will be. But the real gap is the visibility and seeing a situation coming and being able to respond quickly to make sure that to ensure the patient needs are met wherever that disaster may have happened.

>> Leah Mendelsohn Stone: Bill, do you have anything to add to that?

>> Bill Block: Well, we're very concerned about two significant things. One is cybersecurity or cyber event that would occur that as John mentioned earlier in his example, they can be prolonged. And so we have to have enough supply to withstand, typically we don't have a problem getting donors but we have to have supplies ready and available for that.

The other area is, you heard me mention, blood centers don't have a lot of space in most cases to store inventory at their location. So we have established a distribution center basically four or five to carry the inventory across the country. And then what we try to do is make sure that we have that available during any kind of supply chain disruption and there have been quite a few. That gives us breathing room. We only have to ramp up by 10%. What we need is probably somewhere in the 30% range. We're trying to build towards that.

>> Leah Mendelsohn Stone: James?

>> James Knowles: Not much more to add on that. I agree with John and Bill. Only thing I would add is I think the earlier the communication of any potential disruption, even if it doesn't

end up in a disruption, gives people foresight. Obviously from a company perspective, there are suppliers have to inform manufacturers, collectors of immediate supplies. I think if there's a greater transparency and communication, it's a fine line between business practices, et cetera. That will help. That will have a positive ripple effect. Again I'm thinking about seven to between months of plasma derived medicine availability. That's all I have.

>> Leah Mendelsohn Stone: I'd be curious on your perspective on this question.

>> Orieji Illoh: I want to say that I feel like the timing sometimes for supply chain disruptions is sometimes unpredictable.

Sometimes when we hear about this, it's Thursday or Friday. The timing is unpredictable. I know some of things cannot be controlled. A lot of times, short-term solutions. Another challenge I see is sometimes the disruption is because of compliance issues which we have to work around to see how we can resolve that to make sure we maintain the supply chain. There are also limited alternatives. I think Bill mentioned a blood bag for whole blood collection that is being discontinued. So the alternatives while we want to explore alternatives may be limited. And the last thing I have, I thought about is the fact that we cannot control business decisions from companies. That's something internal that they decide and do. But those decisions are made and they really affect the supply chain as well.

>> Leah Mendelsohn Stone: Thank you so much. The fifth question and how do Federal Agencies assist in responding to such supply chain disruptions and shortages? Why don't we start with Orieji for this one.

>> Orieji Illoh: This is a great question. I think our next session-- actually our last session we might hear more about this.

So you know, cross governmental approaches are needed a lot of times to address supply chain disruptions. For example, when we have natural disasters or there are a lot of things that fall outside FDA's purview when it happens. FDA cannot resolve it themselves. In some scenarios interagency collaboration is needed to mobilize resources. So I can share some examples based on what we've seen in the past. And somebody already mentioned, so for example, when we've had hurricanes, Hurricane Maria, for example, comes to mind. In that case, multiple agencies were involved in addressing the logistics, FEMA. HHS, ASPR. In that case, FDA created a dedicated task force to speed up regulatory choices and helping manufacturing plants resume operations. In terms of logistics, other agencies collaborated with local authorities and other agencies to clear roads that were blocking manufacturing plants. You know, assess generator needs aircraft landing, another critical things that were needed at that point. And then also FDA was able to facilitate temporary imports from alternative supplier. We had to work with other partners to ensure that all this can happen.

And another thought that came to my mind is cybersecurity which has been mentioned several times. While that's has directly affected the blood supply which we're not covering today, I think we all are aware that cybersecurity can affect manufacturers as well. So while following several cybersecurity events affecting blood establishments, we were able to engage in

discussions with our counterparts in HHS who had more expertise about cybersecurity mitigations to come up with recommendation and how to prevent future cybersecurity attacks. Like I mentioned earlier, we regulate the blood establishment computer software. So we're heavy in review of those devices, making sure they have systems in place to mitigate cybersecurity attacks. So that's one area we're looking at when reviewing such devices and many other devices as well. And then we've always had internal discussions with our partners in HHS regarding issues with blood supply chain whether it's blood bags or what we can do to make sure more products are available. So BARDA and ASPR others in HHS as well.

>> Leah Mendelsohn Stone: Thank you. John, do you want to talk about this from the task force perspective and

>>John Hagins: The Office of the Assistant Secretary for Health, OASH, even during one of the hurricanes that impacted New Orleans, they were key in finding and arranging generator to go to a blood center that had been disabled during a hurricane.

In addition to that, our federal partners and even our armed services program, have been key in making sure that the message gets spread wide within the Federal Government so if there needs to be cross agency communication and coordination that those activities happen.

So having liaisons for both the armed services blood program and OASH on the task force critical events assessment group is key to be able to engage our federal partners early if there is a situation.

>> Leah Mendelsohn Stone: Thanks. Can you talk about PPTAs and the plasma industry interactions with Federal Agencies?

>> James Knowles: I mentioned the COVID alliance which was not just with FDA was with NHS BARDA.

As regulators think about the supply chain, I encourage them to think about blood and plasma in the same breadth. As Dr. Eder shows, we make 40, 50, 60 million donations a year that fuels a very different supply chain. We obviously have different critical supplies to the blood world as well. I think it's important that we, while we have excellent communication with CBER and FDA, we continue to keep that in mind as we-- I think I'm coming back to the power in numbers, the different perspectives can prompt different conversations. Bill and I have spoken a bit about this and it's good to bounce different ideas from different industries off one another because there could be transferable topic there that could also be communicated to the FDA. That's all I needed to add, Leah.

>> Leah Mendelsohn Stone: Bill?

>> Bill Block: I think the FDA has done a good job relative to evaluating patient risk just in the last six month, we've had two FDA holds on products that are critical to blood supply with really no good alternative. Balance patient risk with what's the regulatory issue and what do they do about it.

If you put a recall in place versus a hold, it could significantly disrupt the way we respond to any kind of supply chain disruption. I think that's one thing that we continue to keep in mind in the future. The other is, you know, I think we need to continue to put, I know that blood and plasma are center and they're on the essential products list. But I also look at it as a national security concern in both cases. I think they should be elevated to that level from a federal standpoint. It would put us in a better position to prepare for emergencies that we know are going to occur. You heard me talk about not having enough inventory in place across the country on consumables. I think James would echo that, that could really help both supply chains support us from preparedness standpoint.

>> Leah Mendelsohn Stone: I want to make sure each of our speakers-- if there's anything else they want to add or didn't get to add, send me a signal or chime in.

>> John Hagins: I would like to finish up by thanking the FDA for hosting today and for giving us this opportunity to at least, as we start, discuss the current state of supply chain and looking forward to the rest of the day.

>> Leah Mendelsohn Stone: Thank you. Thank you so much to all of our speakers. And we will turn it back over to FDA.

>> Anne Eder: All right. Well, thank you. Thank you, Leah, thank you, panelists. Thank you, John, Bill, and James and Orieji. That was a great first session. We are going to take a break.

I want to thank our speakers and panelists. So please come back at 11:00 for our second panel where the manufacturers will tell us about how they maintain resilient supply chain.

So you heard what the critical supplies were. We're going to break until 11AM. So please do come back, and we'll start up again then. Thank you.

>> (BREAK)

>> Anne Eder: Welcome back to the second session. In this session, we're going to hear from supply chain manufacturers on how they build a resilient supply chain.

Our moderator is Mary Homer, she's the Program Director at CBRN radiological nuclear medical countermeasures program at BARDA. So Mary, the floor is yours.

>> Mary Homer: Thank you, Anne. And thank you for the opportunity to participate in today's discussions. Really appreciate it. So far, it's been really, really interesting and I would say that for session two, we have a very impressive lineup with very interesting speakers. Our objective for this session is to identify the root causes of supply chain disruption and propose solutions to prevent such disruptions and shortages. Our lineup includes Janet Johnson, VP Global Regulatory Clinical Affairs and Labeling at Terumo. Team at Fresenius Kabi of Laurent Blime

Head of Supply Chain Management and Eddie Kubo, the Senior Vice-President of Commercial Operations. We have a team from Haemonetics, Helmut Hanske and Julie Ryan VP Global Quality Assurance of Regulatory Affairs. We have Alexandre Mouroz from BPS Supply Chain Manager from Macopharma. Richeal Cline Head of Diagnostics t Global Operations Roche Diagnostics and Jon Arriaga Anchia Vice President of Diagnostic Industrial, Grifols Diagnostic Solutions. With that, I'll ask Janet Johnson to take over sharing her screen, and let's get started.

>> Janet Johnson: Could I ask FDA to share my slides? Sorry. Okay. So I'm Janet Johnson and Vice President of Global Regulatory Clinical and Labeling at Terumo BCT. And I would like to thank FDA for convening the meeting and opportunity to share perspective on strengthening the supply chain for blood manufacturing. I am an employee and compensated by Terumo.

Terumo BCT is part of Terumo Corporation. We have more than 100 years of healthcare innovator. We support blood centers, hospitals, gene and therapy organizations around the world with technologies that collect, process, separate blood cells. We see both the clinical blood system and industrial system required to keep the blood supply operating.

Next slide.

These are the three ideas I want to leave you with today. First, blood availability relies on two independent but interdependent supply chains. One begins with donors and the other begins much further upstream with raw materials, components, manufacturing and logistics. Second most policy discussions around the blood supply resilience understandably concentrate on recruitment and donor eligibility and collection capacity. These are important issues but they can't solve a recent shortage, a critical supplier failure or a quality problem or perhaps a trade relation interruption.

And third, materials resilience deserve greater policy attention not more regulation, but greater recognition of where the risks rise and where the risks arise and what the government can do when threatened by the blood availability. As we know when we think of the U.S. supply it takes, what it takes to get a blood product from a donor to a patient, there are two equally important supply chains that rely on each that and ensure blood quantities are available.

On the donor side, blood proves from recruitment to collection to testing component preparation, inventory and testing to patients. But another supply chain has to work much before that can happen.

Manufacturing starts with raw materials. For example, plastic, resin, electrical components. Before becoming a product that a system can rely on. A failure in either supply chain can interrupt patient access. For the remainder of my comments I'm going to focus on the second part of the supply chain, the materials manufacturing side because this is where our experience can add something to this discussion.

Next slide.

Each supply chain potentially fails for different reasons and the root causes are different. On the donor side issues can be recruitment or retention. We know the donor agent population is aging

and donor demographics eligibility requirements and clinical demands and staffing occur. On the material side issues are industrial, including limited supply, adequate investment in quality and infrastructure, global sourcing, trade exposure and logistics constraints.

But the outcome is the same. It puts the blood availability at risk. So the response has to be different. You can't recruit your way out of a resin shortage. You can't solve a donor participation with a manufacturing policy. The objective should be to match the policy to the tool with the type of risk.

Next slide.

This is an illustrative map but makes an important point. Many of the risks that eventually reach the blood centers and hospitals actually originate further upstream. A blood center may experience a shortage of bags or other supply but has no visibility whether the underlying cause was a resin supplier, transportation issue, qualification delay, perhaps a trade restriction or even a manufacturing problem. By the time that problem reaches the blood center, a lot of the options for preventing a disruption are already gone. The question is, what data or early signals would help FDA and other agencies distinguish normal supply noise from a disruption affecting the blood availability. This is where better information sharing and coordination can add value.

Next slide.

Okay, so now I'm going to focus on the solution architecture. Next slide. We see four complementary levers. Manufacturing resilience, to diversify production locations to allow shifts when needed continue investing in quality and innovation. Helps ensure a quality product is available any time. Regulatory modernization. Remove unnecessary friction when maintaining standards, safety, and accountability.

We need federal coordination, establish and maintain a rapid response where critical inputs are threatened and donor resilience. We need to strengthen recruitment, incentives and access. No single lever is significant, sufficient, together they support reliable blood availability.

Next slide.

One point in particular that I want to make clear is we support a strong domestic manufacturing capability. We design a manufacturer equipment in the United States and also have a U.S. strong based intellectual property. But a blood bag or any sophisticated medical technology is the endpoint of a multi-tier global supply chain these dependencies do not disappear because of the last step of manufacturing occurs in the United States. Cases focusing only on final assembly can simply replace one point of failure with another. It relies global production footprint in order to maintain the U.S. and the global blood bag and processing equipment to supply blood centers that collect and process blood and ensure availability for patients in need.

One lesson that we experienced is that, resilience and reshoring are not the same thing the resilience means something broader for us. It means domestic capability and diversified sourcing and a strong quality system redundancy and business continuity planning. Without a global supply chain in production, we are breaking a link in the supply chain. Because not all

raw materials or electrical components are manufactured in the U.S., and the cost to do so would be too high, outpricing our U.S. market and our healthcare infrastructure.

The objective should be a supply chain capable of absorbing disruption. Next slide.

Resilience also requires sustained investment. Quality systems help prevent failures before they become shortage. They require strong investment. Infrastructure creates reliability and scalable capability. And innovation allows the blood system to be efficient including digitation with automation. These are not optional. If you are supplying a system as important as the U.S. blood supply. Terumo Blood and Cell Technologies has made the investments deliberately and we believe the level of commitment should be expected of manufacturers serving an essential blood system. Those should be an industry expectation, not differentiators. But only some manufacturers choose to fund. And our point here is broader. This should be the expectation for manufacturing serving the U.S. blood system. We should not wait until a quality or capacity problem creates a shortage to ask whether we were investing enough upstream.

Next slide.

Regulatory modernization is another part of resilience. Blood centers can be required to repeat similar validation work site by site. This concerns blood and technical staff which can slow adoption of a process improvement. Consideration of developing, using a shared SOP across blood centers could reduce validation. We are not proposing at all to lower the safety or quality standards of our product or the blood product. We are simply asking whether validation processes could be developed using a more risk-based approach and additional guidance documents from FDA could be provided. Safety, product performance, traceability, quality system accountability and FDA oversight would remain unchanged.

Next slide.

The U.S. platelet demand continues to rise year over year. While the donor base is aging and shrinking. This puts the platelets supply at risk, extending the allowable hold time prior to processing would help stakeholder manage this changing donor landscape.

The platelet usage is tied to the processing time between whole blood collection and component processing. I want to acknowledge and grateful for FDA issuing the guidance for recommendations for the development of blood collection, processing and storage systems for the manufacture of blood components using the buffy coat method. This document is helpful for manufacturers to understand the agency's position on hold times and that with data they're open to allowing processing time similar to regulated markets. Greater flexibility provide blood centers more time for transportation, support, centralized processing, facilitate automation, improve staffing flexibility, and potentially reduce underutilized collection. We believe this flexibility would not compromise product quality or patient safety. And would allow additional opportunities for blood centers.

Next slide.

There is however a broader issue. Blood is simply a hospital commodity. Hospitals cannot provide trauma care, surgery, sickle cell treatment and therapies without reliable access to blood and components. That makes the blood foundational healthcare infrastructure, it has to be sustainable. If we expect quality redundancy, capability and resilience from the system, the policies surrounding the system need to support the investment required to maintain them. We therefore encourage the government to recognize blood, blood components and critical blood system inputs as essential healthcare infrastructure to support policies that sustain their availability over time.

Next slide.

Perhaps, this is the most actionable idea we are putting forward today, predefined rapid response framework for blood supply systems and disruption. We learned during COVID that the government can move quickly when critical healthcare inputs are threatened. Chips and vinyl became constrained and material-- we should not wait for the next crisis to determine who calls whom. A trigger could be cyber attack, raw material shortage, critical supplier failure, planted constitute shut down and trade disruption. FDA and ASPR industrial based supply chain capabilities could conduct initial assessment with Congress BIS, USTR bringing agencies together from CISA, FEMA. Then they're available across the government, can be considered prioritize critical materials, facilitate alternative sourcing, address trade bottlenecks and coordinate communication with industry. Goal is simple. Identify the disruption upstream and act before it becomes a blood shortage downstream. We're not suggesting that the FDA would own every single one of the tools we're suggesting that FDA is positioned to help identify healthcare consequences and activate the right partners. That directly supports this roundtable stated objective of identifying root causes, solutions that can help predict and prevent supply equipment shortages affecting the blood supply.

Next slide. And finally, none of this diminishes the importance of donors. An eligible population does not automatically become a donor. Population awareness, motivation, employer flexibility transportation recognition and other appropriate incentives can help people move from eligibility to first donation and repeat donation. Donor resilience remains part of the solution. Our point today is simple that it cannot be the entire solution. And final slide, let me close with these three points, first the blood supply as two supply chains. We need to think both when we talk about resilience. Second materials resilience is more than something that's manufactured. It depends on quality, investment, diversified sourcing, redundancy and regulatory flexibility. And third we should not wait until materials disruption become a blood shortage to decide how the government or manufacturers should respond. There are opportunities within FDA's authority and others that would require coordination across HHS commerce and other agencies, Terumo BCT welcomes the opportunity to work with FDA and other agencies represented here on this call to find solutions. I'll turn it back over to Mary.

>> Mary Homer: Next up we have the team from Fresenius Kabi. So Laurent Blime and Eddie Kubo, can you please start sharing your deck?

>> Laurent Blime: Can you see my screen?

>> Mary Homer: Yes.

>> Laurent Blime: Okay. So good morning. And thank you for the opportunity to join the discussion today. I'm Laurent Blime head of global supply chain. I will present with my colleague, Eddie Kubo Senior Vice President of MedTech commercial operations. So as we know every blood and every plasma collection depends on the availability of a complete, safe, and functioning collection system.

A shortage of even one critical component can reduce the collection capacity, delay processing, constrained emergency readiness or affect the availability of blood components and plasma derived therapies. Manufacturers, collection organizations, distributors, associations and federal partners each have important responsibilities. Of note, visibility across the end-to-end vertical supply chain network could improve resilience, but up to this point has been difficult to achieve.

Today we will focus on three points. One, the most consequential vulnerabilities, two what the manufacturer can do to manage supply resilience within its own vertical operations. And three, where greater vertical communication can help detect risk early and maintain continuity of collection. This discussion is intended to be high level and a common theme throughout is good customer and supplier communication.

We are committed to a customer-centric approach and invite continued dialogue with customers and suppliers on this topic.

This will not come as a complete surprise to you. Like many industries, we have entered a period of sustained supply chain volatility. COVID-19 was a major disruption but also exposed vulnerabilities that are structural rather than temporary. Since the pandemic supply disruptions have become more frequent, more diverse and increasingly interconnected. First source of disruption is demand volatility. Sudden changes in consumption combined with visibility on inventories across vertical supply chain can create significant gaps between forecast and actual requirements. These effects can be amplified by potential bull whip effect affecting the upstream vertical supply chain.

The post COVID environment, logistic networks remain vulnerable due to a full range of factors, port congestion, transportation capacity constraint and more variable transit times on most of our transportation lanes. Manufacturing execution is also becoming more challenging. It is affected by periodic shortages of specialized materials and components as well as constraints on skilled labor. Finally, market participants are exposed to increased geopolitical conflict, trade restriction, cyber attacks, energy interruptions, natural disasters and extreme weather event which can affect suppliers, manufacturing sites, and transportation routes simultaneously.

In many industries, a supply disruption can be addressed by rapidly switching suppliers, relocating production, modifying a component or using an alternative distribution channel. The manufacturer can strengthen short-term responsiveness through structured early warning, inventory monitoring, manufacturing planning and cross functional escalation processes to identify emerging risks and act before they become supply interactions. However, short-term responsiveness has inherent limitations in our sector. Regulatory requirements then supplier and

product qualification, specialized manufacturing technologies, long replenishment lead times and strict quality standards make it difficult to implement alternative solutions rapidly. Operational agility is essential. But it cannot compensate for potential structural vulnerabilities that have not been addressed in advance. Resilience must be embedded in the vertical supply chain before disruption occurs, not improvised once the crisis has started.

Manufacturers can develop structured and comprehensive risk management approaches. This can combine multi-sourcing strategies for critical materials and-- particularly when alternative manufacturing capabilities can be established. This approach also includes business continuity assessment across manufacturing networks, covering both range of potential disruption scenarios such as supplier failure, loss of critical equipment, fire, earthquake, flood, cyber attack or temporary loss of access to a facility.

Far more business continuity plans can be tested through annual drills to confirm that responsibilities escalation pass and recovery actions are clearly understood.

This measures can be complemented by daily monitoring of inventory, against define inventory corridors, regular assessment of manufacturing risk, alternative scenario through the sales and operations planning process, S&OP and early warning and escalation mechanisms embedded in the sales and execution process which is S&OE. In the United States, geographically distributed inventory and multiple fulfillment options help position products closer to the point of views and provide alternatives when location or transportation route is disrupted. This can allow manufacturer to identify vulnerabilities earlier, reduce the probability and potential impact of disruption, respond more effectively when an incident occurs and accelerate recovery. They provide the essential internal foundation for protecting supply continuity and ultimately supporting continuity of patient care.

But even the manufacturer with resilient internal controls has limitation. Product availability for patients depends on optimized communication upstream and downstream across the entire vertical supply chain. Limited visibility up and down the vertical supply chain can delay the detection of emerging risks and amplified problems. An action by any participant in the supply chain ecosystem can put unnecessary stress on the entire supply chain network. Supply continuity is ultimately an end-to-end outcome. It cannot be achieved by a single organization alone. The higher level of resilience requires a shared understanding of emerging risks, across the entire supply chain ecosystem so as vertical supply chain participants can make informed decision on risk, supply risk mitigation.

So Eddie over to you.

>> Eddie Kubo: The next step toward achieving the higher level of supply resilience for manufacturers really establish the resilience across the entire vertical supply chain. Now to be clear, this would not replace the responsibility of each player in the vertical climb to maintain robust internal processes and business continuity plans. Rather it's more about connecting the individual capabilities through greater communication, visibility, and common risk indicator.

The first component would be a vertical collaborative planning, forecasting and replenishment process within the manufacturer's supply chain. Greater visibility to inventory levels along the vertical and forecasting for the most critical products. This improved visibility would help identify situations in which sufficient inventory exists within the supply chain somewhere but not positioned where needed most. The second component could be supply chain mapping within each manufacturer's vertical relationship. This vertical mapping would cover the flow from the manufacturer's critical suppliers and sub suppliers through its own distribution operations and ultimately to the blood and plasma centers. Manufacturer could identify critical nodes, potential bottle necks and lead times and available alternatives within its own supply chain. And to be effective it should be maintained as a living and evolving risk management tool rather than one time exercise.

And the third and last component would be comprehensive vertical risk supply management once visibility is achieved a across the supply chain ecosystem, participants in that supply chain can communicate about issues that can affect supply. And these participants can work together to mitigate problems.

Other risk mitigation strategies can include training and validation of a secondary product where possible. We heard Bill Block recommend this in Session One as a key element of future preparedness. Another would be the implementation of periodic scenario-based exercises in a manufacturer's vertical chain to test the effectiveness of risk mitigation mechanisms before a disruption occurs. So to conclude, by moving fragmented vertical risk management to better vertical communication with a manufacturer's supply chain, we as manufacturers can enable earlier detection and earlier response to challenges. Ultimately stronger vertical supply chain resilience would help support continuity of care, reduce the risk of any treatment delays and contribute to better outcomes. Good communication across this vertical line is critical and we look forward to continuing conversations with the customers and suppliers to best manage supply chain risk. Thank you for the time and thank you FDA for this opportunity. With that I'll hand it over to Mary to introduce the next panel of speakers.

>> Mary Homer: Thank you, Eddie and Laurent. Next up is Helmut Hanske and Julie Ryan from Haemonetics. please start sharing your slides.

>> Helmut Hanske: Good morning, and we'd like to start off with the saying thank you to the FDA for organizing this roundtable, this workshop and giving us the opportunity to present this certainly very important topic.

Moving to the next slide, please.

We would like to start off with just giving you an overview of Haemonetics role in the blood collection ecosystem which has actually changed a little over the last couple of years in that, we focus on automated apheresis collections, moving away from manual whole blood collections.

Talking about the apheresis collections, we are producing apheresis equipment that is used in component collections, several components such as red cells, platelets and plasma used for industry and transfusion purposes. With those apheresis devices we provide full range of single

use, sterile disposable sets and I think one area to focus on is cell processing which is a small niche area but mentioned today's due to the fact that one of the solutions required for cell processing, I'm referring to the cryopreservation of red cells here, the Glycerolyte solutions has become obsolete which is one of the challenges we are facing today and discussing today. Haemonetics provides software solutions to incorporate, integrate devices and technology into computer systems offering donor management systems especially focused on plasma industry.

Next slide, please.

So Haemonetics is structured in a way that we look into diversifying our global manufacturing locations as well as suppliers. As you can see on this map here, we have production sites close to our four markets here, close to core countries, obviously in U.S. and Europe and Asia Pacific, holding these distribution centers close to customers. And one of the principle areas of focus here is around the diversification of suppliers making sure that we have multiple suppliers qualified for a raw materials and components for the end products we produce.

Next slide, please.

So the challenges we identified, talking about supply chain issues and supply chain challenges are common. Listening to presentations that we had so far within the workshop, I think we are talking about common themes here. And the four elements that listed here, first starting with regulatory challenges. It's very much about changes in regulations, changes in regulatory requirements and some extent inconsistency in regulations and regulatory requirements which are creating some challenges which we are going to focus on later on in this presentation. Well, looking into the upcoming geopolitical issues and challenges affecting transportation of goods but also the cost of transportation talking about tariffs and longer lead times for raw materials as well as finished product.

Many global supplier phase is becoming an issue since we need to qualify material changes and supplier changes on a more routine and base. And lastly we are facing resource challenges in certain areas, specifically talking electronics where some of the components are used more often and frequently in the growing AI industry, talking data centers here. There's truly competition here in the resource front as well that's creating challenges when talking supply chain.

Next slide, please.

So one focus area or area I want to focus in our presentation relates to solutions. Talking standard on solutions here are used in combination with apheresis systems, apheresis disposables, and also in cell processing operations. Haemonetics offers a dry sets, meaning the solutions talking anticoagulants as well as additives are coming along as standalone products connected to the systems. When we look at this standalone solutions we are looking into two different groups of products here. One, we would really categorize this commodities. They are produced, manufactures in multimillion of units every year and I'm referring to the anticoagulants used in plasma and saline used for compensation purposes. On the other side we're talking about specialty products, produced in much smaller quantities. Those are the solutions that are used in red cells, talking specific dedicated to anticoagulant and additive as

well as in the cell wash and prior preservation procedures referred to early on. The Glycerolyte solutions and various more solutions required in this process such as wash solution as well as hypotonic saline solution to deglycerolize frozen red cell units.

We're looking at a limited number of suppliers that are offering those products. One hand, commodity products, there is tremendous cost pressure on high volume products. On the other side, we are facing regulatory challenges for a number of those products. So this makes the production and release of these units or products quite costly. And profitability is questionable whenever looking into the production of those items. One of the challenges comes in the fact that a number of those solutions are classified as pharmaceutical products as drugs and puts greater disadvantage for a traditional medical device companies such as Haemonetics since we don't have the structure and the necessary departments to support the commercialization and production of the pharmaceutical products. That's one of the challenges we're facing here.

With that said, this has been discussed earlier today. It creates one of the most critical supply challenges we are seeing right now in that the Glycerolyte supply that is used for freezing red cell products as mentioned has come to an end. And we are looking for alternative sources here. Briefly presented in the discussion, that Haemonetics is working with an Italian based company, supplier, to support international outside U.S. markets and looking into possible ways to work together with the supplier to bring Glycerolyte solution or a replacement for Glycerolyte into the U.S. again. With that I'm handing over to Julie.

>> Julie Ryan: Thank you, Helmut. So to continue on that Helmut was touching on, there are numerous critical elements in the blood supply chain. The anticoagulant and additive solutions which have tended to be one of the challenging elements for the supply chain for us. The global source plasma supply comes from the U.S. and products used to collect plasma in the U.S. often need to meet regulations in countries where the plasma will be fractionated. Manufacturers typically desire to minimize the number of variance or SKUs of a given product having to manage, ideally having one product that works globally. This is not achievable for blood processing solution due in part to the non-harmonized global regulatory landscape for these products. And here I outline the situation for U.S. and medical device single audit program for countries as well as the EU.

In the U.S. and Japan most of the solutions are regulated as drugs. In Canada and EU, they're in between state with Canada having moved this to the drug side a few years ago but allowing solutions registered as devices to remain grandfathered as such. And the EU we see variability in classification across the notified bodies anything from a drug to class 3, 2B or 2A devices. In Australia and Brazil these are classified as devices. However countries like Australia where you can leverage a reciprocal approval, this is only doable if a reciprocal product approval is same type and class. Instead of reciprocal arrangement, in some cases a more likely onerous direct conformity assessment is required. What this situation leads to higher overall regulatory burden for manufacturers, often leading to proliferation of product variants based on country specific requirements which makes it difficult to respond and recover in a shorter situation because the products used across the globe are not interchangeable. Here were some long-term regulatory enforcement discretion can come into play but does not address the root cause. It requires

manufacturers who are primarily medical device manufacturers to maintain expertise and drug in combination drug combination and meet higher burden to obtain initial approval to enter the market, maintain compliant manufacturing and longer timelines for approval. We're left with a situation where accomplished drug companies are little incentive to engage in this small volume manufacturing but high bar for med device companies to maintain their expertise and infrastructure for these products when it's not their core competency.

So next slides. So now I'll touch on some of the supply chain constraint for blood collection supplies. Historically there was a move to lower cost manufacturing overseas with local material sourcing. But recently the winds have shifted and created significant challenges for overseas sourcing whether it's due to tariffs or the high cost of global transportation or due to geopolitical challenges, that's a desire to reconsider domestic manufacturing or multiple manufacturing sites which brings its own challenges for the initial long-term cost and efficiency and the long lead times associated with qualification, validation and global regulatory approvals. This assumes there's a supplier willing to engage in these endeavors, by the time it's up and running the global climate may have shifted again.

Finally this is a basic outline how we operationalize supply chain resiliency. It's a constant cycle of review of portfolio, demand and supply, to feed into the financial reconciliation, overall business reviews analyze trade-offs and cost versus flexibility as to whether to maintain multiple supplies. It's a typical model. There has to be an element of long-term strategy but there will always be element of act to short-term issues.

With that I'd like to thank you and hand it back to Mary.

>> Mary Homer: Thank you, Julie and Helmut. Much appreciated. I have to say I’m impressed with everybody staying on schedule. Much appreciated on that front as well. Next up we have Alexandre Mouroz, from Macopharma. Wonderful.

>>Alexandre Mouroz: Hello, everyone, Alexandre Mouroz, speaking I'm the Supply Chain Director Macopharma. And I will try to present what we did at Macopharma. Those who don't know Macopharma, manufacturer specializing in production of medical blood devices and equipment software to transfusion professionals. We do offer complete solutions for preparation of blood component and-- a way to say it, to get the best out of every drop of blood.

So for me, if I want to speak about how to build the supply chain resilience, everything started ten years ago. Ten years ago, I did receive a call from my previous CEO Monday morning, you can imagine an 8:00A management call Monday morning, say, Alexandre come to the meeting room. We have a situation. We cannot export products anymore to our customers. We have to find a solution. This was the first exercise on the journey of business continuity at Maco. And I will remember it all my business life. And ten years later, we at Macopharma we are having a renewal of ISO22301 on certification. During the COVID pandemic we delivered 100% of the orders. And today, as all my colleagues explained just before, we are mitigating the risks even during geopolitical conflicts and tensions.

What I'm going to present is Macopharma with supply chain resilience. As like everyone we try to identify the root cause of disruption. This is exactly the same issues this my all my colleagues met to build their supply chain.

What is interesting, it is that at Macopharma, we decided to have a business continuity corporate approach. We didn't want not only supply chain to be oriented in business continuity but we decided all the company must be a business continuity team. So we implemented a business continuity management system. We have a business continuity manager in place which is to follow as I already say, ISO22301 standards. What is key first, it what we deployed training plan in all production sites, all subsidiaries and every employee at Macopharma is receiving training of business continuity. We have training on the business continuity for managers. But why do we do all that? We are thinking at Macopharma supply chain risk is included in all the operational process. Quality is a risk. Manufacturing is a risk. Transport is a risk. Industrialization is a risk. Regulatory could be a risk. So all those departments are creating a supply chain. And we decided to integrate all those in our business continuity risks analysis for every and each process that we do, we implemented risk registers. And they're reviewed annually or in the case of event and crisis. So of course, this is one of the most important message I will give you today, we have to experiment and do the business continuity exercise every single time.

So when we do speak about risk in manufacturing, we have implemented two organizations. So we have an internal organization where we decided from the three plants having the Macopharma, putting one in Poland, one in France and Tunisia, we decided to have double orientations for finished goods. It means all customers, we are able to produce finished goods. This is key for us to double interoperability between sites. Of course, to produce finished goods we need semi-finished goods with critical component and in the same way, we implemented various workshops, those workshops are able to produce the same product to be able to react in case of any issues in one of the plants. We also have external organization because we are relying on suppliers and the suppliers are key for us. We have double sourcing implemented for filters, media and injected parts. The manufacturing, one of the key for us is to not organize the production in only one production site. Moreover, to be a better produce, we need to have raw material and we implemented three things at Maco. We implemented the five year business continuity plan for the critical materials. We are having long-term partnerships with many European based partners. This is a robust player portfolio. And we have an S&OP process, this process is communicated transparently with the critical suppliers on a monthly base and a collaborative approach. This collaborative approach is helping us to anticipate and to have read time agility to prevent issues from the suppliers to our production to our customers.

Moreover, what is very key for us is to prepare a very strong operational supply chain. So what do we do? We are having in place set an operation planning enabling us to always us anticipate and through early detection of risks but not for tomorrow, in a zero to 24 month period. It means that our target is to not being in front of the problem but detect it very early in the process.

Of course, without having the view from the market and business, we are not able to run any operation planning, so we have implemented demand planning and sales operation planning. They're to support the execution of the customer order.

To manage the daily process of having the right inventory at the right place and produce the right product at the right time, we have decided in 2021 to implement the DDMRP process which is a process to help us monitor inventory, to provide early alerts and have risks and anticipations. This is very simple. We have first all of our critical supply chains, we put buffers to react and alert on time. To deliver to a customer, we need to start and transport and of course, we have a very strong validated logistics provider portfolio. And for every risk we have defined one, two, or three routes. We have very strong audit system for the suppliers. So everything is made to have the right quality in our supply chain.

Another important topic is the cyber resilience. This is what we call it. We base our cyber resilience on the NIST. Those standards are helping us to do five things.

First of all, we need to identify the IT assets. And we need to assess the risk. This is the first thing we need to identify where could be the problem. Then we are protecting those assets. Then we are putting in all those assets some points to detect the problem. We are responding to an incident with a very critical applications, and we are having cyber assurance. And finally and not the last, we are doing a very fast recovering. It means that we are testing very often our capacity to react to identify the program and moreover to recover from this program. So this is part of the business continuity in terms of cyber resilience.

One key point at Macopharma to build the supply chain resilience, so you understood, we have in place risk register, some risk analyses, risk assessments. We have some S&OP in place, robust supplier portfolio. But the most important for Maco is really to do business continuity exercises. So the one I spoke at the beginning which is the first key and the first stone of our journey is the geopolitical challenges so we are looking at the vulnerability of the production sites. We built everything around this exercise. We led this exercise during the three months and helped us to be prepared. This is the most important. And this is why COVID was, let's say we were ready for COVID. I don't like to say it. But finally due to this organization, we were ready for COVID. We didn't test only this challenge. We tested transport flow problems. We test purchasing issues, IT problems. Human resource issues, communications issue. We had quality problem or even fire in our production facilities. What do we do? Every time we ask ourselves what do we have to do to prevent it and reduce as much as possible risks. We are not doing live exercise. We cannot learn from it. And we cannot do the things.

So what are the next steps for us? Of course, the next step is it to help the U.S. blood supply. So we are pushing to have the integration of BCMS in all of our new projects. processes, all the change control must maintain continuity including for the U.S. blood supply.

We are going to, of course, continue investment into modernization for facilities. But we would like also to, as already explained in the first part of the day, the buffy coat- derived platelet implementation in the U.S. can also bring advantageous and can stabilize the platelet inventories in the country. And what is key for us is to address external factors. We are going to work with

FDA and the European medical device regulation to do and to react every time we have updates. We will still face geopolitical situations. We'll try to anticipate those issues and transport issues and cyber risk activity. And finally part of the continuity on the supply chain is also to be able to have corporate responsibility and follow all those regulations. Globally we decided to be business continuity, not only supply chain buts as a world company to be prepared and be ready. So thank you very much. Thank you very much for the invitation. And throw it to--

>> Mary Homer: Thank you, Alexandre. Next up we have Richeal Cline from Roche Diagnostics.

>> Richeal Cline: Good afternoon. I am delighted to be with you today. Thank you for the invitation. I am Richeal Cline from Roche Diagnostics, Head of Global Operations. I have responsibility for the end-to-end supply chain which includes planning, procurement, manufacturing supply chain and logistics.

Donor screening is an important part of our business. And we take it quite seriously. And thank you for the invitation.

Roche has supported the US donor screening and blood supply for over two decades with our first licensed product in 2002. Since then, we've grown our portfolio of both nucleic and serology testing portfolio that covers the entire spectrum of infectious disease, testing required for U.S. blood and plasma donations. Over the last 20 years our experience has shown that donor screening and safeguarding the blood supply is essential because every patient is end of the result. And there is no margin for error.

It also demands long-term commitment and this has shaped our approach to resilience which I look forward to sharing with you today.

In donor screening our responsibility goes beyond delivering an assay. It covers every step from testing a donation to reporting a result. Donor screening relies on interconnected supply chain of instruments, reagents, controls, consumables, software, technical service, replacement parts and cold chain logistic. Every single component must perform reliably and to the defined specifications.

Because these elements are interconnected, a constraint affecting one critical component can reduce overall availability or testing through push. That may ultimately affect a blood or plasma center's ability to test donations and release product in a timely manner. Roche recognizes the importance of our role in this critical ecosystem and our responsibility is to build a resilience across the portfolio to minimize the risk that our portion of the system becomes the constraint in donor screening.

To safeguard continuity, Roche operates a global network of 13 manufacturing sites across four continents with our significant portion of our presence in the U.S. Six sites here in the United States spanning from Branchburg New Jersey where most of our assays are manufactured, Tucson Arizona, Indianapolis, Indiana which is one of our three global distribution centers and our California facilities in Pleasanton, Santa Clara and Carlsbad. Five European sites together

with sites in Asia and Africa support the U.S. sites. Each site directly or indirectly supports our donor screening capabilities.

More than 90% of our diagnostic active ingredients and reagent kits are manufactured in-house. For our instruments, two-thirds are built with long-term partnerships including our over 40-year partnership with Hitachi. With the remaining of our instruments produced in-house which includes our NAT instruments, consumables are supported by specialized regional partners.

These integrated proportional structures provide stability and the scale to support uninterrupted supply of the U.S. market. As you can see on the slide and what some speakers have talked about, external disruptions are a real reality across global supply chain. On the left we capture external trigger that can strike without warning, ranging from pandemic outbreaks, geopolitical instability to infrastructure failures and labor constraints because donor screening is a tightly integrated ecosystem a disruption to one single raw material, electric component, cold chain logistics issue doesn't stay isolated. It can cascade directly into the testing capacity at blood center. Disruptions may be unpredictable but their potential impact can be anticipated. And that is why Roche has built the layered safeguard shown on the right. We invest in manufacturing, dual sourcing and scalability.

We expands our regional distribution capacity and our external partner network. We maintain comprehensive business continuity and risk management plans that can catch vulnerabilities early. And we hold strategic safety stock of critical raw materials while maintaining biologics grade compliance. These layers measure protection against unforeseeable operational shocks and we prepare rigorously for what is within our control. When an extraordinary unprecedented crisis emerges internal safeguards reach their limits. Sustaining uninterrupted supply during those times depends on advanced collaboration.

This slide explains why responding to those events may not be immediate even with mature safeguards in place and with the global network. Donor screening systems are specialized and integrated and highly controlled and alternate material, supplier manufacturing location, distribution pathway or instrument component may exist. But that does not mean it can be substituted immediately. Critical materials and components must make defined specification. They may require qualification and validation, manufacturing or release activities cannot necessarily be transferred to another location without demonstrating that that new pathway continues to meet the established criteria for both quality and regulatory standards. Specialized storage or transportation requirements are limited to how quickly the distribution can go through a new pathway.

The same principle applies at the customer sites. For instrument component replacement parts must be compatible with the system installed at that given customer or blood center. Software changes require verification and controlled implementation and specialized service capabilities may not be immediately transferable.

These requirements exist for important reasons, to protect the safety, quality, and reliability of the U.S. blood supply. The challenge is not to bypass these controls. But to recognize time they

may be adding to a disruption and where possible establishing qualified alternatives and response paths in advance.

The take away here is that donor screening specialized and integrative requirements can limit how quickly a manufacturer can adapt and restore availability in a crisis. And here, collaboration with CBER is key.

Now, let's bring this to the potential opportunities to strengthen preparedness through collaboration. And let me start with an example that shows the value of collaboration. For both our molecular and serology screening products, Roche and FDA worked together to establish an approach in which Roche can perform the batch release protocol, testing internally and submit the results to FDA for review and formal batch release.

This helps significantly reduce the turnaround time, while preserving FDA oversight. It's a good example of a practical science-based collaboration that we hope to continue to build upon.

Now let's take the opportunities to strengthen that partnership. First, coordinated emergency prioritizations. When a disruption threaten the donor system, screen, early engagement and clear prioritizations helps us identify the act upon the most critical issues first. Secondly critical solution, dependency identification. Before the disruption occurs industry and government could develop a clearer shared understanding of the materials, components, manufacturing and release capabilities logistics and infrastructure and solution support dependency that are critical to ensure the continuity.

Third, predefined risk-based response plans. As an alternative material, processor supply pathway for temporary measures needed, establishing a scientific and evidence expectations in advance could shorten the response time while continuing to protect the safety, quality, and performance.

This would not mean lowering the quality or performance requirements. Because such a pathway could be looked at, from a risk based approach where we have appropriately supported data that we are limiting the shortage circumstance and that is implemented in partnership and with FDA oversight.

Finally, an early warning and escalation process. Clear notification triggers, communication channels and information expectations could allow engagement before developing constraint becomes an actual shortage. This would also help manufacturers communicate emerging risks even when the duration or ultimate impact may not be fully known. These proposals are intended as opportunities for further discussion. This roundtable creates as a great opportunity to build upon existing collaboration and advance practical science-based mechanisms to protect donor screening continuities during a disruption.

In closing, I'd like to leave you with three key messages. First, Roche takes our responsibility in the donor screening as a core priority. We have established layered safeguards across manufacturing, supply chain, logistics and life cycle support. These measures reduce the risk but no manufacturer can eliminate all potential risk. Second donor screening resilience depends on the availability and performance of the complete diagnostic system. It's not the assay alone.

Instruments, reagents, consumables, software service, replacement parts, the supporting infrastructure must work together to support the customer testing and blood center testing.

Third, preparedness matters. Identifying critical dependencies, communication pathways and potential response mechanisms before the disruptions happen. This can help industry and FDA to respond more quickly while continuing to protect the safety and performance of drug screening products.

On behalf of Roche, I would like to thank CBER for their dedicated partnership the last more than 20 years. We look forward to continue our work to ensure an uninterrupted supply of U.S. blood. Thank you again.

>> Mary Homer: Thank you, Richael. And next, our last but not least presentation is from Jon Arriaga Anchia from Grifols Scientific.

>> John Arriaga Anchia: Hi, good morning. Good afternoon for most of you already. My name is Jon Arriaga Anchia, The VP of Diagnostics Industrial. First of all, I'm thankful to the FDA for inviting us to the roundtable

Starting from the beginning, I want to show you Grifols' overview. It's a company that was founded in 1909. By itself it already says our commitment with the society. The second important point is the mission of the company, when it says to improve and health and well-being of the people, that would include as well the innovate to deliver differentiated biopharma therapeutics and diagnostic solutions globally and sustainability. So that means the deliver word is in our mission.

Grifols was mentioned before in the session one. And I don't want to give you all the public information. We have an interesting relationship with the blood banks because in some cases they act as suppliers and some cases act as customers. So that means that we do have that constant communication in one way or another.

We focus now on the diagnostic business unit, we have this three business lines which are the molecular donor screening and the blood-typing solutions and immunoassay donor screening. For the —MDS one, we have one manufacturing plant in San Diego, California, and the responsibility of this manufacturing plant is huge since 80% of the donations happen in the United States are tested with our assay, our Procleix assay. For the BTS it's a different story. We have four manufacturing plants around the world. One of them a brand new one released by FDA a couple of years ago. Even if we're new here in the U.S. has a manufacturer, we are more than three decades delivering products. One decade of that since 2014 in the U.S. market. The third business line we have is the immunoassay donor screening. We have a manufacturing plant in Emeryville California. In manufacturing and developing of the recombinant proteins.

We will narrow our conversation to the first two business line, the MDS and blood typing solutions. We have the end-to-end for both. We have the concept from the concept until the final delivery of production. And this is why these two will be the ones that we'll be talking today.

So going to the point of today's conversation for the molecular donor security and business line. We identified two big potential challenges. The first one is that we only have one single manufacturing plant licensed by FDA. And this manufacturing plant is responsible for the manufacturing of the 100% of the reagents which always makes by itself already a challenge.

And not only that, we have a single source for certain raw materials. We are in a very complex environment, our product is new to the complexity and criticality of some of the raw materials. For certain ones we have one supplier that is qualified. During the following slides, I will try to see how do we mitigate all these challenges that I have mentioned right now.

The first one is something that you mentioned previously from other speakers, inventory is one of our collaborators here. So just to give you an idea, the manufacturing plant that I mentioned before we have here in California. That inventory stays like hundreds and hundreds miles away from our manufacturing plant. That means we have for U.S., we have the manufacturing plant in the West Coast and the inventory far away from here.

Not only that, the same product is registered in many other countries and in those countries we have inventory for our main portfolio that stays there so in case of emergency, in case of a need, we have the possibility to take those products and bring them back to the United States with no problem. Each of our manufacturing lots is a split around the world to diversify the risk. We have an agreement with a third party that in case of disaster, when at one point a manufacturing plant can suffer a huge damage, whatever disaster we have an agreement with them backing up each other that they are fully licensed for FDA as well that they can manufacture for us in case of that disaster. The manufacturing plant is in the United States as well.

Again, a little bit of numbers about what I just said now, those hubs that I mentioned before and the important piece here is that the level of inventory that we are managing, at least we always maintain the five months on hand that we feel comfortable with. But for some special customers and here in the United States we can go up to 12. Our product has 24 months of shelf life. We have the 12 months and hands for some key customers that we agree with them that level of inventory. We have a collaboration with yearly inspection and from their site to our inventory. We have this ability and end-to-end either way have visibility to our inventory. And the second comment in the slide is we talk about the reagents. I want to extend that comment for even for the main consumables we use in our platform. MTUs and tips, we have more than one source. We have more than one country where we are sourcing from. And we try to expand as much as we can in that sense as well.

And for this business line, the last comment that I want to mention is that, in some cases, the best way to-- put in perspective about what happened in the past. The graph that we have in front of us is showing which is our manufacturing volume. And as you can see we try to balance it out to be stable year over year. This itself, you can see a good way to not having the peaks, surprises, et cetera. But as you can see, 2020 was obviously a challenging year for all of us because COVID and Grifols in constant communication with BARDA offered the possibility to develop and manufacture the molecular test for COVID. For that reason, we were having the most challenging year with the peak of manufacturing capacity which was interesting because at that

time we were able to do more than one shift to extend to weekends. We were competing especially in 2020 we recall that pretty much all of us were competing for the same raw materials. Actually some of our key raw materials like the oligos were obviously needed for the vaccines. And they were able to compete with them in the way that we're able to in-source most of our production. So that gave us the opportunity to develop something that we already had in our records.

So I think it's self-explanatory that at that time we were able to react and respond in a timely manner.

Moving now, and talk about the blood typing solution. We identified these, too, that they are highlighted in white. We are new manufacturing in the United States. Even when as I said before we started with this technology in the 90s. We got the license to start selling in the United States in 2014. But the manufacturing plant that I mentioned before was released in 2025. So that means that by itself that became a little bit of a challenge. In terms of raw materials, we do have that relationship with the blood banks. In this case, the relationship with the blood banks, in this case, the key raw materials for manufacturing our red blood cells, the blood bags are one of our challenges as well.

We do have in this case, more than one manufacturing source for this business line. The two main reagents, the red blood cells and gel cards, they have two manufacturing plants-- and under the same license we operate here in California. Similar situations for diagnostic Grifols in Barcelona. And this license of the FDA is as well extended to our manufacturing plant in San Diego. In a difference with the situation for MDS here for BTS we have two manufacturing plants licensed by FDA.

Probably because this always changes a little bit, the levels of inventory that we have to maintain for this business line, they can be lower as mentioned in session one, inventory itself costs a lot of energy and space and money. And here rather than having those four, five and up to 12 months that we had, here because we already invested a lot in the manufacturing plant we only need something 2.5 and three months on hand. All that inventory is already here in the United States in the country.

Same comment here as well about the instruments and spare parts, inventories that they are always on hand and always located in the United States. Let's talk a little bit about the supply of the blood bags. As I said, if we can't identify one key raw material for manufacturing of the red blood cells is one recommended with the blood bag itself. We cannot do anything without them. This is why we're diversifying a lot with the blood bags and qualified with the rent agreements with the blood bags you see here. And provides possibility to have many sources and having different cause as well. In case of emergency we can be at the same time zone as well as having like in a closer blood banks that we are closer to the manufacturing plant.

So here what we see is we have the many sources for our key raw materials. So in conclusion, finally what I think we can say is that the challenges, either for the MDS and BTS, they have been like already identified. Both business lines have the mitigations plans. We have a strong business continuity plan documents already signed by the top management. And as a

consequence of that, U.S. market, this is the main reason we decided to come here to manufacture in the United States to San Diego.

The second conclusion that I would like to mention as well is we do have more than three decades of manufacturing reagents either for both, for NAT and for IH both in the 90s, very strong systems with capacity from manufacturing in the beginning and having end-to-end analyses from the beginning. Even when this we are new in the United States, manufacturing for IH it's more than ten plus years operating in the U.S. As a conclusion, the challenges are there and we can talk in the open discussion but we can see as well that our company has been already working hard on mitigating them as much as we can.

And this is it. This is what I have for today.

>> Mary Homer: Thank you, Jon. Our first question is consistent manufacturing. So how do you maintain consistent and reliable manufacturing of an adequate amount of your products to enable blood centers to meet demands to sustain an adequate blood supply? I'd like to start with Laurent and Eddie.

>> Laurent Blime: We presented what we do in this direction. First it has the basics of what we can do within a given company to make vertical supply chain more robust. We are talking about manufacturing robustness tools that we all know about multi-sourcing on critical components, what we do in business continuity, risk assessment and all of this. And I noticed, by the way, that most of the panelists today mentioned exactly the same tools. So that by the way, the bread and butter of risk management that most companies have if place.

The second layer is we are big believers in advanced planning processes not only as S&OP because it's good when it comes to tactical horizons. Aside from S&OP we have S&OE sales operations execution to make that we have a weekly drum beat in terms of scanning the risk that we have across the supply chain. It's about detecting the early signals of execution, getting away from planning. On a weekly basis screening of old data, monitoring the risks that we have and drum beating the entire organization.

And the third point presented extensively by Eddie is improving end-to-end view on what's going in the vertical supply chain. Having a broader communication and making that we have more transparency vertically in the supply chain.

>> Mary Homer: Eddie, do you want to add anything?

>> Eddie Kubo: No, for the sake of time, I'll defer to the others.

>> Mary Homer: Janet, do you have anything you want to add here?

>> Janet Johnson: Sure. So for us at Terumo, Blood Cell Technologies which I mentioned it starts with quality and then the manufacturing infrastructure. We have made significant investments in both. Like everyone else have a strong business continuity planning. But we have a global manufacturing footprint that allows us to operate across multiple regions. So that if something occurs in one region we can rely on another region. It gives us options when demand changes or disruption occurs. We have a strong operations planning process. It helps us

anticipate the demand and align the manufacturing capacity with that. We also work across functionally, we identify and qualify second suppliers. We've done a lot of work in this in the last, six, seven years. And we're super proud of the work we've done that helps us mitigate that. For us, resilience is something that we have built before the disruption happens. And it requires an ongoing investment. Every year we look at the amount of money we're going to invest in quality, capabilities and manufacturing infrastructure along with business continuity planning.

>> Mary Homer: Thank you. And actually that's a decent lead in. Several of you rely on dual multisite manufacturing across continents, so is geographic redundancy alone sufficient or does true resilience require the validated interoperability so that production can shift quickly during disruption? And let's go to Jon.

>> Jon Arriaga Anchia: I will say I'm aligned with the rest of the speakers. So specifically diversifying the risk is what makes sense. As you mentioned now, having more than one source, could be coming from logistic center, coming from a different manufacturing plants, having the same license with expanded to more than one manufacturing plant, having different sources, having different countries that reduces mitigates a lot, the risk.

The only thing I want to mention in addition to that is when we put in place BCPs we test them as well. We don't analyze it. Have it on paper, we have materials from Europe, and logistic centers that we check that the route works. What I'm trying to say is that it's not something we only have it on ideal situation. On paper we put that in place. We have once a year the obligation of doing that.

>> Mary Homer: Julie anything to add?

>> Julie Ryan: Also we try to stay close to how suppliers, especially the ones who are smaller or critical or single source to make sure we maintain a good relationship with them so we get the early indicators and signals so we can react to it sooner to mitigate it.

>> Mary Homer: And one last question here, I guess this will go to Macopharma. Business continuity certification is a norm. So Macopharma has a certification and an annual live exercise program that they explicitly call out. Should FDA consider recommending or incentivizing similar certification types across critical suppliers as a resilient signal? Alexandre?

>> Alexandre Mouroz: Yeah, definitely, when we decided to go for this certification, it was because one of our main customers decided to give to Macopharma a single-- to be the single suppliers on the contrary they said, you are going to be single source. But you need to prove you are able to do this as a single source. We developed the business continuity. And for me the certification was pushing us to go very deeply into all those processes and to be, to go deeply into the exercises because, for example, every time I speak with my suppliers or logistics provider, everyone is telling me, I have the business continuity. Okay, show me the proof. Uh, you know, I have issues. I have a plan. It's on Excel but no proof.

With the certification we are about to prove to FDA that we are consistent with our, the way we're going to address and manage the risk and be prepared and be ready with this exercise. Definitely I encourage to not be only business continuity but to go for the certifications. So we

at Macopharma we started more than 10, 15 years ago, this is now really a stone in our organization.

>> Mary Homer: Other thoughts about this from the other panelists?

>> Richeal Cline: Yeah. Just to add, I think business continuity is a topic with many of our customers as well. It often times, defined in contracts and goes along with the risk mitigation, the first question you asked, Mary. There isn't one particular thing that you can do to mitigate risk. It's a multi-prong approach. What we do at Roche, in addition to what has been shared is a two lot strategy. At any given point we have two lots of blood donation products available in our inventory at our distribution hubs with a third lot in production in parallel, supported by inventory across the globe at varying affiliate level as well.

We also look at the dual sourcing mentioned. Minimum stock levels for example. So on those two lots we minimally have eight weeks of inventory available based on historical demand and manufacture our critical raw materials inside so we minimize disruption risk with external suppliers.

>> Mary Homer: Okay. Great. Let's move on. So question number two. What are the greatest challenges in manufacturing to maintain a robust and resilient supply chain. There's a reference with challenge areas that perhaps that you can focus your discussion on. Please comment on how these challenges have affected or could affect your firm's ability to maintain a robust and supply chain. We'll start with Haemonetics, Helmut and Julie.

>> Julie Ryan: I'll touch on the regulatory aspect which I spoke to in the presentation a bit. Clearly it would help to have some harmonization across the globe, I think. You can always go to sort of the highest complexity and across the drug and device world, the terminology and documentation is different. It doesn't always work that way. You end up duplicating something. So the cost is still there.

I think there could be review of some of the requirements in the U.S., particularly around some of the API suppliers. I know, Helmut touched on some of these things being commodities. Not a lot of them who want to have to register as a API supplier and pay those fees. That's something that can be looked at to see if there are exemptions and reductions.

>> Mary Homer: Any other thoughts from the panelists?

>>Jon Arriaga Anchia: I can take this one. Many of them have already been discussed and analyzed. Probably because we are in a very challenging environment here in the California about the labor and workforce. I want to bring this one to the table as well. Obviously everyone knows that we definitely compete for talent as well. And the human talent that is fully qualified, some cases that makes the difference.

So basically here the mitigation plan is just to believe in a lot of our strong training system. We invest a lot in that training. We put in place many initiatives that they go for like a global training for the process as well as on job training which is required to have more than three laws

that you participated before you're autonomous for that. We have that constant communication with our operators and try to engage them in our project.

I think this one, definitely obviously there are peaks. And we know how the work market works. But it's definitely one that we invest a lot definitely here in California.

>> Mary Homer: Great. Thank you. Let's talk about, I'm sorry. Go ahead, Alexandre.

>> Alexandre Mouroz: I'm sorry, Mary. I want to reinforce what Jon was saying regarding labor and workforce. We faced it in Europe after COVID, a lot of push around the market to keep people onboard. And also what has been addressed, we had some HR actions. Moreover what we did to focus on that, we worked a lot on investment in automatizations and equipments to, not to replace people but to minimize the impact of the workforce absenteeism. Automations to keep reliable and let's say recurring production.

>> Mary Homer: Great. Thank you.

>> Janet Johnson: Could I come into this one? Is it okay?

>> Mary Homer: Absolutely.

>> Janet Johnson: I don't think anyone said this, but I think everyone on this call has this challenge that we are small. Right? The healthcare industry is small when you consider that we are competing for some of the same components that are used in technology, AI data centers, and much larger industries. We're all competing for the same thing. This was featured in the Beckers report. And AdvaMed constantly highlights this. Although we're small and competing for the same component, it's simpler for them to make a change than it is for us. When we make a change, obviously for safety we have to do validations, qualifications, sometimes submissions. It's very difficult for us to change that, that component potentially.

And we saw this during the semiconductor shortage in 2021 and 2022. And I will say we had strong supplier relationships that helped us manage through it. They understand what our business did. But we also reached out to the FDA supply chain team. And Tammy Beckham's team. And they were very helpful to us. We encourage support for that capability in the future. But the pressure today is dramatically increasing with the AI data centers and the changes in the electronics market.

So you know, we're asking and we're aligned with AdvaMed's call to memory chip makers to recognize MedTech as a priority segment to take steps to avoid disruptions. And we welcome support from FDA and other agencies about advanced notifications if they can give us more notification in order to allow us to plan. Because if a supplier has a short turn around and their discontinuation of a part that causes a problem about the qualifications.

So the other thing I was going to say is, as we think about blood bags, we know that the EU is moving away from DEHP. So global suppliers are going to move away from producing DEHP products which means, regardless of what the regulatory pathway is in the U.S. for DEHP products, we have to switch. We don't have a choice. And therefore, we need to make sure that

we're looking ahead because we only have until 2030 which is not a long time to get through all of that. We need to manage these before they're problems.

>> Mary Homer: Thank you. I'll do a call out for my own program. Pay attention when I give my presentation. So coming back to like the Glycerolyte example, should the FDA consider a harmonized risk tiered classification approach to these legacy solutions? Giving a heads up if you maintain a strict risk classification, you'll have at least a heads up on where the problems may arise. I don't know. Thoughts?

>> Janet Johnson: I think so. So my opinion is yes. I think along to Julie's point the API manufacturers which I can tell you FDA is open to those conversations because we've had them in the past. So FDA's actually a really good partner when you reach out to them in advance.

So consider that. Yes, I think there should be something done around that.

>> Mary Homer: This is a follow onto that. Are there policy or incentive solutions that could prevent further supplier exit from these low volume, high criticality product lines that you think of? Anybody? Aside from obviously money. All right. We'll move onto the next question.

>> All right. What are the root causes of recent supply chain disruptions and potential solutions to prevent them? Starting with Roche.

>> Richael.

>> Richael Cline: Thank you, Mary. For the supply chain issues that we experienced and not just in the blood screening space, we see it's due to severe weather. We had a cold chain event during distribution or there's been some type of transportation limitation that's held product longer than we anticipated.

Obviously recently geopolitical events and trying to get product into certain countries has been a challenge. And then Jon mentioned workforce. So particularly as we try to build up and supplement with external workforce, there's constraints and limitations and shortages there. Or in the rare event, sometimes the raw material issue, you know, with our donor screening products. They're complex. The manufacturing process is complex. An example I would use is our negative human serum plasma NHP product relies on large donation pools. And when we test those pools, if one has one infectious disease target the test positive, we end up scrapping the whole pool. That could be a challenge when that happens to be able to recover quickly and continue to process and manufacture.

And the second part on your strategies with quality management systems, since I'm chatting, I'll comment on that, too. We have implemented a unified quality system across all of Roche Diagnostics.

And that has the same requirements irrespective of where a product, raw material we produce internally and instrument to consumable, they need to meet the same requirement and it allows us to have common language, common requirements and standards. And we utilize for the most part our CBER and BLA requirements in our assay production facilities because it simplifies for

our operations and manufacturing so that they have one set of standards. They're working towards in. It's not one thing for BLA and one thing for 510K. We employ the highest standard.

While that might be viewed as challenging, I think for our employees, it makes it simpler.

>> Mary Homer: And Alexandre? You have anything you want to add?

>> Jon Arriaga Achia: Sorry.-- I mean, the root causes, I think, they've been identified and-- more about which ones are the one geopolitics is one of them. In terms of potential solutions the way that Grifols look at that, the long-term view rather than the short-term view. In the short-term view in some cases, costs pretty much everything in that strategy. And some cases-- the long-term view what I mean is self-sufficiency is one of them. Investing in our process provides much robust solutions. Basically what I mean is we take the end to end process. We try to break them down in different sub processes and validate all of them internally and the decision to do something internally or externally could make at that time when the conversation-- although the views are part of that. The long-term view is an important one. And just as well, we're talking about the GMPs, the way we understand the GMPs and align with what it was said previously. We take that more as a partner, applying properly the GMPs, provide more reliable end-to-end process. At the end that, if you apply them properly, you want to avoid last minute issues, surprises about the equipment or about the calibration. So that means that everything is ready to go. You start having like a repetitive and reliable process. And that even by itself provides a better solution in terms of supply chain and strength.

>> Mary Homer: Any other additions for these two questions? I have a couple of follow-ons.

>> Eddie Kubo: Mary, real quick from a critical healthcare infrastructure perspective, it's more about resilience. That should be our healthcare preparedness lens and not just efficiency. Lessons learn from our side, continued collaboration with the customers in blood and plasma centers, and the industry association, ABC, AABB, PPTA, government agencies, FDA. We've reached out in times of crisis and supply chain disruptions. It's incredible the network that can be made available. We don't always have to figure things out in our own house and our own roof. Early warning, faster identification, communicate these emergencies upfront. Maybe it doesn't turn into anything. But maybe it will. If you have that early notification and bring in a collective group of industry associations, FDA, and key customers, that really helps to come up with ideas, leveraging other people's networks to figure out how we can resolve or mitigate a supply crisis. I want to share that lessons learned.

>> Mary Homer: That totally leads into one of the questions that you answered. Is there, based off of the, what FK presented about the vertical supply chain mapping, is there an appetite among you for a shared sector-wide early warning system rather than each manufacturer independently monitoring its own tier. I see head nods.

The other question I had, I haven't necessarily noticed that there's a problem here. But do you feel like there's enough standardization across industry taxonomy for what counts as critical or do you think we need more harmonization on that front? Are we using consistent risk definitions? Everyone's chewing on it.

>> Janet Johnson: I was going to comment. I'm not sure we are. I'll just say it. I don't think everyone uses the same definitions for risk and how to mitigate those. Thinking of things upfront and not letting them become a risk is the most important thing. Right? Investing in quality, investing in your manufacturing facility before it's a risk. What we do is critical. And I know that here as I said we've invested a lot in our facilities, in our people and in our processes and quality management system. And we do it continuously every year. But I don't think the definition is the same across companies.

>> Julie Ryan: And I'll touch on the prior comment about the shared warning system and monitoring. That really helped because I know from experience, when you get to the shortage position when you have to report voluntarily or because it's required, your partners are mired in trying to solve the shortage. It distracts them to have to gather the information needed to report the shortage. At that point, you're late. Share with partnership on that with help prevent some of that disruption.

>> Janet Johnson: Can I just comment on that as well? So I've been part of some discussions about these types of topics in the past. What I would say is, I think if everyone has the same intent, it works. But it's the group of people that maybe doesn't have the same intent and is looking to steal business and take advantage, that would be the problem.

>> Mary Homer: There would be a memorandum of understanding, yeah.

>> Janet Johnson: Right.

>> Mary Homer: All right. Any last comments from any of the panelists before we wrap up this session?

>> Janet Johnson: I'll just say thank you. And I look forward to being part of the solutions that we have going forward. So thank you.

>> Mary Homer: This has been a great panel. Appreciate everybody's input and proactiveness in answering the questions.

>> Panelists: Thank you very much.

>> Mary Homer: And I'll turn it back over to you, Anne.

>> Anne Eder: Thank you so much. Thank you Mary, to our speakers, our panel. Thank you so much. We're going to take a break until 1:30. So please come back at 1:30. And we'll have our final session where our government speakers are speakers from the HHS agencies will speak. Please come back at 1:30. Thank you.

>> (BREAK)

>> Anne Eder: Welcome back. Thank you for joining us again for the third session. In this session, our speakers from the Department of Health and Human Services will discuss the government's role in the supply chain.

In their role of managing supply chains, and it may not directly relate to blood manufacturing. But in the panel, that CAPT and Dr. John Oguntomilade will discuss with the panelists how it might apply in the future. And there's been a last minute change in the order. Wayland Coker is going to speak first because he has been called into a meeting. So I am going to turn this over to CAPT John Oguntomilade and he is going to introduce our speakers and moderate the panel discussion. John, the floor is yours, and thank you.

>> John Oguntomilade: Thank you, Anne. It's a privilege to be here and on behalf of our leadership in the Department of Health and Human Services, we want to thank you for convening this very important meeting and facilitating this very important conversation. Thank you very much.

I'm hoping my screen is being shared if everyone can see it. So I am CAPT John Oguntomilade and I have the privilege to serve as the lead of the blood, organ, and tissue activities in the Office of Assistant Secretary of Health and Office of Infectious Disease and HIV/AIDS Policy. I want to welcome all our participants to the third session. Thank you for coming back from lunch and joining us again. In the first two sessions we've been able to learn a lot about the current state of the nation regarding supply chain for blood manufacturing and also we heard from our supply chain manufacturers on their perspectives on opportunities and challenges regarding supply chain for blood manufacturing. In this session, the national progression of conversation is to tie these discussions altogether by identifying the role of Federal Agencies in supporting and facilitating supply chain for blood manufacturing.

So our objective for this session is discuss the roles of various Federal Agencies in strengthening the supply chain for blood manufacturing. We have exceptional speakers for, four exceptional speakers lined up to help us in this session, the representative leadership from various Federal Agencies and offices that are associated with supply chain for blood manufacturing and provide updates from their agency and office perspective on the role of Federal Agencies in supply chain manufacturing.

At this time, I will turn it over first of all, before I turn it over to the first speaker, I want to introduce all the speakers today.

We have four speakers, our first speaker will be Mr. Wayland Coker, the acting Deputy Director Center for Industrial Based Management and Supply Chain in ASPR. Then our next speaker will be Ms. Brooke Courtney the Senior Regulatory Counsel in the Office of the Commissioner at the FDA. Our third speaker is Dr. Tammy Beckham Director for Office of Supply Chain Resilience at the Center for Devices and Radiological Health at the FDA. Then our final speaker will be Ms.-- Dr. Mary Homer Program Director CBRN Radiological Nuclear and Medical Countermeasures Program at ASPR. So at this time I want to turn it over to our first speaker, Mr. Wayland Coker. And I'll pull down my slides and give you room to upload yours.

>> Wayland Coker: Somebody would let me know that you can see this.

>> John Oguntomilade: I can see your slide.

>> Wayland Coker: Okay, very good. And also, to apologize to my colleagues for jumping the line, Brooke, Mary and Tammy. Sorry about that. Thanks very much. I've been listening for the last few hours. Interesting event, learning several things, made good notes that I can take back to my leadership. I appreciate the invitation.

So I was asked to give you an overview of IBMSC, supply chain office and a couple of thoughts as it relates to the blood supply chain. We will do that. Let me go ahead and start.

So within ASPR, you may not have heard of IBMSC. I know you heard of the SNS and BARDA. So all of that is within ASPR. So we reside within ASPR, and our job is to keep an eye on the industrial base, specifically the medical industrial base. Preparedness, response, ASPR's mission is growing and more pertinent than after. At IBMSC, we're led by Arlene Joyner. I'm the acting Deputy Director. We also have Matt Hubbard who leads testing diagnostics and critical medical equipment combined domains for the time being. We have Jaison Eapen, enabling innovation and technology in drugs area and Defense Production Act led by Paige Ezernack. And we'll talk about that later. And Joe Hamel who was here in the beginning of the formation of this office, he's our Senior Advisor.

Now, our IBMSC started in 2020 out of Operation Warp Speed. There was no one looking at the manufacturing industrial base as a full-time job. There were lots of people doing stuff in manufacturing, you know, FDA doing lots and lots of manufacturing but focusing on actual production and those related types of issues and supply chains in that sense, outside of the regulatory and qualitative role that FDA plays wasn't anybody doing that.

It was decided somebody to take on that industrial based policy role like the Pentagon has. So we were created in 2020. So we're only six years old. And we're growing and we can hire, we can grow even more. But we're in the middle of a freeze. As you may or not have heard, there's been change in ASPR leadership. That's happening and hoping for the Senate confirmation here soon on new leadership.

Okay. Our vision is pretty straightforward. Is to be the watchdog, watch for industrial base and make sure we have it as modern, agile and secure, can respond to public health emergencies. And we focus on the public health preparedness piece. We don't focus on the industrial base, in a sense we're watching it all of the time and product and commodities, we're watching it in terms of ASPR's mission, public health and emergencies. You don't need everything for emergencies, just the commodities we need in the areas of drug and medicines, PPE, testing and diagnostic and so forth. This is our four filters that we look at the world through. Five, excuse me.

Domestic manufacturing resilience. That's our main focus. We want to make sure we have a resilient domestic manufacturing industrial base. Visibility and supply chain, visibility in supply chain so we have guarantees that our orders will get to us and the front line and patients and physicians and nurses who need it. Being able to surge and respond if we need to and public private collaboration. We will spend a lot of time on that. We spent a lot of time working with industry. We invest heavy in innovation and sustainability issues. Just a quick snapshot of spending, give you an idea where our emphasis has been in the last four or five years. In the top left. This is our drugs and medicines area, spending almost $2 billion. This year is going to

buffer up the number a little bit. Then Defense Production Act. If you don't know much about the Defense Production Act, it's basically that especially authority that we have that Congress passed and has been delegated to HHS and to ASPR to put companies at the head of the line in terms of their supplier so they can get product out the door and get it to the public in an emergency. This is one of the acts of the Defense Production Act. A lot of investments made there. In the middle red box, critical medical equipment. There's the investments we've made in PPE and devices. Testing diagnostics has gotten the bulk of our money because during the pandemic we ordered and delivered over $2 billion test kits through 33,000 distribution sites. If you went to COVID test.gov to order your free test kit. It started here. Our team put that together, and you can go to the Postal Service, sign up, and delivered right to the house or to the 33,000 sites we distributed through soup kitchens, nursing facilities and so on.

We're also what I call the Swiss Army Knife of the Federal Government. If you need something gone, we get called to do something that's not exactly in our swim lane, like Operation Saline Shield when Hurricane Helene brought down Baxter and we had a shortage of IV saline. They brought the problem to us and we built an air bridge and helped Baxter get back on their feet, using DPA authorities give them head of the line privilege. If you remember the baby shortage, formula shortage years ago, that was another one where they asked us to build air bridge. Flew that product from overseas and help Abbott get back on their feet. Some of the things we've done.

The bigger things we've done, the President last year in August, signed Executive Order 14336 to build a stockpile of APIs. And so we started that. It is operational. We've got a fourth of the SAPIR, strategic API reserve built in the warehouse, and released new RFPs in the street a month ago, looking at proposals now. And awarding contracts to deliverers to continue to fill warehouses that we own loading them up and rotating stock as it expires. This is a vendor managed, to the manufacturers who make these finished dose form drugs will had holding the APIs for us and managing that. Holding aside these APIs for emergency should we need it. That's one part of a two part strategy. This being the near term strategy to build the stockpile in case we need these drugs in another public health emergency. To be complemented long-term strategy to build production capacity for apps in this country when we have to replace it, we'll replace it with American-made APIs. That's the major effort there. We're already in this.

We've accomplished priority list of medicines as ordered by the Executive Order. We took the ASPR 86 list to start with. The ASPR 86 was derived from FDA list, started with the FDA list. And derived the 86 list from that and took it into, went into, talked to clinicians and spent another day talking to industry and another day talking to the government agencies and accomplished a new list of essential medicine that we needed to carry. The APIs we needed to carry in the API reserve. We have done that, we have done the listening sessions, collaborated and gotten that out the door. Where are we now? We're loading it up. Buying more. Funding is coming in bits and pieces but getting the funding. And it's going to be in the billions, and also we're going to be working hard to onshore this API manufacturing capacities.

And beyond the Executive Order we have elected, real quick we ReshoreRx program which focuses what we need to bring manufacturing back to the United States that left. Start

manufacturing here that never left and build up what we have here as well and expand the capacities for drugs and medicines in the country. On the right side, Equip-A-Pharma is our advanced manufacturing investments we made in Bright Path Labs, Mark Cuban began Cost Plus. And we're going to be going national scale next year we believe and is applied for and working on FDA. Doing a great job. This very new technology and everyone has to get used to it. It will greatly reduce the price of medicines and put it back in the market through competitive basis and through innovation. Moving on to look at our Defense Production Act authorities, this is where I said, Title I is ahead of the line privileges, Baxter needed materials and supply, so we gave them through DPA authority head of the line privilege to all of their suppliers had to supply them first to make sure we have that plant back up and running. We had to make sure they had to get back on their feet.

Title III is grants where we issue contracts for production capacity. And a lot of investments there in antibiotics and other kinds of drugs and medicines. So under-- it has to meet a stringent requirement to be used as a defense production activity. It has to be related to national security. As long as you can relate it to national security you can use these authorities. We may be able to use-- during COVID we used it over 70 times. Recently we used it a few times. Look at supply chain optimization, the area I lead. We have three major things we focus on, surveillance, which is keeping an eye across the industrial base. Making sure that we get the earliest signal possible of any potential disruption or actual disruption whether it's logistics, raw materials, whether it be in labor strife and intentions. Whether geopolitical conflicts whatever it may be. What can we do and offer courses of action to leadership in ASPR and HHS and the White House what could be done to mitigate the disruptions. Resilience, what we can do to make the supply chain resilient and engaging with industry. Our main task, engaging frequently with industry.

Also, coming very soon to a neighborhood near you is the MMIDS. We believe this is the first industrial development strategy at HHS to focus specifically on manufacturing. And it's close to be ready for signature. It's an ASPR-wide policy that applies to a lot of folks, certainty over to FDA very soon. We're glad to get this industry wants this, they want to know where the north star is, where we're headed where is industry going and what is government thinking and how can I help align resources for you and future procurements. We'll be releasing that.

It's hard for to say where it's going out. It's going out in the next week or so. From there, I don't know, I lose control of it. And let's see how long it takes.

And then I talked about investing in the supply chain. The digital stockpile manufacturers network is one way we're investing. This is a digital version of the strategic national stockpile where we pull down data packages, if there's a shortage, product shortage and heavy industry can't provide. Pull these files down end send it to folks, upload the information, start making the things we need to get past this chronic shortage and ship them and go back to the regularly scheduled business. Idea is to form a network of companies. We don't have to invent anything. It's stuff approved by FDA, sold by everyone. It's just in a shortage and chronic position and we can go out and get stuff done and ask others to make these things in the meantime while until heavy industry gets back on its feet and respond to the major shortage. And there's my timer

says that's all the time we have. Our testing is a big program. You can see the places where we have test kit production all across America.

And that's all-- doctor, over to you.

>> John Oguntomilade: Thank you so much, Wayland. That was an impactful presentation. I know you had to quickly go through your 19 slides. Thanks for all the information you were able to pass across. Thank you very much.

Our next presenter will be Ms. Brooke Courtney. She's a Senior Regulatory Counsel at the FDA. Over to you, Brooke.

>> Brooke Courtney: Hear me okay? Sorry. Can you hear me?

>> John Oguntomilade: Yes, I can hear you.

>> Brooke Courtney: Okay, great. I am going to try to share my slides right now. Okay, great. Can you see this?

>> John Oguntomilade: Yes.

>> Brooke Courtney: Okay, great. Thank you. Thanks so much for having us here today, for this really important discussion. Always good to hear from Wayland and all the work that IBMSC has been doing in a short period of time. I'm Brooke Courtney, Senior Regulatory Counsel in the Office of Public Health Preparedness and Response in FDA's commissioner office. Our office coordinates supply chain resilience and CBER and countermeasure efforts that impact or cut across multiple product centers and programs what we call COPS and involve Department of Health and Human Services, White House, and other agency collaborations. For today's panel I will provide overview of U.S. Government and FDA roles in medical products supply chain resilience.

Starting in 2020 at the outset of COVID public health emergency, government and healthcare partners became engaged in ensuring availability of at first PPE such as gloves, masks and gowns and diagnostic testing materials needed for the response. And later certain medicines and vaccines. Throughout the last six or seven years, multiple government partners including our HHS sister agencies like ASPR and CMS, the executive office of the President, Department of War have increasingly recognized the healthcare, public health and national security imperative of ensuring security supply chains for FDA regulated products as well as other critical products like infant formula. Many government efforts over the past years, have focused on the supply chain of essential medicines in active pharmaceutical ingredients, API and recently key starting materials. Primarily concern is foreign dependence on APIs, SSMs and low cost generic drugs. Some meetings like this were important to help inform government partners and bring stakeholder together. Each partner as a unique role without no one owning the space. There's a wide range of interrelated factors like underlying economic issues, Europe policy, procurement, investments regulation from the FDA side, international aspects, as mentioned earlier today multiple sectors competing for the same limited resources and with healthcare sometimes not being prioritized for those resources. Allocation of scarce resources and how global trade and

geopolitical risk including impact to shipping and transportation. They can impact the FDA regulated products, a lot falls outside the FDA mandate. In generally we don't have full end and end visibility of the supply chain for the products we regulate. We don't buy our stockpile products or set reimbursement rates or allocate them with limited supply. And we don't invest in large scale industrial based products.

To name a few examples of past or current U.S. Government efforts to help support strength and resilience include issuances of Executive Order to strengthen supply chain increase domestic manufacturing. Multiple ASPR IBMSC efforts like Wayland covered, CMS payment and policies and proposals such as recent RFI on potential of approaches for separate payment for domestic procurement of PPE and other essential medicines. Other RFIs have been issued as the one published on the management and budget last week market research to identify new and unused or idle domestic U.S. based. Associated with ASPR essential medicines list. Additional efforts include developing plans and strategies like the national strategy for resilience public health supply chain. Coordinating efforts like ASPR led joint supply chain, bringing wide range to talk about aspects of supply chain issues across product areas as Wayland mentioned, Defense Production Act activities and efforts to map the supply chain from starting materials to finished product identify risk, vulnerabilities and opportunities for onshoring partnerships. So while these efforts haven't specifically focused on blood they are actions taken or being taken or can be taken to support supply chain resilience.

These are examples of executive actions taken to help better understand the resilience of medical product supply chains. Just a quick overview in 2020, FDA was directed to develop a list of essential medicines, medical countermeasures and inputs posted in 2020. In 2021, EO 14001. Directed a development of supply chain strategy. And moving forward, to more recently EO 14123 established a White House Council and Supply Chain Resilience. And really of interest to FDA is EO 14293 in 2025 focused on streamlining regulation of manufacturing pharmaceutical products and inputs of facilitate restoring a strong domestic pharmaceutical manufacturing base. Some of you may heard of this programs, FDA's precheck pilot program to help firms that are building new drug facilities in the United States. The Executive Order that was issued last year, to help further build out the strategic API reserve.

So as mentioned one area of supply chain resilience is identifying the essential or critical medical products needed for the delivery of healthcare during a public health emergency or routine times. Several efforts over the years have been undertaken to develop list of such products primarily these efforts focus on drug products to identify supply chain risk and opportunity for policy development and investment. Each list has been developed for somewhat different purposes although there is an overlap.

So again as mentioned in 2020 under EO, this list of essential medicines but also countermeasures including medical device countermeasures and critical inputs that are encountered in U.S. acute care medical facilities and stabilize patients with those conditions so patients can be discharged. Criteria for developing that list did not include longer term chronic management. Including those that would be needed to cure a condition through weeks and

months of outpatient development, not to say those aren't important but the intent of the direction of that list.

The list also includes references to blood and blood products including devices on MCM section of the list. List and criteria for development of the list are posted on FDA website if anyone needs the link we can make that available later.

And as Wayland mentioned in 2022 ASPR worked with army on a consensus effort to develop what is called the ASPR list. To narrow the medicines in the longer, larger FDA essential medicine list down to 50 to 100 products considered by consensus to be most critically needed. Acute patient care was defined as rescue, lifesaving, ICU, CCU, emergency departments, urgent or emergency surgery, that level of care which then resulted in this list of 86 critical medicines.

And regarding blood, effort focused on assessing the critical small molecules and therapeutic biologics including blood and blood products were not included in that effort. And I want to mention Dr. Beckham can speak in detail. Under Executive Order 14001, and in coordination with the HHS joint supply chain resilience workgroup led by FDA's Center for Devices and Radiological Health at CDRH, there was a collaborative effort to develop a critical medical device list.

So the group developed criterion and identified 142 type of medical devices that align with five clinical functions. Blood is mentioned multiple times in the report.-- there are other lists that exist in essential medicines, the Department of War for operational readiness purposes, WHO, has a number of essential product list and some recent private sector efforts.

So just a quick overview of FDA's supply chain roles. While FDA has been engaged in shortage and supply chain issues, each medical product center has a short team and maintain shortage list. FDA collaboration and supply chain issues significantly increased during and after the pandemic. To ensure the availability of FDA regulated products with are they're needed. FDA works to advance supply chain resilience through monitoring, preventing, mitigating and responding to signals disruptions and shortages, manufacturing reliability and domestic manufacturing. It's a broad mission we have in the space. But again it's part of the overall ecosystem of supply chain resilience. And our efforts within FDA cut across product areas. They include human medical products, drugs, biological products, medical devices, human foods including infant formula, focusing on the critical foods. Animal medicines, animal feed and critical input including API vitamins and amino acids and involve multiple COPS. Across FDA collaborative effort we have.

Organizationally, the Office of the Commissioner provides leadership and coordination on critical and cross cutting issues. Those issues that cut across multiple product centers or involve multiple agency partners and centers and programs have foundational critical shortage and supply chain resilience. For example, CDER's drug shortage staff and CBER's office and supply chain resilience. FDA product centers and certain products to monitor and mitigate product shortages within their authorities as discussed earlier by CBER and Dr. Beckham will discuss next and coming together as an agency to work together with HHS and the White House and state and local official during serious supply chain issues, disruptions like the Hurricane Helene in had 2024.

We also engage with the White House again HHS and a number of other government partners on various supply chain efforts when they're under EO or other efforts. We recently stood up recognizing the need for enhanced coordination across the agency. We stood up in FDA's supply chain council and a coordinating function in the commissioner's office to strengthen and support internal collaboration across FDA product areas. We engage with our international partners especially through our international office and work on monitoring and assessing impacts of trade and tariff actions and working on tools to help analyze supply chain data and implementing initiatives to support domestic manufacturing right now of medical products. These are examples of some of the efforts on the FDA's taking. So through a number of these domestic drug manufacturing efforts, as an agency, we're taking steps to help strengthen U.S. pharmaceutical manufacturing, improve supply chain resilience and reliable access to safe, effective and high quality medicines in the U.S. and these initiatives reflects FDA's commitment to engaging with manufacturers earlier in the process, modernizing oversight tools, streamlining processes where we can and helping to incentivize adoption investment while upholding FDA rigorous standards. These are examples. If you're interested in additional information on them, I've provided a link that has more detail on each of those efforts.

So that's all I have. Thank you so much for your time. And I'll turn it over to Tammy.

>> John Oguntomilade: Thank you very much, Brooke, for your very insightful presentation. I know that we've been going through the slides very quickly, hoping during the moderated discussions, items you couldn't unpack during your slides you will be able to talk more about them. At this time we're going to be turning it over to Dr. Tammy Beckham. The Director office of supply chain resilience for her presentation.

>> Tammy Beckham: Thank you. I'm going to share my slides. Can you see my screen okay? Great. All right.

>> John Oguntomilade: Put it on presenter mode.

>> Tammy Beckham: Hold on a second. Let me do that. How's that?

Thank you all, nice to be with you today. Like the other speakers, I've will not listening through the day. It's been interesting and looking forward to follow-up on some of the items that were mentioned in the previous session.

This order change probably worked out for the best because we're going to high level and drill down a little bit. It's nice to be with you this afternoon. And we're going to talk a little bit about the federal government's role and in particular what I'm going to focus is what CDRH is doing, in supply chain and how we see our role and things we do and how we work with manufacturers and suppliers and other stakeholders, healthcare professionals to build resiliency in supply chain. And mitigate shortages when they happen for medical devices.

So I'm going to go to the next slide.

So as I mentioned I'm going to provide an overview of CDRH supply chain program. As you know, CDRH is responsible for protecting and promoting public health. We do this by assuring

patients and providers continued access to safe, effective and high quality medical devices. Office of Supply Chain Resilience resides in CDRH. And we really work across the medical device ecosystem to built supply chain resilience and prevent shortages that can impact healthcare delivery.

So this end, like Wayland mentioned and Brooke mentioned we work across the spectrum where we have a very proactive monitoring surveillance component. We assess the risk. We communicate the risk. Once we understand the risk or aware of a pending supply chain issue or medical device supply chain challenge, our work and our analysis can help inform the use of both regulatory and non-regulatory mitigations. I am going to talk about that.

We really protect patients and providers by looking at end-to-end supply chain. But to Brooke's point we don't have visibility all the way up the supply chain. Many times we're limited with that respect and we'll need to work with manufacturers and suppliers to better understand what the challenges is for them in the supply chain.

So as mentioned we work with a broad group of stakeholders, so we work process suppliers, manufacturers, group purchasing, organizations, and work with our professional associations as well.

So I'm going to spend the few minutes going over what our authorities are and what CDRH's authorities are for shortage reporting and our shortages activities. So our program was built to Wayland ASPR point. They've been around six years. We built our program as well during COVID. And it was an all hands on deck. You were building the program, building the plane while flying it. We have been fortunate that we have been able to build a robust system that allows us to do data analytics and vulnerability analysis and allows us to work with our manufacturers and our stakeholders across the supply chain.

But one of the things that we have and that came about in 2020 and for the first time, the CARES Act, gave FDA for the first time the authority to help prevent or mitigate medical device shortages. It was signed into law March 2020. And those authorities have helped us hopefully helped the medical device community. Section 506J requires manufacturers to notify the FDA during or advance of a public health emergency about a permanent discontinue notes and interruption of manufacturing of devices likely to lead to a disruption and domestic supply of that device. We work with manufacturers, one they do report those instances to 506J. So understand the impact of the shortage, the duration, is there a shortages, et cetera.

And under the CARES Act, section 506J, FDA is responsible for maintaining a publicly available up to date list of devices that we determine to be in shortage. Once report comes in through 506J, we would do an analysis work with the manufacturer, try to understand is there a shortage? If there is, we post that shortage and communicate about that shortage on the medical device shortage list. And that is our responsibility to make sure that we maintain an up to date medical device shortage list. So in order to guide manufacturers of what they need to be reporting on, we also have the responsibility to maintain something called a 506J device list. We developed this device list and published this device list back in 2025. And the 506J device list is intended to assist manufacturers in providing timely notifications to FDA.

Devices on this list are considered lifesaving and life supporting and intended for use in emergency of a medical care during surgery. So of note though, and I think important to today's conversation, and I'm going to talk more in a few minutes how we work across the centers and FDA, but the list also contains CBER-regulated medical devices and the reporting occurs in accordance with the criteria set forth in 506JA and a couple of those listed at the bottom. We have the device warming, the blood warming devices and also have the blood transfusion sets which are often included in kits and procedural kits as well.

So just a good example of how we work across centers and how we coordinate across centers. I'll talk a bit about that in a few minutes.

So I talked about the authorities and how our program was stood up and what our program is responsible for with the medical device shortage list. I want to talk about what we have been able to do and what we do with the information that comes in through 506J or information that comes in, in another ways. Like Wayland talked about earlier, we get shortage reporting through 506J and signals that come in from healthcare providers, hospitals, other Federal Government agencies about issues that could be occurring or developments. What we do were that data is we do shortage assessments to look again is there something going on? Is the medical device in? If it is, we take a series of steps to determine whether or not FDA action in some way shape or form could be necessary or appropriate.

So in order to do the things that we do in the surveillance and risk assessments with our program we developed a robust analytics platform where we actually marry internal and external data and we use AI and ML tools looking at import analysis. We do vulnerability assessments. We look at specific issues related to a certain classification of device or category of devices. So we develop both vulnerability assessments and patient impact assessments. Part of the reason we do assessments is to give us that proactive stance that allows us to look at vulnerabilities across the supply chain, things we know cause issues or could cause issues. Develop vulnerability, assessments, impact assessments. And we use all of that information to support cross government decision-making. And so our body of work and our analysis essentially used to inform regulatory and non-regulatory mitigations. And it also helps us work with industry when we identify an issue to build resiliency. So hopefully getting on the front end of some of the supply chain issues.

So some of the things that we have helped inform in the past or that we currently work on are the need for, for instance, prioritize inspections, regulatory discretion. We work with the ASPR DPA office. Is there a shortage? What is the patient impact going to be? Should we consider use of the DPA? We will inform a lot of those decisions as well. We work closely with our sister center, CBER, CDER. The medical device kits and procedural kits contain drugs. They had contain CBER-regulated devices. They contain CDRH0regulated devices. It's important we communicate across centers and do that only a regular basis.

We'll provide information that help inform USG policy decisions as well. CDRH has-- we don't have visibility end-to-end, but we have a very end-to-end program where we're marrying all of our data, using it in analytics to conduct patient impact assessments, threat assessments

vulnerability assessments to inform government policy and inform use of different tools in the event of a shortage and work across our sister centers together.

So as I mentioned, we kind of serve as a liaison to many of our government partners. You can see on this slide some of the things that I talked about, if we have with a potential shortage we will work with our regulatory team, look at can we expedite a premarket submission? Is there a need for regulatory discretion? We'll communicate, by providing letters to healthcare providers, et cetera. And we work with Departments of Transportation, DPA, customs and borders if there's something stuck in the ports. You know that as well. There have been many instances where we have worked across the interagency to help unstick things that might be sitting on a boat somewhere or waiting to get in through customs.

We have ongoing engagements with manufacturers. Some manufacturers have been proactive and set up meetings to get on top of emerging issues. We hear earlier what the issues are that we could be facing and get ahead of that as part of that building resilience and prepositioning mitigations as well.

So allows for early detection. We continue to do the monitoring and analysis and doing routine vulnerability assessments to try to understand what could be the next thing. We have been instrumental in addressing potential issues with sterilization and the PFAS issue as well as many of you guys already know.

So I think the thing that makes CDRH and the government a little bit unique is we have an ability to see across the supply chain, across manufacturers to see commonalities things we're hearing and piece that together.

We also have the ability to say, are there alternatives in the event we know there's going to be a supply chain disruption? What is the alternative and what is the capacity? We have the ability to bring the parts and pieces and comments together. We have the unique combination of supply chain and medical device expertise because we'll reach back obviously to the OHT. We play a novel role in the government and work closely with ASPR, Commerce, just across the USG so the government can make better decision and help build resiliency and driver the mitigations.

I heard somebody speak about this earlier. I'll call it out. A lot of times the medical device community or medical community is a small portion of buying a particular commodity at this, a processor, a chip. Semiconductor. Many of those things. And sometimes when you have FDA either voice or advocate on behalf of the medical product, stakeholder community, we can get the message across about the potential patient impact and the importance of medical device manufacturers having access to that particular raw material or component they need to continue manufacturing. And we've done that in many instances particularly in the semiconductors but other things as well.

And I think we bring as a government and FDA, bring that to the table. And that is our role. Part of our role.

And so with that, I'll stop. That's all I have for today. I look forward to some of the questions and conversation that will happen in the panel. Thank you.

>> John Oguntomilade: Thank you so much, Tammy, for your informative presentation. We would now mover onto our next presenter, Dr. Mary Homer Program Director, CBRN radiological and nuclear medical counter measures program at ASPR.

>> Mary Homer: You see my slides?

>> John Oguntomilade: Yes.

>> Mary Homer: Okay, great. Good afternoon, everyone. And thank you to the FDA for the opportunity to speak today about our work in the blood product space and how it connects to the broader supply chain conversation we're having today.

I hope to familiarize you with BARDA as a resource and to clarify how we potentially partner to address supply chain issues.

So before diving into the details, I want to ground into ASPR's mission to strengthen national security by helping the country prepare for, respond to public emergencies and disasters. I'm going to walk through today from the blood product development to supply chain resilience connects up to our mission. This is a critical point as we can only fund programs that clearly connect to our mission space.

ASPR organizes its work around four key priorities. Executing the rapid efficient, and adaptive federal response, securing America's medical supply chain. Strengthening preparedness through state and local resiliency and addressing emergency health security threats.

Obviously supply chain security is central in today's conversation. So BARDA sits within ASPR and is built around three core program areas, so the actual programs which is the medical countermeasures program, including the chemical biological radiological nuclear MCMs which is where my program sits. Infectious diseases, detection and diagnostics in our innovation arm drive. And I want to call out the pharmaceutical countermeasures infrastructure because this is like IBMSC, a program where we can fund certain supply chain infrastructure programs.

The other two programs are support services. So these are expertise based divisions so regulatory clinical development, nonclinical development and of course, absolutely critical to everything we do is our division of contract management and acquisitions. BARDA's approach is built on a private public partnership, given authorities through the policies that created us. And we have multi-year funding specifically so that we can move innovation off the bench into the patient's hands. We pair the funding with technical expertise and portfolio management, managing, regulatory affairs, clinical and nonclinical development, as I showed you.

And then we make the expertise available to the industry partners to help bring the products through approval and fruition. We're always looking for new innovations whether it's new countermeasure or response capability.

The proof of our model is in the numbers. To date we have supported and received 116 FDA approval is licensures and clearances. You can see the drill down. This is almost unheard of. We have only been in existence under 20 years and that's a lot of FDA approvals.

These approvals span our entire threat space made possible through annual and supplemental appropriations. So turning now to my program specifically, Homeland Security has determined through two threats, that present a material risk to the U.S. national security, nuclear detonation and radiological dispersal devices. Given our political climate, nuclear detonation is our highest priority.

And to just put some scale into perspective, our planning scenarios are built around a 10-kiloton detonations which is the size of the Hiroshima bomb. Nuclear detonation will produce different casualty picture. There's infrastructure damage, severe resource limitations and large casualty population with combined injuries and all happening at ones. This exact mix depends heavily on the location and nature of the detonation. Every scenario the demand on the medical response system is unlike anything we typically plan for.

And now, you'll understand why can we, the blood products are housed within our portfolio. They're critical to our response. In a nuclear detonation, you have two major injury pathways that converge. Radiation that damages cell through pathways like bone and marrow suppression. Both pathways converge on the same endpoint. Hemorrhage and hemostatic deregulation. It's essential to maximize and survival in this particular mass casualty incident. One recent success worth highlighting for this is we are involved in the pre-hospital transfusion coalition. And a lot of end user outreach effort help secure a CMS policy change, change that allows for billing for pre-hospital blood transfusion which is a critical step. We didn't get a commensurate increase in the funding that is yet to come.

So when we're thinking about what our gap is going to look like after a nuke det, it's unlike anything we've faced before. I'd say that in the reference I usually give is our anticipated platelet gap in a nuclear detonation scenario is five times our annual production capacity and needed within two weeks of the detonation. That's a different order of magnitude.

To close that gap, we model six interconnected areas that we work on with all our interagency partners to build a resilience blood supply that is scalable and sustainable including database to track available products, increasing inventory through donor campaigns and specialized campaigns for products like low titer O whole blood or walking blood banks. So our role in all of this is we're supportive to OASH. But in the areas where there's a specific product that is in need of development, that's where we can step in. So in, next generation blood products we are funded in the past variety of different dried blood products but conducting a dried plasma which will help extend the shelf life and stability for these products. We're looking at manufacturing solutions. We're talking about very forward looking things like ex vivo blood farming and whole blood platelet production, like buffy coat platelets.

And the last area is getting a lot of new attention as you will shortly hear as you heard earlier from Wayland. ASPR has an office, IBMSC that is focused on supply chain issues and may in the future. And Wayland you will have to correct me, currently since blood is not on that list of 86, I don't think that your position to fund anything currently but that will probably be up-and-coming. We have a manufacturing group within BARDA that could have flexibilities for funding programs in this area.

And none of these levers work in isolation, obviously sustainability and surge capacity have to be built together. This is a map that I made for myself mostly because when I brief leadership on various aspects of the blood industry, they tend to get a glazed overlook and don't have an understanding of the complexity.

So you know, I made this map for myself. I want to focus where the circle is. Currently that is where I envision our highest impact for our funding would be with the blood bag manufacturers. Getting approval for buffy coat, getting approval for bags like whole bloods bags. I think people mentioned we've talked about the Glycerolyte. I don't think we can help with the manufacture of Glycerolyte. But it was mentioned that there's this new technology for red cells for storage that sort of innovation would be something where BARDA could step in and partner.

And I think -- yeah, okay. So what I would recommend is that is examples of things we can fund. If you're-- if you have any questions, reach out to me. We'll have a discussion. And even if it's not something that BARDA could fund, we may be able to point you in the direction of something that could help you out or a program that would we'll be able to fund you.

We have what's called a TechWatch where this is where you can engage with BARDA. We kind of look at your program, given you feedback on it. And basically it's the first step to determining whether or not a partnership would make sense for us. And then there's also some websites where you can follow us in our resources and check out when we issue new initiatives.

So there's my contact information. And thank you for allowing me to present today. And I'm looking forward to the Q&A panel. Back to you, John.

>> John Oguntomilade: You it, Mary for a captivating presentation when we think about in the event of a nuclear blast. What's our level of preparedness. So thank you for that captivating presentation.

We want to thank all of our presenters for the various presentations. It's been very enlightening. At this time, we're going to be transitioning into a facilitated discussion where we would begin to answer some questions. And I'm hoping some of these questions are coming up on the screen for you all. If somebody gives me a thumbs up, let me know if you can see the questions yet.

>> Mary Homer: Yep.

>> John Oguntomilade: Excellent.

>> Mary Homer: But you're in? Weird mode.

>> John Oguntomilade: Oh, it's not in the presenter mode?

>> FDA AV: It is in your presenter mode but we see the notes and not the full screen.

>> Mary Homer: Exactly.

>> FDA AV: If you click display setting in the upper left-- and then click swap presenter view and slide show. Perfect.

>> John Oguntomilade: Excellent. Thank you very much. So we just want to take the opportunity within the last few minutes that we have up until 3:00PM to look at various questions. And I want to encourage our presenters to come on camera as we examine some of these questions.

These questions are grouped in various categories, some questions have to do with agency roles as it recommends to communication and coordination. Some questions have to do with the federal scope and limitations. Some questions have to do with blood and blood components and essential medicines and question that have to do with ongoing and planned initiatives.

I will start with the first question. And I think Wayland already had to go to another important appointment. So that gives you all an opportunity to expand a little bit more on your responses, even some of the aspects of your slides that you couldn't go into in quite some detail. This may be an opportunity to expand on that more.

We'll start with the first question.

What are the roles of the United States Department of Health and Human Services agencies in addressing supply chain challenges for essential medical products, including those critical for the collection and manufacture of blood and blood components?

Probably we want to start with Tammy.

>> Tammy Beckham: Yeah, thank you. I mean, I think, you know, I addressed a little bit of that that could be extrapolated specifically to the manufacturer of blood and blood components the in any talk. We talk about our role and what we do in supply chain and our abilities to utilize regulatory and non-regulatory mitigations or inform those and the use of those to help strengthen the medical device supply chains.

And I think a lot of those apply here as well when you're addressing supply chain challenges. A good example was, you know, I want to go back. I didn't mention this. During Hurricane Helene when there was the IV shortage CDRH also had a role in that. That was we regulate the empty bags. We worked closely with CDER and across centers and with the manufacturers of the empty bags to understand what the landscape looked like who had the capacity to produce. We connected them with hospital systems and pharmacies looking for empty IV bags. These are the types of roles, the coordination roles, these understanding who can step up to the plate, who has the capacity, how we address the challenges, how we learn from that and build on that in the future. How we build resiliency and where are our critical nodes? Where do they reside and better prepare for that, too.

I think the government can play a role here and we should be playing a role here working with the companies and stakeholders to understand the vulnerabilities preposition the mitigation to address them before they occur.

I heard a lot in the previous sessions about wanting to share more information and surveillance and how to get early on events. Wayland talked about this as well. How to get an eye on it when

it's early to you can stem the duration and stem the patient impact. I think that's more of the role the government plays and obviously we coordinate across government so we can, we can leverage each other's capabilities. And I think that's an area where we should and at CDRH we have been playing a role. I know we work with CBER and CDER all the time, too. And going through the Office of the Commissioner and Brooke and the coordination activities that happen there across the interagency. I think we've learned a lot. We learned a lot from COVID. How we take all of that forward and continue to develop that in a sophisticated way is what we should be doing in the next few years. Brooke, I don't know if you have in I go you want to add to that.

>> Brooke Courtney: You said that so well, Tammy. I agree with that. I think coordination is as a huge component of it. We're working not only a complex space of a lot of different interrelated factors that impact supply chain and availability of products. They're starting materials on their components but also dealing that a preparedness posture, mitigating posture and working on complex responses when they occur. It's a lot of different layers to building resilience, ultimately needing to respond to emergencies when they occur because they will occur no matter how resilient we are. They still occur. How do we get through those and mitigate the impacts?

So I think that coordinating element, as Tammy mentioned even within FDA it's very complex if you have certain product that's touch upon multiple product centers. And we're dealing with imports and inspections and tariff impacts recently and getting to the coordination within HHS. But the coordination with HHS especially with ASPR. We work closely with BARDA, closely with IBMSC on a daily basis. And that's critical and also other parts of HHS, many other parts of HHS. And then with our interagency partners. There's been a lot of important work occurring on supply chain. Again a lot focused on drug products but increasing interest in looking at product areas, especially medical devices and even certain veterinary medicine and how it impacts supply chain whether it might be inter-- whether the equities might cross. There's a willingness to learn and that gets into the second thing aside from coordination is the supplies supply visibility aspect. And being able to have good data that's accessible within for us within FDA within also the partners and thinking about how we use data and interpret data to look at signals of disruption and when to act and use authorities or mitigating tools or not.

You know, balancing that with not wanting to alarm the public if something's inadvertently leads to disruption or shortage. That's always top of mind. And getting-- the third thing that HHS agencies can do is looking at that IBMSC and BARDA components of helping to drive that innovation and supporting investments and developments in those areas where we can look at things like point of care, manufacturing, that type of thing where it can help in routine times and especially during public health emergencies.

So I will-- and turn it over to Mary if she has anything to add.

>> Mary Homer: Well, both these questions are very explicitly about supply chain challenges. And to re-clarify, my portfolio is not about supply chain challenges. It's preparing for a nuclear detonation where supply chain challenges become an adjacent issue.

So we also have our program has responded essentially supply chain challenges. I don't know if everyone remembers under Zika, we stepped in and shipped blood to Puerto Rico for some

period of time. The other piece where we ended up stepping in was during COVID where we created the convalescent plasma program.

But as I said, the sorts of things that we can fund are the ones where you can directly tie the impact of fixing that supply chain challenge with improving our ability to respond to a nuke det.

>> John Oguntomilade: Thank you for your informative responses. I know we started with the first question but we got a little bit into the second one already which is great. I want to shift to federal scope--

>> Mary Homer: Wait. Wait. Before we move on, John. You need to talk about your role. You're the moderator. But you are sitting in a very key position.

>> John Oguntomilade: Yes. I would do that towards the end. I wanted to give you the opportunity to expand on your roles first because we have probably 15 minutes to go for this session.

So let's look at the second set of questions here. Federal scope and limitations. What supply chain challenges involving essential medical products can HHS or other federal agencies address? And what challenges are outside HHS or the Federal Government's control. Anyone want to start with that

>> Mary Homer: I'll make a general statement in that, any supply chain challenge could be within our purview if appropriately authorized.

>> Tammy is this

>> Tammy Beckham: Brooke, you want talk and I'll jump in.

>> Brooke Courtney: Sure, quickly, my response would be similar to my response to the previous question. But I think also added to that would be, I think some of the aspects of the supply chain space are similar especially with the innovative technologies. So I think there are important lessons we can learn from countermeasures and how we coordinate as a Federal Government around development of countermeasures and availability of products during emergencies. And there is overlap in some of our portfolios.

But I think that really providing and supporting opportunities for domestic manufacturing and also quality management maturity types of efforts, building manufacturing systems and supporting manufacturing systems and approaches that are less likely to result in quality issues and disruptions in manufacturing. And also I think a key area for federal partners is really helping to ensure sustainable markets for domestically manufactured products. There are a lot of efforts right now, important efforts to bring domestic manufacturing back. At FDA we have programs, spurred initially by an Executive Order to help facilitate domestic manufacturing and providing incentives there.

But there's other work that's ongoing as well. You know, and if it's looking at API production in the U.S., KSM production in the U.S. and other products and components, how do we ensure as we across the government are working with range of different prepares and different efforts and

funding streams and different authorities. How we ensure sustainable markets for firms that are willing to go that route and invest in adoption manufacturing.

>> John Oguntomilade: Excellent. Any other additions to that?

>> Tammy Beckham: Yeah, Brooke, I think the sustainability question is here. It's something that we saw post COVID. And how you onshore, how you incentivize and how you sustain that long-term is something that I don't know that we've cracked that nut yet. I know there's a lot of effort towards that right now. But that is a challenge. The Federal Government plays a really important role in some of the more complex challenges at least for medical devices where you see something, for instance, the PFAS issue where manufacturers are going to have to stop using the specific raw material or component. And they need to quickly or maybe not so quickly switch out materials and so forth. But it's going to impact many, many manufacturers and many thousands of products. Federal government plays a rouge role personal FDA and understanding how we can assist in those changes and how we can manage that with the industry so that we avoid supply chain challenges and shortages and patient impact. What does that look like from a regulatory perspective? How can we work with the industry to address the questions?

The challenges that are outside, we saw a lot of it post COVID and sustainability, the cost of manufacturing here. The ability to market those products and be competitive. There's a lot of challenges that are out of the Federal Government's control. There are things that we can do but to incentivize, but there are challenges that we need to think through that. I'll leave it there. This is a large open-ended question.

>> John Oguntomilade: Yeah, but thank you so much for your perspectives. I think these are real good feedback that we can deliberate upon, think about, understanding our limitations and what we can do to facilitate and resolve challenges.

I'll move onto the next question here. And it's on blood and blood components and essential medicines. How can blood and blood components be included in the broader HHS efforts to optimize the supply chain for essential medicines? And many of us are familiar with the context below.

>> Mary Homer: That's for Wayland.

>> Brooke Courtney: I'm happy to speak to it if that would help. And please jump in.

Yeah, I think that, again these kinds of discussions are critically important for elevating equities that need to be addressed either not being addressed sufficiently or need to be addressed moving forward. Again, we had, just start somewhere with supply chain resilience. Medical product supply chain resilience. Initially during the pandemic, initially started with PPE and diagnostics. And then moving forward to other medical products and the current sort of, or recent focus on in particular generic drugs and API and KSMs.

This is an evolving field and space. Knowing what those are and having situational awareness around those which gets to the importance of collaborating and coordinating both in the government and outside the government. For the supply chain resilience workgroup, it's about

200 different federal and private sector, public sector. With respect to the ASPR list of 86, as mentioned earlier there are different essential medicines list for different purposes. So the original FDA list of essential medicines MCMs and critical inputs were really developed to prepare for future public health emergencies. And thinking there needed to be a narrowly tailored list, down selected list from the larger list to look at the most essential products for acute patient care. And I think that gets to the importance of lists though. There's a lot of interest in lists and there are lots of lists out there. The FDA list, ASPR list are not the only ones out there. There are others. And I think it gets to the question of how do we want to be defining, what is essential and what is critical?

As we know how we define terms have implications own what RFIs go out. And so, you know, I think it's important to continue to have discussions around lists. And again I think there's been debate whether there needs to be an essential medicines list and device list. We have a great critical, medical device list already. And then maybe separate list for other product areas or does there need to be one overarching list. These are questions that experts working in the space have grappled with. How do we best-- we can't include everything. Everything can't be essential. But how do we focus on what is? And again does it make sense to have one big list or narrow list by product area? Those are questions that are still open for discussion and debate.

>> John Oguntomilade: Thank you so much, Brooke. I don't know if Mary or Tammy wants to quickly chime in. We have five more minutes to end our session.

>> Tammy Beckham: I think it's education. I think it's continue to educate and communicate. We see that with devices, too. The focus is on drugs. And to Brooke's point it's an evolving pathway forward hopefully. But I think, continuing to advocate for and educate the importance of the products and the role they play in emergency situations is going to help facilitate the movement forward for some of the policy changes and for some of the inclusion and some of the RFI and knocking on Wayland's door. I'll throw him under the bus since he left. [Laughter].

I knock on his door all the time. But anyway, yup. I think that-- that's what we have to do. I mean, you know, at the beginning of COVID it was devices, ventilators, tests, PPE and I think somehow we quickly forget that in order to inject the drug you need a device. Same thing with blood and blood components. You have to have that for disasters and emergency preparedness and be able to deliver the blood as well. We need to continue to communicate the importance of these as well.

>> John Oguntomilade: Excellent. Mary, do you have any last minute thoughts you want to share?

>> Mary Homer: No.

>> John Oguntomilade: Okay. So I want to thank each of our presenters from Wayland to Brooke, Tammy, Mary, for very, very, insightful and excellent presentations, your informed responses and answer to the questions. Even some of your responses make us think about additional things that we should really consider in moving forward in the future from the OASH OID perspective. We still coordinate across Federal Agencies. We coordinate the public health

service, blood organ tissue meetings. We sub on the AABB disaster task force, I serve on the task force and help facilitate the dissemination natural special security events report that has to do with national security, communicating these with ASPR, communicating this with office of rural health operation and from a leadership perspective coordinating closely with the Assistant Secretary for health regarding these emergencies and seeing ways in which he can leverage his office even in campaigns when we have clinical shortage of certain blood and blood products. We come into play even at those times.

But as I wrap up this session, I want to thank you all not just for your excellent presentation and the work you do on a daily basis. But I want to thank each of you for your leadership. Thank you for your commitment to service. Thank you for your strategic collaboration with industry partners to move things forward. And most of your dedication to problem solving and mitigating challenges associated with supply chain for blood manufacturing and advancing solutions to secure a national security. Thank you so much for your leadership and your service. We will be turning this over back to Dr. Eder.

>> Anne Eder: Thank you, doctor. Dr. Oguntomilade I appreciate your service and moderating this. Thank you, speakers.

Now we're going to move into the open public hearing. It's not a hearing. The open public comments. Thank you. And for that today, we have seven individuals who will be making a comment. We're not going to have a timer on the screen. But we are going to ask you to keep to time. So don't make me interrupt you. We have seven commenters. So when I introduce you, please turn your camera on, unmute, and begin speaking.

You will have three minutes to speak. But like I said we don't have a stopwatch on the screen but just please make your comment and, if you start to go over time by a lot, I'll alert you to please wrap up.

So our first speaker, first commenter is Leslie Brady. She is the senior policy officer with the national bleeding disorders foundation. Leslie, please come on camera and unmute your line. You have the floor.

>> Leslie Brady: Hi. Thank you. I'm here today on behalf of the National Bleeding Disorders Foundation and the entire community we represent. NBDF is the leading patient advocacy organization working to ensure that individuals affected by hemophilia and related blood disorders have timely access to high quality medical care and treatment.

NBDF appreciates the opportunity. Strengthening the supply chain for blood manufacturing and blood products is of the utmost importance to the bleeding disorders community. Many in our community continue to rely on plasma derived products manufacturing from source or recovered plasma from whole blood donations. Contamination of the blood supply in the 1980s meant that people who depended on clotting factor derived from thousands of pool blood donations were infected with HIV, HCV or both. Now, in 2026 in the U.S. still rely on plasma derived factor replacement. Many countries depend on the plasma products manufactured in the U.S. Over 60% of the plasma used worldwide to manufacture plasma-derived medicinal products is

collected within the U.S. As FDA and federal and other partners consider policies to ensure the safety and adequacy of the blood supply we ask that you always include plasma when appropriate. We appreciate past effort. For example during the COVID-19 Congress and the administration worked together to ensure the safety and adequacy of the blood supply.

The U.S. Government quickly designated both blood and plasma connection as essential activities that must continue during the crisis. It included the importance of plasma collection. Ensuring the strong supply chain requires the ongoing functioning of the Advisory Committee on blood safety and availability which was established in 1997.

ACBTSA helped guide policy and issues related to blood banking and transfusion medicine including preparedness for blood supply disruptions.

We urge the FDA to work with federal partners and reinstate the committee and ensure patient participation is included. Thank you for the consideration and we appreciate the opportunity to provide these comments.

>> Anne Eder: Thank you, Leslie. Our next public commenter is Dr. André Cap.

>> Andre Cap: Good afternoon. Both U.S. Department of Health and Human Services and Department of War have identified U.S. capability for dried plasma manufacturing as critical to national security. U.S. Government has invested significantly in ensuring both military and civilian needs. According to historical precedent and observed blood product demand, military needs for dried plasma in war time could reach to millions of units per year. Civilian use is predicted to be substantial and surge requirements could be similar in magnitude to military requirements.

>> U.S. HHS through BARDA can fund-- medical based-- accordingly they have developed a compact system installed in blood centers and integrated in standard operations. System produces spray dried plasma with sterile water for injection. Each I don't remember is a size of-- it could produce up to 24,000 units. And several additional installation-- Velico stands ready to produce over 100,000 units a year of dried plasma for the U.S. Velico has developed trial. The BARDA funded and distributed manufacturing approach for dried plasma ensure scalability, resilience, and domestic self-reliance.

Velico is proud to support U.S. support resiliency in blood supply chain manufacturing. Thank you for your attention.

>> Anne Eder: Thank you, Dr. Cap.

Our next commenter is Kate Fry. Kate, you have the floor. Okay. If she joins later, we'll add her back onto the list.

Our next commenter is Monica Klein from Mayo Clinic, Senior Associate Consultant in the Division of Transfusion Medicine and Medical Director in the Components Laboratory and

Associate Medical Director in the Human Cellular Therapy Laboratory and Assistant Professor of Laboratory Medicine and Pathology.

>> Monica Klein: Thank you for the opportunity to participate in today's roundtable and the excellent roundtable speakers today.

As I'm sure other hospital-based blood centers and regional blood collection facilities can attest we have encountered and continue to encounter difficulties in the healthcare supply chain that has put at risk the safety and adequacy of the blood supply in our institution but also brings into concern the resilience of the entire manufacturing chain that supports the U.S. blood supply.

This is in part due to the relatively limited number of suppliers for critical materials and some instances a sole supplier dependency. The most recent example I will use is the sole source manufacturing for glycerol that is used to cryopreserve red cells. Our blood center receives notification in April that the sole manufacturer of glycerol will stop manufacture with an end date of supply of quarter three of 2027 . Without an FDA approved alternative, this will cripple of all blood U.S. suppliers to cryopreserve critical red blood cells. These disruptions have occurred in numerous instances ranging from reagents and processing kits to equipment. And have shown the tenuous state of the blood manufacturing supply chain. I want to encourage members on this roundtable and manufacturers of the need transparency to earlier warning of shortages.

Along with manufacturers and blood establishments should have clear transparency, understanding and communication regarding critical materials particularly in the instance of sole suppliers and disruption in the entity of issues in manufacturing.

To the manufacturers, I would emphasize the continuity of supplies to this industry is not only a commercial issue, they are patient safety and national security issues. I encourage us to work together to identify and share information earlier when potential disruptions emerge. A blood establishment should not be informed a critical supply would not be available when the decision to manufacturing has been made and allotments have been decided. My hope is we can move from reacting from shortages and anticipate vulnerabilities, increasing the resiliency of the healthcare supply chain. Thank you.

>> Anne Eder: Thank you, Dr. Klein. Our next commenter is Katie Risvold. The Executive Director of Circulate. Director of Circulate.

>> Katie Risvold: Our current data contributors represent more than 60% of the U.S. blood supply and the comes daily frequency ISBT128 code level and standardized which ensures consistency across time within our dataset.

We have positioned ourselves to be a resource for the established expert entities. Many are in the roundtable table that can take our data and insights, do further analysis or act on the data available to them in the meaningful way and the ways that have been discussed today. I think we know that understanding the inventory and collection environment as a whole is important to ensuring resiliency of the broader fabric of blood collection and shocks to the system are not limited to a single operator or region.

Understanding and speak to go that level, that national scale is Circulate identified significant gap and working to fill that gap and make that data available as a resource across the industry.

Examples of our data sites include understanding, rebuilding blood inventory, the other side of the same coin is measuring proven surge capacity. The U.S. has demonstrated an ability to collectively increase bloods cell inventory by 2,000 components per day and sustain that growth over period of weeks. Conversely as Brooke and Tammy touched upon earlier, we need to understand what is a normal state and how that normal state changes throughout time.

This year we're look at estimated national daily average inventory of platelets which is different from previous annual averages closer to 9,000 and 10,000 components

It's possible to have a detailed using of blood supply, not just snap shots. This data can be critical at all times and as a part of being proactive about resiliency and shock to the system, Circulate was found object a public good and partner to public organizations and welcome to work with entities mainly in today's roundtable. I would love to be a resource for government partners for industry stakeholders and organizations across the industry as well. Thank you very much.

>> Anne Eder: Okay, thank you, Katie. And Kate Fry has joined. CEO of America's Blood Centers. Thank you for joining us.

>> Kate Fry: Thank you, and good afternoon, everyone. I am Kate Fry and I would like to thank FDA for convening this roundtable and ongoing work to harmonize data standards and product approvals. ABC represents the community-based independent not-for-profit blood centers across more than 1100 communities. We ask that community blood centers continue have a seat at the table for managing issues along the supply chain. My comments today cover three topics.

But first topic. First is redundancy. Blood community has limited suppliers for essential products. As the ACBTSA recommended in 2020 it's essential that alternative manufacturing sites and cross manufacturing capabilities for key products be mapped and authorized. We support execution of recommendation 4.2 of HHS' report to Congress to develop and maintain industry wide plans that incorporate business continuity plans for all necessary supplies for blood collection and storage.

Second point is in building the resilience of a blood supply we must take a comprehensive vein to vein view. They found that critical blood infrastructure breaks down at only 10 to 20% above base production level. We ask our federal partners to promote policies that address the full ecosystem of blood, including donors, workforce, reagents computer systems and cold chain. We must strengthen our early warning system the catch here, mandatory notification for the supplies only applies during a declared emergency not during ordinary times when slow exits happen. We requested FDA include blood collection and manufacturing supplies by product code, the device shortage notification list and support extending mandatory notification beyond declared public health emergencies.

One fundamental ask ties this together. As you heard blood was left out of the essential medicine and supply chain assessment that CMS and other agencies rely on-- they ask they

brought in to qualify for the same supply protection as other medical products. Resilience is not built during a crisis. It is funded before one occurs. ABC stands ready to partner with FDA, HHS and industry. Thank you for the opportunity to comment.

>> Anne Eder: Thank you, Kate. Now we're going to go to Jennifer Yonemura Vice President regulatory affairs at Cerus.

>> Jennifer Yonemura: Thank you. Good afternoon, thank you to FDA and the Office of Blood Research and Review for convening this important discussion. As is evident from the number of stakeholders engaged today, supply chain resilience involves more than maintaining inventory and depends on the framework in which manufacturers and regulators can respond effectively when changes are needed. Existing regulatory pathways, serves an important role to make sure changes do not compromise product safety, quality and effectiveness. We believe there may be an opportunity for FDA and industry to work collaboratively to better define how regulatory communication mechanisms are applied in supply chain circumstances with risk based requirement and timelines that reflect the nature of the change and potential impact on continuity of supply.

This could include clearer expectations for early engagement when an emerging supply concern was identified, guidance or another published framework establishing expectations for common types of manufacturing changes. And clarity around applicable review pathway from the timing of unnecessary change can affected supply. This could support changes to the materials, components, suppliers, manufacturing practices or manufacturing site.

Changes may be driven by external events that manufacturer could not participate or control. Manufacturers have a finite window in which to qualify, validate obtain clearance for and implement alternatives particularly for products essential to the continued collection and manufacture of blood components for transfusion. This would not mean lowering regulatory standard or assuming the proposed change would be accepted. It would provide predictability by allowing FDA and manufacture to engage earlier align on proportionate data expectation and address vulnerabilities before they become urgent shortages. Finally we would like to recognize BARDA and other partners whose sustained engagement have been fundamental in advancing innovation and helping bringing new technologies to the blood community. That is important in ensuring that those technologies and the BARDA blood manufacturing system remain resilient over time. Thank you for the opportunity to comment.

>> Anne Eder: Thank you, Jennifer. And our final commenter is Wendy Fong, Chief Procurement Officer American Red Cross.

>> Wendy Fong: Thank you, Dr. Eder. On behalf of the American Red Cross I want to thank the FDA for bringing us together today and every day.

We very much appreciate the opportunity to participate in today's important conversation.

From a supply chain perspective, I want to focus on one challenge that we believe could further strengthen resilience. Having an alternative supplier technology does not mean we have an alternative that can be deployed. Many critical products are part of integrated systems including

equipment, disposals, software and manufacturing processes. When one of those products becomes constrained, the existence of another supplier doesn't provide immediate redundancy. Moving to an alternative may require qualification, validation, training, systems changes and regulatory action. What appears to be a diversified market is a single point of failure. For our critical technologies, the question isn't simply is there another supplier? Is if this supply becoming unavailable tomorrow is there an alternative we can deploy and how quickly? We see two opportunities. First the FDA and other U.S. agency partners, blood establishments and manufacturers could identify critical technologies where alternatives are not interchangeable. Understand what prevents the alternatives from being deployed and whether the challenges are technical, operational or commercial or regulatory. Where it could reduce those barriers. There is an opportunity to think about this globally, a theme echoed in this presentation. Many of these products and technologies are manufactured and used across multiple markets. Greater alignment around standards were appropriate could expand the range of qualified alternatives available across global markets and strengthens the resilience of the nation's blood supply. We welcome the FDA's leadership in convening this work and helping identify where greater standardization and interoperability could meaningfully improve supply resilience. Second where regulatory requirements are part of the transition, we could ask FDA to help define the accelerated pathway in advance. To transition to a qualified alternative and how that transition could be accelerated when continuity of supply is threatened. This is an opportunity to do work before shortage occurs. For critical dependencies and quality standards to support public health. Thank you for this opportunity to comment.

>> Anne Eder: Thank you all for the staying on for this roundtable. What a day. I think I've heard a lot. I will try to summarize it. We'll end a bit ahead of schedule. I will try to provide summarizing remarks. This is really just a first conversation.

So in session one, some take home points. So at least on the FDA's list, blood components and plasma for further manufacturer are essential medicines that are medically necessary to have available at all times in an amount adequate to serve patient needs. The current state where shortages in the supply chain for blood manufacturing are reported by blood establishments or by the manufacturers to FDA or otherwise come to our attention for us to intervene with the end user to intervene and for us to manage in a reactively is really unsustainable.

You heard in the first session, I heard really great discussion. I also heard an ask that BCA manage a back up supply of critical supplies of a 30-day supply that they rotate. And this takes money and space. A one-time investment where they rotate the stock out might enable a 90-day supply. I think that's an idea worth having a further discussion. Keep in mind FDA is not a funding organization. We heard discussion around redundancy and second suppliers. Although the final commenter did point out that just having a second supplier doesn't mean that you've solved the problem. Blood establishments need to be able to use the supply. That means training, computer changes and so forth.

However, we heard PPTA say that saline is so important that they do have back-up SOPs. It is complicated. In the case of cybersecurity, we talked about downtime SOPs briefly. And you know, it's important to keep in mind that cyber events can last a long time, can go on for a long

time. And your downtime SOP should be viewed through that lens. So it's a lot of synthesize, chew on. But session one was a very insightful, very productive. And I thank the moderator and the speakers.

In session two, the manufacturers talked about -- it was jam packed, I thought. So our manufacturers have built resilient supply chains. And there were a lot of common themes that emerged such as multiple sourcing for critical materials and resilient supply chain requires sustained investment in quality systems and infrastructure innovations. And the risks are many, global regulatory challenges, transportation, geopolitical situations, supplier base, resources, business continuity, and demand variability can intensify shortages. It's important to establish communication pathways and early triggers to identify and escalate emerging supply risks before they become critical shortages.

And we should explore government industry collaboration to identify practical, science-based mechanisms to protect continuity during disruptions.

I also heard an important regulatory, an opportunity between regulatory and between us and manufacturers to have coordinated emergency prioritizations and risk-based response plans. And the question was asked if we are using the same definitions. And I'm guessing that we're probably not. So we definitely need to have more conversations.

And then in session three, we're from the government. We're here to help. HHS leads critical nationwide initiatives to prevent and mitigate essential medical product shortages. These efforts though currently aren't focused or really don't include the blood supply. And that's something we really need to talk about.

These initiatives include strengthening domestic supply chain and accelerating U.S. based manufacturing. And you know, FDA defined blood components and source plasma as essential medicines. And different lists define things differently for different purposes. But we need to talk about blood and the blood manufacturing supply chain as an essential medicine because it's certainly essential for public health and preparedness for emergencies and surge and response. I know I'm preaching to the choir. But I don't see how you can see it any other way.

And FDA has a number of efforts to support, supply chain strength and resilience efforts and to help ensure the availability of FDA regulated products.

And we can merely tap into the expertise of FDA and at BARDA. And I know many want to talk to Mary because we have a pivotal opportunity to extend the existing HHS resilience framework to the blood manufacturing supply chain to close a critical gap in our national health infrastructure.

So I want this to be a first conversation in strengthening the blood manufacturing supply chain. Because it's so crucial to healthcare in the U.S. So I thank you all for participating today.

And even though we didn't use the Q&A or the chat function during this roundtable. We want your feedback. Submit feedback about the workshop or questions to this address. CBERpublic events@FDA.HHS.gov. And include OBRR Roundtable 2026 in the subject line. Send us your

questions and comments, and we will respond and consider posting them and put it on the events page in a few weeks. And we welcome your feedback. I want to give a round of very loud virtual applause to our moderators and speakers.

This is really an exceptional day. So thank you.

And I have to say that without the support of the people on the-- slide, this would not have all come together the way that it did. So I have to thank the CBER Center Director Karim Mikhail, Stacey Rivette, Loni Warren Henderson, Yeowon Kim, Jennifer Scharpf, and AnnaBelle Lowe. And I am going to conclude this roundtable and thank all of you for participating. And I look forward to your feedback.

Thank you, this concludes our roundtable on Strengthening the Supply Chain for Blood Manufacturing. Thank you.