UNITED STATES OF AMERICA

FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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GENERAL HOSPITAL AND PERSONAL USE DEVICES ADVISORY COMMITTEE

MEETING

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GENERAL ISSUES PANEL

MEDICAL DEVICE SUPPLY CHAIN RESILIENCY AND SHORTAGES & PROPOSED 506J

DEVICE LIST

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Call to Order

Dr. Jarvis: Good morning. Welcome, everyone. Before we begin, one housekeeping note. When you are going to speak, please press the red button on the microphone in front of you. And when you're done, be sure to turn it off because we only have four mics that can run at the same time. So, if everybody has theirs on, they're in trouble.

First of all, welcome. Thank you for coming here. I'd like to call this meeting of the General Hospital and Personal Use Devices Panel to order. I'm Dr. William Jarvis. I'm President of Jason and Jarvis Associates Consulting Company, Infectious Disease and Healthcare Epidemiology. Before that, I spent 23 years at the Centers for Disease Control and Prevention Primarily, in healthcare associate prevention, but also in extramural research. So, it's a pleasure to be here today and I look forward to meeting and discussing these issues with you all.

I note, for the record, members present constitute a quorum, as required by 21 CFR Part 14. I would like also to add that the panel members participating in today's meeting have received the required training in the FDA Device Law and Regulations. For today's agenda, the panel will discuss and make recommendations on medical device supply chain resiliency and shortage issues, including the 506J Device List which has been developed as a requirement of Consolidated Appropriations Act from 2023, specifically, Section 2514(c) of the Consolidated Appropriations Act of 2023, which directs the FDA to publish a list of devices by FDA product code subject to mandatory notifications under Section 506J of the Food, Drug, and Cosmetic Act.

Manufacturers of the devices on the 506J Device List will be required to notify the FDA during, or in advance of, a public health emergency about any permanent discontinuation in the manufacturing or interruption in manufacture of devices listed on that list.

The committee will also discuss the 506J Device List relates to medical device used, and pandemic preparedness and response to satisfy, in part, a requirement under 3302 of the Food and Drug Omnibus Reform Act of 2022.

Before we begin, I would like to ask our distinguished committee members and FDA attending to introduce themselves. Please say your name, state your area of expertise, your position and affiliation. And I'll start first with Dr. Jordan. We'll move around that direction. Thank you.

Panel Introductions

Dr. Jordan: Good morning. John Jordan. I'm a physician with a background in internal medicine, preventative medicine, and clinical informatics. I work for Central Health in Austin, Texas. Clinical informatics, electronic health record. I also have many years of experience with public health planning and response. I formerly worked for the CDC, also the state of Texas Department of State Health services.

Dr. Cassiere: Good morning, everyone. Dr. Hugh Cassiere. My expertise is in respiratory devices, critical medicine, and patient care monitoring. I'm the director of critical care services at South Shore University Hospital, I'm an affiliate. I'm also on the anesthesiology and respiratory devices panel for the FDA.

Dr. Carrino: Good morning. Hi. I'm John Carrino. I'm, my expertise is in radiology. I work as device chairman for radiology and imaging at the Hospital for Special Surgery in New York City. And professor of radiology at Weil Cornell. And also serve on the FDA panel for devices.

Dr. Beavis: Good morning. I'm Kathleen Beavis. My area of expertise is in clinical pathology, particular microbiology. I'm a professor of pathology at the University of Chicago. Former member of the microbiology resource panel.

Dr. Allen: My name's Keith Allen. I'm a cardiac and vascular surgeon at Mid America Heart Institute in Kansas City. I'm director of surgical research. Surgical director of structural heart. I'm a member of the device panel for the FDA.

Dr. Morgan: Good morning. I'm Charity Morgan. My expertise is in statistical clinical trials. I'm a professor of biostatistics at the University of Alabama Birmingham. And I'm a member of the device panel.

Dr. Siddiqui: Good morning. I'm a plastic surgeon in Detroit, Michigan. I'm here representing plastic surgeons and also associate professor, Michigan State University.

Ms. Diaz: Good morning, everyone. My name is Theresa Diaz. I'm a passionate advocate for patient's rights. And the cofounder of Global Patient Advocacy Coalition and also a member of this panel.

Ms. Sauer: Nancy Sauer. I'm with regulatory affairs, currently a senior director of regulatory affairs in general surgical technologies business within Medtronic. I'm here as the industry representative on this panel.

Dr. Beckham: Good morning. I'm Tammy Beckham. I'm the Director of Supply Chain Resilience at the Center for Devices and Radiological Health.

Dr. Schwartz: Good morning. I'm Susan Schwartz. And I'm Director of the Office of Strategic Partnerships and Technology Innovation at FDA Center for Devices and Radiologic Health.

Dr. Van Der Pol: Hello. I'm Barbara Vander Pol. I'm a professor of medicine and public health. I work at the University of Alabama at Birmingham School of Medicine. And I serve as the chair of the Microbiology Devices Panel for the Medical Devices Advisory Board for the FDA.

Dr. Petersen: Good morning. I'm Paul Petersen. I'm the Director of the Emergency Preparedness Program for the Tennessee Department of Health. And so, my expertise is in both pharmacy, emergency management and public health.

Dr. Jennings: Good morning. My name is Lisa Jennings. My area of expertise is in thrombosis hemostasis in the broad area of vascular biology. I'm a professor at the University of Tennessee. Health Science Center in Memphis. And I'm a member of the devices panel.

Dr. Fischer: Good morning. I'm Gwenyth Fischer. I'm a professor at University of Minnesota College of Medicine in pediatric critical care. My background is in pediatric drug and pediatric medical device.

Dr. Dominitz: Good morning. I'm Jason Dominitz. I'm a gastroenterologist and professor at the University of Washington in Seattle. And I'm the Executive Director of National Gastroenterology and Hepatology Program for the Department of Veterans Affairs. I'm also a member of FDA panel for devices.

Mr. Collier: Good morning. My name is Jarrod Collier, and I'm the designated federal officer for today's General Hospital and Personal Use Devices Panel. Thank you.

Dr. Jarvis: Thank you all.

Now, Mr. Jarrod Collier, who just told you he's a designated federal officer for today's General Hospital and Personal Use Devices Panel will provide the conflict of interest statement for today's meeting.

Mr. Collier: Thank you, Dr. Jarvis.

Conflict of Interest Statement

I will now read the conflict of interest statement. The Food and Drug Administration is convening today's meeting of the General Hospital and Personal Use Devices Panel of the

Medical Devices Advisory Committee under the authority of the Federal Advisory Committee Act of 1972. With the exception of the industry representative, all members and consultants of the panel or special government employees or regular federal employees from other agencies and are subject to federal conflict of laws and regulations.

The following information on the status of this panel's compliance with federal ethics and conflict of interest laws covered by, but not limited to, those found at 18 U.S.C. Section 208 are being provided to participants at today's meeting and to the public. FDA has determined that members and consultants of this panel are in compliance with federal ethics and conflict of interest laws. Under 18 U.S.C. Section 208, Congress has authorized the FDA to grant waivers to special government employees and regular federal employees who have financial conflicts when it is determined that the agency's need for particular individuals' services outweighs his or her potential financial conflict of interest.

Related to the discussions of today's meeting, members and consultants of this panel who are special government employees or regular federal employees, have been screened for potential financial conflict of interest of their own as well as those imputed to that. Including those of their spouses or minor children, and for the purposes of 18 U.S.C. Section 208, their employers. These interests may include investments, consulting, expert witness testimony, contracts, grants, CRADAs, teaching, speaking, writing, patents and royalties and primary employment.

For today's agenda, the panel discuss and make recommendations on medical device supply chain resiliency and shortage issues. Including the 506J Device List, which has been developed as a requirement of the Consolidated Appropriations Act of 2023. Specifically, Section 2514(c) of the Consolidated Appropriations Act of 2023, directs FDA to publish a list of devices by FDA

product code subject to mandatory notifications under subject, excuse me, under Section 506J of the Federal Food Drug and Cosmetic Act 21 U.S.C. 356J.

Manufacturers of the devices on the 506J Device List will be required to notify the FDA during or in advance of a public health emergency about a permanent discontinuance in manufacture or interruption in manufacture of devices included on this list.

The panel will also discuss how the 506J Device List relates to medical devices used in pandemic preparedness and response to satisfy, in part, a requirement under Section 3302 of the Food and Drug Omnibus Reform Act of 2022.

Based on today's agenda, all financial interests reported by the panel members and consultants, no conflict of interest waivers have been issued in accordance with 18 U.S.C. Section 208.

Miss Nancy Sauer is serving as the industry representative acting on behalf of all related industry. Ms. Sauer is employed Medtronic Incorporated General Surgical Technologies.

We would like to remind members and consultants that if discussions involve any other products or firms not already on the agenda, for which an FDA participant has a personal or imputed financial interest, the participants need to exclude themselves from such involvement, and their exclusion will be noted for the record. FDA encourages all participants to advise the panel of any financial relationships that they may have with any firms at issue.

A copy of this statement will be available for review and will be included as part of the official transcript. For press inquiries, please contact the Office of Media Affairs at FDAOMA@FDA.HHS.gov or by phone at 301-796-4540.

For the duration of the General Hospital and Personal Use Devices Panel, on February 6th, 2024, Dr. Gwenyth Fischer has been appointed to serve as a temporary non-voting member.

For the record, Dr. Fischer serves as a voting member of the Pediatric Advisory Committee in Office of Pediatric Therapeutics, Office of the Commissioner.

These individuals are special government employees who have undergone the customary conflict of interest review and have reviewed the materials to be considered at this meeting. The appointments were authorized by Rachel Bressler, Acting Director of the Advisory Committee Oversight and Management staff on December 26th, 2024.

At this time, I will turn the meeting back over to Dr. Jarvis. Thank you.

Dr. Jarvis: Thank you, Mr. Collier.

I will now call on Dr. Suzanne Schwartz, Director of the Office of Strategic Partnerships and Technology innovation to make some opening remarks.

Opening Remarks

Dr. Schwartz: Good morning. And thank you, chairman Jarvis and DFO Collier. Members of the General Hospital and Personal Use Devices Panel, as the Director of the Office of Strategic Partnerships and Technology Innovation at FDA Center for Devices and Radiological Health, it's a privilege for me to provide these opening remarks as stage setting for today's discussion on medical device supply chain resiliency.

I'd like to begin by extending a thank you on behalf of FDA to all today's panelists, invited speakers and participants for your engagement in this very important and impactful dialogue.

Let me start by providing some background on CDRH's work to mitigate medical device shortages, share some context around recently published 506J guidance documents and explain why we are convening an advisory committee to discuss this topic.

At the FDA, our mission is to protect and promote the public health. And for CDRH that includes assuring safe and effective medical devices are available for our nation's patients and healthcare providers.

As the COVID-19 public health emergency demonstrated, the medical device supply chain is incredibly fragile and complex. We saw, firsthand, how existing vulnerabilities and dependencies in the global supply chain became amplified and most pronounced as COVID drove surges in demand and disruptions in supply.

While the supply chain disruptions from acute COVID-19 disease have mostly disappeared, the underlying supply chain vulnerabilities exacerbated by COVID-19 remain to this day. The medical device supply chain continues to face disruptions from geopolitical events, economic forces, regulatory changes and the ever-present threat of emergencies, including pandemics, natural disasters, and chemical, biological, radiological, and nuclear CERN events. Meanwhile, the supply chain is returning to some pre-pandemic behaviors, hence, abandoning practices implemented to build resiliency during the public health emergency, such as qualifying multiple suppliers, holding additional inventory, reducing foreign dependence, and investing in domestic nearshoring production.

In doing so, the medical device supply chain is reintroducing the same complexity and fragility that put vulnerable patient populations at risk and caused widespread disruptions during the COVID-19 public health emergency.

The good news is that CDRH now has the Resilient Supply Chain Program recently elevated and re-branded as Office of Supply Chain Resilience or OSCR to strengthen public health supply chains by proactively monitoring, assessing, and communicating risks and vulnerabilities to prevent shortages of medical devices.

Over the past several years, the Office of Supply Chain Resilience has analyzed hundreds of potential shortages and collaborated with stakeholders to mitigate shortages or essential devices, including blood collection tubes, saline flush syringes, tracheostomy tubes, and more. As part of its role, the Office of Supply Chain Resilience identifies and communicates shortages under Section 506J of the FD&C Act, which was established by Congress in March 2020 as a result of the widespread disruptions early on in the COVID-19 Pandemic.

Under Section 506J, manufacturers of certain devices are required to notify the FDA of an interruption in the manufacturing or discontinuance of certain devices during or in advance of a public health emergency. During the COVID-19 PHE, we provided a suggested list of devices that were deemed critical for the COVID-19 PHE to assist in fulfilling their obligations under Section 506J.

By nature, this list of devices was scoped in a targeted manner to the specific clinical care needs of individuals suffering from COVID-19. As the COVID-19 public health emergency ended, our focus has shifted from shortage response to a more proactive posture of planning and preparedness.

In doing so, we must acknowledge the breadth of potential emergencies, including infectious disease, epidemics and pandemics, natural disasters, and CBRN events and recognize the myriad ways in which medical devices may be needed during a public health emergency.

In December of 2022, the Prepare for and Respond to Existing Viruses, Emerging New Threats and Pandemics Act; otherwise known as, PREVENT Pandemics Act, was signed into law as part of the Consolidated Appropriations Act of 2023, also referred to as the 2023 Omnibus, which included three relevant provisions. First, it directed the FDA to issue draft

guidance to facilitate voluntary notifications and clarify our ability to receive notifications outside the public health emergency.

Second, it directed the FDA to issue or revise guidance regarding requirements under Section 506J. And to include a list of each device by product code for which a manufacturer of such device is required to notify the FDA in accordance with Section 506J during or in advance of a public health emergency.

Third, it directed the FDA to convene one or more panels of the Medical Devices Advisory Committee not less than once per year for the purposes of providing advice to the secretary on topics related to medical devices used in pandemic preparedness and response. It is these last two provisions, the creation of a proposed list of devices for which manufacturers are required to submit notifications to the FDA under Section 506J and the convening of an advisory committee on pandemic preparedness and response that brings us together today.

In November of 2023, the FDA issued two guidance documents to address Section 506J of the Federal Food Drug and Cosmetic Act as it relates to notifying the FDA of a permanent discontinuance or interruption in the manufacturing of certain devices likely to lead to a meaningful disruption in the domestic supply of that device during or in advance of a public health emergency.

As part of this guidance, the FDA included the proposed 506J Device List, which is intended to assist manufacturers in providing timely notifications to the FDA for devices which are, per the statutory language, critical to public health during a public health emergency including devices that are life supporting, life sustaining or intended for use in emergency medical care or during surgery.

Convening an advisory meeting on this topic recognizes the importance of thoughtful dialogue with medical devices experts on the topic of emergency preparedness, and the medical device supply chain. In particular, finalizing the 506J Device List requires us to obtain as much feedback as possible, given the breath of potential emergencies and the wide variety of emergent medical conditions for which medical devices may be life supporting, life sustaining or intended for use in emergency medical care during surgery.

As such, today's advisory committee meeting is different from other meetings, in that, usually FDA advisory committees are usually tasked with a smaller scope, for example, committees often discuss a single device, related subset of devices or devices for a specific medical condition.

In this meeting, we will discuss the proposed 506J Device List, which includes nearly 128 device types, representing 284 medical device product codes across five clinical functions: care delivery, clinical diagnostic assessment, clinical laboratory testing, infection control, and medical imaging.

Our purpose today is to discuss and make recommendations on this list. In other words, do the device types on the proposed 506J Device List meet the requirements for a critical device?

And furthermore, how should the resilience of a supply chain be considered when determining which devices should be included on the 506J Device List? Feedback provided today, and in the docket for this meeting will inform the final 506J Device List and CDRH's effort to strengthen public health supply chains generally.

In this charge, I want to thank members of the General Hospital and Personal Use Devices Panel of the Medical Device Advisory Committee, as well as stakeholder representatives and members of the general public for your participation and thoughtful comments regarding the

506J Device List and opportunities to enhance the preparedness of our nation in advance of future disruptions. At this time, I would like to now turn the meeting back to Dr. Jarvis. Thank you.

Dr. Jarvis: Thank you, Dr. Schwartz. We will now proceed to the FDA presentation. I would like to invite the FDA representative, Dr. Tammy Beckham, to begin. The FDA representative will have 30 minutes to present followed by questions for the FDA. You may now begin your presentation.

FDA Presentation

Dr. Beckham: Good morning. It's a pleasure to be here with you. And thank you, Dr. Jarvis. I'd like to start out by thanking our panel members for their time today and their expertise. We are looking forward to hearing the discussions and the feedback on this very important topic.

And I would also like to just thank our guest speakers and other participants, whether you are participating in person or listening to the webcast. Also want to thank the Booz Allen consulting and MITRE team that helped put this together, as well as OM, and FDA. Thank you all for everything you did to help us get here today. Just wanted to acknowledge that.

During my presentation today, I'm going to provide an overview of FDA's medical device shortage reporting authorities, as well as the legislation that led to the creation of the proposed 506J Medical Device List. I'm going to spend a few moments discussing how the FDA uses the information that is submitted under Section 506J of the FD&C Act. And then I'm going to pivot to discuss the process that was utilized to develop the proposed 506J device list and how the list is organized.

And finally, I'm going to give a very high-level overview of the product codes and device types that are included on the proposed list, specifically, highlighting examples of product codes that were proposed for inclusion.

As mentioned by Dr. Schwartz, the objectives for today's meeting are to obtain feedback on whether the devices proposed for inclusion on the 506J Device List meet the requirements outlined in Section 506J of the FD&C Act, to discuss how supply chain resilience and vulnerability should be considered when determining device types by product code for inclusion or exclusion on the list. How we should look at specific characteristics of a device type and how they should be considered when finalizing the list.

For example, are there specific characteristics of devices like single use disposable devices or multi-patient reusable devices that should be considered when determining product codes for inclusion or exclusion on the list? And lastly, but certainly not least, are there additional considerations for proposed 506J Device List that should be taken into account for pandemic preparedness and response activity?

So, I just want to give you an overview quickly on the recently elevated Office of Supply Chain Resilience within CDRH. So, as Dr. Schwartz said, the FDA Center for Devices and Radiological Health is responsible for protecting and promoting public health by assuring patients and providers have timely and continued access to safe, effective, and high-quality medical devices.

And within CDRH, the Office of Supply Chain Resilience in the Office of Strategic Partnerships and Technology Innovation is responsible for working with our partners across the medical device ecosystem to build supply chain resilience and prevent shortages that can impact healthcare delivery and patients.

And to this end, we proactively monitor, assess, we communicate risks, and we use information that comes in through 506J along with other external resources to inform the use of both regulatory and non-regulatory mitigations to help prevent shortages.

And again, we do this by working across a broad group of stakeholders to include suppliers, manufacturers, group purchasing organizations, distributors, transportation companies, healthcare systems and certainly, last but not least, again, the United States government, our other federal partners.

Notifications under Section 506J of the FD&C Act provide critical information that will allow us to proactively prevent and mitigate these shortages. I'm going to spend the next few moments providing an overview of the medical device shortage reporting authorities and specifically highlight the legislation that directed FDA to develop and publish the 506J List.

The CARES Act signed into law in March 2020 gave FDA, for first time, authorities to help prevent and mitigate medical device shortages. And specifically, Section 3121 of the CARES Act amended the Food Drug and Cosmetic Act by adding Section 506J to the statute.

As previously stated, Section 506J of the FD&C Act requires manufacturers to notify the FDA during or in advance of a public health emergency about permanent discontinuance or interruption in the manufacturing of certain devices that's likely to lead to meaningful disruption in the domestic supply of that device. Devices that require notification under 506J, per the statute, are those that are critical to public health during a public health emergency. Including devices that are life supporting, life sustaining or intended for emergency medical care, or during surgery. As well as any devices for which FDA determines information on a potentially meaningful disruption of such devices are needed during or in advance of a public health emergency.

I think it's also important to call out the FDA has obligations under 506J. These include establishing and maintaining a publicly available list of medical devices that the FDA determines to be in shortage. Distributing this information to the maximum extent practical on device discontinuances and interruptions to appropriate organizations. Issuing and publicly posting failure to notify letters should manufacturers fail to comply with their requirements. And expediting premarket reviews or facility inspections, as appropriate, if they could help to mitigate a potential shortage.

As previously noted, in December of 2022, the Consolidation Appropriations Act hereafter referred to as FY23 Omnibus was signed into law. Section 2514 of the Omnibus, amended Section 506J of the FD&C Act to add Section 506J(h) which directed FDA to issue guidances to facilitate voluntary notifications for manufacturers and issue a revised guidance regarding requirements under 506J and include a list of each device, by product code, for which manufacturers of such devices are required to notify the FDA in accordance with 506J. In other words, publish a 506J Device List.

So, in accordance with the FY23 Omnibus, in November of 2023, FDA issued draft guidance titled, Draft Updates for the 506J Guidance, 506J Device List and Additional Notifications. As directed by legislation, the draft guidance includes a list of device product codes for which a manufacturer of such devices is required to notify the FDA in accordance with Section 506J of the FD&C Act. The list when finalized, is meant to assist manufacturers in providing timely, informative notifications about changes in the production of certain medical device products. Once finalized, the FDA expects this list will evolve over time. And we intend to periodically reevaluate the list, following the FDA's good guidance practices.

So, just to give some context for today's meeting as well, I want to talk just a minute about how CDRH utilizes information provided in 506J notifications.

FDA utilizes the information provided through 506J notifications to help prevent and mitigate medical device shortages and impacts to patients. Information provided through the 506J notifications is used in combination with other internal and external data sources to help develop impact assessments. Those impact assessments are subsequently used to determine if a medical device is in shortage or shortage is eminent, to determine potential impact of patients and healthcare delivery in the United States, and to inform on the need for implementation of both regulatory and non-regulatory mitigation strategies, such as enforcement discretion, expediting premarket review, conservation strategies, or defense priority rating.

So, just to give you an example, U.S. Government partners rely on FDA's impact assessments, that again, are built off of 506J notifications and other data to determine potential mitigations and for us to inform the implementation of potential mitigation such as the Administration for Strategic Preparedness and Response, or ASPR, priority ratings using the Defense Production Act or priority request letters.

We also work with the Department of Transportation, especially during COVID, to inform the need to prioritize shipping containers coming out of the ships at ports. So, our impact assessments, that we build, are utilized across the board by our federal government partners, to inform different types of mitigations to help prevent shortages.

In addition, we talked a little bit about FDA regulatory mitigations as well. The FDA uses the impact assessments to inform those regulatory mitigations. If FDA concludes that there is, or likely to be, a shortage of a device, then the agency will, as appropriate, prioritize and expedite the review of a submission or a facility inspection.

FDA's ability to prevent and mitigate shortages really depends on timely notifications. As you all know at this table, medical device supply chains are incredibly complex, and they have long lead times. Oftentimes, by the time we hear about a potential shortage, patients are already being impacted and our ability to prevent or to mitigate that, is limited. This is why the FDA 506J authorities and early notifications outside of a public health emergency are also important. The earlier FDA receives notification of a supply interruption, the greater our ability to mitigate or prevent a shortage.

So, now, I'm going to turn to talk a little bit about the process that was used to develop the proposed 506J List. The proposed 506J Device List was developed, collaboratively, by an internal FDA working group that had representatives from the Office of Strategic Partnerships and Technology Innovation, Office of Product Evaluation and Quality, and the Office of Policy. The working group used a multi-step process to develop the proposed list. During the course of deliberations, experts from the Office of Technologies within OPEQ and the Center for Biologics Evaluation and Research were consulted as needed.

The first step in the development of the proposed 506J Device List was to develop an initial list that could be evaluated against the statutory criteria that are included in Section 506J. This initial list was developed using a broad and diverse set of inputs. As an example, the FDA working group utilized lessons learned during prior device shortage events and public health emergencies, including COVID.

The working group also took into account considerations from various other sources of external information to inform our deliberations. These include, but were not limited to, an analogous list published by the World Health Organization, the SMI Critical Product Attributes Framework, and factual inputs that were gleaned during the process utilized to develop the

Healthcare and Public Health Sector Joint Supply Chain Resilience Working Group Critical Medical Device List.

Once the initial set of product codes were established, they were evaluated against the statutory criteria. And when finalizing the proposed list, the FDA working group also considered a variety of resiliency factors as well as the specific device characteristics that I mentioned earlier.

Each product code on the initial list, as I said, was evaluated against whether or not it met the statutory criteria outlined in Section 506J. Specifically, were the product codes and the devices that were considered critical to public health during a public health emergency, including a device that is life supporting, life sustaining, or intended for use in emergency medical care surgery.

The FDA also considered the device, whether the devices is used to diagnose, treat, monitor, or prevent a disease for medical condition, and whether the lack of availability of the device is reasonably likely to cause serious injury or death to patients and healthcare workers, if not available, and there were no suitable alternatives.

Since the spirit of 506J is to facilitate timely notifications to the FDA of disruptions that may impact patient care, the FDA also considered the characteristics of the device and resiliency of the devices supply chain. For example, certain types of devices may be more vulnerable or resilient to disruptions or changes in demand. We considered inherent differences, for example, for single-use versus reusable devices, convenience kits and capital equipment, which I'll describe more in the following slides. We also discussed and considered known vulnerabilities in the supply chain for raw materials components for a given device.

So let me walk through some of our discussions on certain characters of devices that guided our thinking on the proposed 506J List. For single-use disposable devices, such as N95 respirators, masks, syringes and needles, catheters, PPE, etc., the FDA considered these devices more vulnerable to supply chain disruptions and acute increases in demand. And thus, we have included these on the proposed 506J device list.

For multi-patient reusable devices, such as hospital beds, personal assist mobility devices, IV poles, and stethoscopes, FDA considered these device types more resilient to sudden increases in demand and supply chain disruptions given their inherent reusability.

One exception was wheeled stretchers, which we consider met the criteria and were critical for transporting patients in a variety of emergency settings and trauma events to include CBRN and other mass casualty events.

Convenience kits, containing two or more medical devices packaged together, were not included under the presumption that individual devices would still be available in separate packing if the convenience of kits themselves were unavailable. One exception on the list, on the proposed list, was urinary drainage collection kit, which was included because of clinical use and because its components were part of a closed system.

Finally, capital equipment, let me go back. Let me go back. Here we go. Finally, capital equipment, such as the ethylene oxide sterilizers, x-ray systems, CT scanners, and ultrasound systems were deemed critical for supporting the continuity of healthcare and necessary for diagnosing and treating patients in emergent medical and mass casualty situations. Although they are multi-use, these devices are potentially vulnerable to ongoing regulatory pressures and component shortages.

So, now I'm going to take a few minutes to provide an overview of just how the proposed 506J Device List is structured and I'm going to walk through, at a very high level, giving specific examples of product codes that were included on the proposed 506J Device List.

First of all, for the purposes of this meeting, and to facilitate review by the committee members, product codes on the proposed list have been organized by FDA medical specialty panel. FDA has classified and described over 1700 distinct types of devices and organized them in the code of federal regulations into 16 medical specialty panels such as the cardiovascular devices or ear nose and throat panels. The use of product codes to develop the 506J List facilitates this timely reporting and assists manufacturers and understanding their reporting requirements.

The proposed 506J Device List contains 284 product codes that, again, organized under these medical specialty panels. And as you can see, the majority of the product codes included on the proposed list fall under the anesthesiology, cardiovascular, clinical chemistry and clinical toxicology, and general hospital panels.

So, now I'll walk through each panel and give examples of the types of devices on the proposed list. Product codes proposed for inclusion on the 506J Device List that are classified under anesthesiology and ear, nose, and throat panels include those used to deliver anesthesia and those required to deliver optimal levels of oxygenation and ventilation to patients. In addition, product codes and device types used to visualize and maintain patent airways and facilitate intubation were also proposed for inclusion. Examples of product codes include ventilators, gas analyzers, anesthesia machines, spinal needles, flow meters, oxygen masks, tracheostomy tubes, bronchoscopes, and suction tubes.

Product codes proposed for inclusion on the 506J List that are classified under the cardiovascular panel include those that are required for maintaining adequate profusion to tissues and organs with oxygenated blood. These device types include those that are used for extracorporeal membrane oxygenation procedures and ventricular assist devices.

Other devices that were proposed for inclusion under this panel include those that are used for physiological monitoring, ECGs, those that are used to maintain vessel patency such as stents, angioplasty catheters, endovascular grafts, and AEDs, which are utilized to analyze and restore heart rhythm in instances of cardiac arrest.

Device types and product codes proposed for inclusion on the 506J Device List classified under the clinical chemistry and clinical toxicology panel included those that are used to measure aspects of the body's chemical balance and metabolism, those used for specimen collection, and those used to deliver and maintain appropriate glucose levels. Examples of product codes included here include complete metabolic panel tests, cardiac enzyme tests, sterile specimen containers, insulin infusion pumps, and glucose sensors.

Device types and product codes proposed for inclusion on the list and that are classified under the gastroenterology and neurology panel. Include those that are used to treat life threatening instances of intestinal obstruction, those used to deliver peritoneal dialysis and hemodialysis, and those that are used to diagnose and treat life threatening situations such as acute gastrointestinal bleeding.

So, some examples of product codes and device types here include gastrointestinal stents, urinary catheters, endoscopes, femoral catheters, dialysate tubing, dialysis systems, and the dialysis aid itself.

Device types and product codes that were proposed for inclusion on the 506J Device List classified under the general and plastic surgery panel include those that are used to perform general surgery, those that are used to control bleeding, and those used in incision and wound care. Examples of these product codes includes surgical drapes, hemostatic agents, cautery devices, tourniquets, sutures, gauze, sponges, etcetera.

And product codes that are proposed for inclusion on the list, that are classified under the General Hospital Panel, included those needed to support nutrition, for food delivery and other basic physiological functions. Devices used to protect wearers from spreading infections and devices used to disinfect and sterilize medical devices were also proposed for inclusion.

Device types and product codes that are proposed for inclusion on the 506J List under the Hematology and Pathology as well as the Immunology and Microbiology Panels include those devices that were used to test for coagulation abnormalities, collect and transport patient specimens, culture and identify microorganisms, and test for sensitivities and direct resistance.

And those device types and product codes that were proposed for inclusion on the 506J List that are classified under the Orthopedic Physical Medicine and Neurology Panels include those used to measure intracranial pressure, cerebral oxygen levels, and those used for spinal stabilization. As an example, product codes include aneurysm clips, drills, and trephines. These were all included as well.

Device types and product codes that are proposed for inclusion under the Obstetrics and Gynecology as well as Radiology Panels included those used to monitor fetal heart rate and oxygenation. Those used to treat post-partum hemorrhage and imaging devices.

So, this concludes a very high-level walk-through of the very comprehensive 506J Device List. And I will want to note for folks that are participating in today's session, either in

person or online, we welcome your feedback on the proposed 506J Device List. And you can submit comments, via the public docket for today's advisory committee by searching on regulations.gov for the docket number FDA-2023-N-4807. And the docket will remain open until March 6th.

So, just let me reiterate again my appreciation for everybody's participation in today's meeting. And I'm now happy to take questions from the panel. I know that was a lot of information. Thank you.

Questions from the Panel

Dr. Carrino: Hi. Good morning. Thanks for the presentation. So, on the radiology side, as I was looking through the list, you had mentioned devices and some of the support components, so meaning to have parts that would normally break down for routine maintenance to have those available; is that, explicitly, in the list or how is that handled?

Dr. Beckham: So, the list itself is finished devices. So, it does not include raw materials or components.

Dr. Carrino: Not raw material, like, example a CT scanner has an x-ray burnout? Often there's a spare available, one available by the manufacturer that has to be brought in, so those are the types of things that would be important that are like not part of the main device, it already had to install the base of the machine, but having that kind of x-ray tubes available, because those are the consumable, they are not consumables, but those are things that could potentially break and not have function but would be, should be readily available.

And then the other part on sort of doing CT imaging, specifically it's a contrast material as we notice experienced contrast material shortage because of the, most of the manufacturing was offshore at the time. And that CT contrast material should certainly be included. Many of

those exams will have, you can do it without, it will have a lot of added value to have contrast material.

Dr. Beckham: Thank you.

Dr. Carrino: Thanks.

Dr. Jarvis: Just as a note, please say your name before you ask your question so the transcribers can know who's saying what.

Dr. Carrino: Sorry, that was John Carrino.

Dr. Beckham: Thank you.

Dr. Beavis: I'm Kathleen Beavis from the University of Chicago. In terms of microbiology, one of our biggest shortfalls was with collection swabs. I notice you have collection devices there and I want to make sure that includes swabs that are compatible with FDA cleared tests that we are using. Thank you.

Dr. Beckham: Thank you.

Dr. Siddiqui: Hi. Thank you very much. So, when I was in our hospital, when we ran out of gloves, masks, personal protection equipment, it wasn't so much that the manufacturer didn't make it, it just went up 50-fold, a hundred-fold. Can you explain how this system works in that setting where, just go up, we know they are running out? So, a letter to you may not help us prepare. I'm just curious. Thank you.

Dr. Schwartz: That's a great question. So, during the public health emergency, as you mentioned, acute increases in demand manufacturing at that time having to ramp up, needed access to raw materials and components. So, what happens typically and what happens during a public health emergency is either through 506J notifications or other sources of information that came in, we worked with our other partners in USG and with their manufacturers, specifically in the USG

priority ratings for raw materials and components help manufacturers to get the raw materials and components they needed to increase their manufacturing.

So, whether that was with gloves or PPD or other types of critical devices, we helped inform those ratings. We were also able to use the Emergency Use Authorization as well, as you're probably aware of, and different types of regulatory mitigations that we can implement.

So, in addition to working across the USG to implement those non-regulatory mitigations, to inform those, even if that was just as simple as we have gloves, we have gowns, we have something sitting on a ship that needs to be prioritized, syringes, catheters, needles, whatever that is, our impact assessments, our understanding of the problem helps solve – helps us inform others that can implement mitigations to help alleviate or mitigate those shortages.

Dr. Morgan: Charity Morgan, University of Alabama at Birmingham. Could you provide some guidance on what is considered advance of a public health emergency?

Dr. Beckham: I absolutely can. Give me two seconds. I want to make sure I get this exactly correct. So, for the purposes of the guidance, FDA interprets, during a public health emergency to mean the time period when the Health and Human Services Secretary declares a public health emergency under Section 319 of the Public Health Services Act, that includes any renewals made by the HHS Secretary in accordance with Section 319. And then for the purposes of this guidance, FDA interprets in advance of a public health emergency to mean the time period before the secretary may determine that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks otherwise exist.

If certain conditions exist, prior to the occurrence of an outbreak or natural disaster that signal the potential for such an event to occur and that may lead to the declaration of a public

health emergency, FDA considers such conditions to be in advance of a public health emergency. Hopefully that helps.

Dr. Van Der Pol: Barbara Van Der Pol, alsoC UAB. I have a couple of questions to follow on to both of two of the previous questions and the first is, given that infectious disease outbreaks are one of the largest causes of concern for many of these things, which doesn't mean that we don't need other products to actually manage patients routinely, but Kathleen's point about having sample collection devices and also having transport media that's appropriate for that. I see some things on here, but I don't see swabs, in particular, and I know that that's just a minor thing but most specimen collection looks like it's blood draw information and that was one of the problems that we routinely had during COVID, so it's worth noting.

The other thing is that I work with a lot of manufacturers, and did during COVID, of course, and they were manufacturing at full capacity, so even if you say you are going to provide more raw materials, that's not necessarily going to fix the problem, so I think it's sort of worth being aware.

And then, finally, if we are using nucleic acid amplification technologies, and it's an emergent pathogen, we are necessarily going to need products that aren't already approved products because we didn't know to approve a product for that pathogen. In that case, how we make sure that we are getting access to those supplies that go into nucleic acid amplification testing such as primers and probes, DNA and RNA sequence. That's a whole lot in one question, but I just wanted to make sure we were having continuing conversations.

Dr. Beckham: And those are all very good points. Certainly, what we saw early during the public health emergency.

Dr. Cassiere: Good morning. Hugh Cassiere. Just a question about the convenience kits. I understand the urinary bladder convenience kits, but placing arterial catheters in central lines in intensive care unit, do you consider those convenient kits that are left out? Because those individual components require, you can get them separately, but if you detach them, it makes it very difficult to keep sterile technique and everything together and get the procedure done in a safe and efficient manner.

Dr. Beckham: They were not, the kits were not included, but we are asking the panel today to provide feedback and advice on those topics.

Dr. Jennings: Lisa Jennings, University of Tennessee. I don't know if this is the time to make comment or list some items that were perhaps missing on the device list; is this the venue to do that?

Dr. Beckham: So --

Dr. Jarvis: Yes, I think, a summary would be wise.

Dr. Jennings: Okay. Well, in general I agree certainly we were limited somewhat on nucleic acid PCR testing. I noticed in the list, since my expertise is in thrombosis and hemostasis, you know, we certainly had need for automated hematology analyzers, and particularly during the COVID pandemic, coagulation analyzers for D-dimer and tests like that, I notice the tests were somewhat limited to PT and aPTT and activated clotting time. I think we need to upgrade that list to reflect other needs in the clinical chemistry area.

For oxygenation, I was just curious about CPAP and just the supplies associated with that, for diagnostic MRI, I believe was missing, perhaps surgical mesh for incision and wound care, more related to patient and staff wheelchairs are not listed, but stretchers were.

And my only question is having read lately about the importance of laboratory glass for the COVID vaccine, you know, are we going to dive into suppliers that may be providing, you know, treatments or treatments for any type of pandemic that may require certain laboratory glass in order to be an effective drug? So, I don't know how suppliers for pharmaceuticals and certain vessels for those treatments might impact a pandemic.

Dr. Beckham: So, as you point out, I mean I think it's certainly impact. We're focusing this 506J Device List on medical devices and then finished medical devices. So, while I very much want to hear discussions around resiliency today and how those should be, the factors there should be weighed into that, because, obviously, to create a resilience supply chain, you have to understand what those tier 1, tier 2 and 3 suppliers and the tendency there. So, that's certainly, we would like to hear from the panel about how resiliency should be considered. But for the purposes of this discussion today keeping it focused on medical devices and finished medical devices.

Dr. Jennings: Okay, good. Except for the laboratory glass, the others were applicable.

Dr. Beckham: Yes.

Dr. Jennings: Thank you.

Dr. Jarvis: Dr. Tjoumakaris, before you arrived, we all introduced ourselves with our name, our affiliation of what we do; so, if you could do that and then ask your question.

Dr. Tjoumakaris: Sure. Sorry about that. My train came in late. I'm Stavropoula Tjoumakaris. I'm a dual trained endovascular cerebrovascular neurosurgeon at Thomas Jefferson University. And my expertise is anything vascular in the brain and spinal cord.

This actually pertains to my question. I know a little after COVID, we had a profound shortage of angiographic closure devices and we used them for treatment of, for example a patient who had a mechanical thrombectomy, when they're suffering a stroke, not just

neurosciences, obviously a cardiology colleagues with acute MI, et cetera. This was actually confounded by the hurricane in Puerto Rico where one of the major plants, the manufacturer, where some of the main devices was located, and we were in such severe shortage that performing these procedures, often times large bore catheters became very dangerous because we didn't have a safe exit with the closure device. I did not see those listed, doesn't mean that they are not. I wanted your thoughts on that and how do we prevent this double whammy natural catastrophe in the setting of, you know, a pandemic emergency.

Dr. Beckham: I wish I had the answer to that last one. [Laughter] We saw that a lot during, you know, winter storm Uri as well, right, in resins. I will have to; we'll have you get you answer for sure about the specific product codes related to the device you mentioned. And I have to, we can certainly do that. The team is back there. But was it a raw material or was it just pure manufacturing issue?

Dr. Tjoumakaris: I'm not sure, you know, what supply chain issues that the manufacturer had, but I'm sure it was combination of everything because after COVID, we noticed that it was probably a raw material issue and then the plant was hit with a hurricane so combination of both.

Dr. Beckham: Right.

Dr. Tjoumakaris: In terms of mitigation strategies, there, for example, if you have a single plant that is responsible for the greatest majority of a particular device, how do we prevent that and increase resilience?

Dr. Beckham: So, again, another good question. So, at our program at CDRH works across the government to look at different vulnerabilities and identify those vulnerabilities, where there could be one manufacturer in a market with a major market share that if something happened, could, obviously, lead to device shortages. And so, some of the things that we, you know, have at

our fingertips is to work with the industry to help build resiliency. Our federal partners have the DPA authorities on industrial base expansion, if that's called for.

But there are different ways we can work with the industry, whether it's through risk management plans to understand what the risks are within that particular device supply chain, the geographical, lack of geographical diversity. So, it's a complex problem that's really going to involve all of the medical device ecosystem, right, to solve these things. I think where our program and where the FDA comes in to get ahead of those vulnerabilities and risks is to understand what those vulnerabilities and risks are so that we can then look at the variety of options at our fingertips and others to help mitigate those and reposition mitigations, whether that's, you know, another source OUS for a particular product. Global market share, those types of things. That's what our program is designed to proactively look at specific vulnerabilities for patients.

Dr. Tjoumakaris: Thank you.

Ms. Sauer: Thank you. Nancy Sauer, industry representative, a few comments here. This is great discussion. One is we see a little bit of a structural issue in the way, in the focus on product code, certain of these cover such a wide variety of devices, and I'm particularly very aware of the elected surgery platform. And there are within that product code some highly essential and low diversity items such as patient return electrodes needed in, essentially, every surgery. Those, of course, weren't the highest level of scrutiny and proactive approach. But there are others, capital equipment, that are likely to have a 10-, 20-year life span.

And then the actual pencils to deliver energy. Many, many alternatives there with a lot of different shapes, sizes, coatings that manufacturers maintain those to really meet many surgeon preferences, but are they all equally essential, right, and can they substitute for one another? So, I

think industry would welcome a real hard look at whether product code is the most appropriate mechanism.

With regard to the capital equipment as well, it's about really maintaining continuity. We can't scale up things like the capital equipment used in surgery or imaging unless the hospitals are also able to be so linked into their infrastructure. So, I think –and I know– we'll be discussing that later on.

And then, finally, that was a good, right, question, the Puerto Rico hurricanes, those have certainly affected my business and I know other manufacturers, right; can that be prevented? There are so many decisions that go into the focus on a secure supply chain, but I can say that when major manufacturers really are looking carefully across multiple approaches and sometimes that is multiple locations for supply, but also there's a lot of business continuity emphasis on how to harden and protect those facilities that we have that are in areas vulnerable to natural disasters.

Dr. Beckham: Thank you.

Dr. Jarvis: Great. I'm going to have to cut this off. We're going to have time for questions, more questions later. I want to thank Dr. Beckham for an excellent presentation. We're going to take now a 10-minute break. I just want to remind panel members that during the break, please, do not discuss the meeting topic amongst yourselves or with anyone who is attending this meeting and we will resume in 10 minutes.

Dr. Jarvis: Welcome back, everybody. A couple of things. One, some of you have mentioned that you have a number of devices that you'd like to address. Hopefully, we won't wear Dr. Beckham out with these. But we'll try to get to those during the later discussion and we're trying to figure

out a mechanism for if we don't get to every one of the devices that you want to address, for a way for you to provide those so we can get those to the FDA.

Second is, Dr. Schwartz wanted to make a brief clarification before we begin out next presentation. Please.

Dr. Schwartz: Suzanne Schwartz, FDA. Thank you, Dr. Jarvis. Really just two clarifications on points that came up in the Q & A that preceded our break. Number one, a commenter came up with a recommendation regarding inclusion of contrast agent, so, FDA just wants to make the panel aware that imaging contrast agents are actually regulated as drugs. They are regulated under CDER, not CDRH, and while it's important to bring up, we appreciate that, it would not be something that would be inclusive under the CDRH under the 506J Device List. That's one.

The second point that we wanted to make as well was the challenge that was raised regarding use of procodes. And again, to take a look at the actual PREVENT Act, which was included within the omnibus, which specifies, statutorily, that the list be developed with the use of procodes. So, recognizing that's a challenge area but that's not something that FDA has the ability to, you know, to say we cannot do it that way. Thank you.

Dr. Jarvis: Thank you.

Stakeholder Presentation: Medical Device Manufacturers

Now I'd like to invite our first guest speaker, Dr. Mark Leahey, president and CEO of the Medical Device Manufacturers Association. To begin, Mr. Leahey, you'll have seven and a half minutes to make your presentation.

Mr. Leahey: Thank you.

Dr. Jarvis: Good luck. [Laughter]

Mr. Leahey: Thank you, Dr. Jarvis. I'm actually yielding one minute to our friends at AdvaMed. Although I have a juris doctorate, I'm not an MD. So, you can call me Mark Leahey.

Thank you to Dr. Jarvis, to members of the committee, the FDA for inviting MDMA to speak here today. MDMA represents about 300 primarily small-sized medical technology companies. They drive a lot of innovation and really positions engineers working together. As folks probably know, you know, unlike the pharmaceutical industry, there are thousands of medical device companies across this country. According to the Department of Commerce, 80% of the companies have fewer than 15 employees, 98% have fewer than 500 so, this is really, I think, a unique industry. We're a world leader. Our members, just as you all, are committed and concerned patients have timely access to safe products. I had the great fortune of being at MDMA for over 20 years. We've had a lot of wonderful collaborations with FDA over the years. And I think Tammy, Suzanne, and the team, what they had been able to stand up during COVID and help facilitate the interaction with all the different stakeholders to be proactive, identify these issues, and certainly something that MDMA supports.

Candidly, it predates COVID. Go back to the storms in Puerto Rico, issues around sterilization facilities in 2019. These are times when our members saw issues out there related to supply chain and proactively engaged the FDA. And the FDA, to their credit stood up building that muscle. Engaged other stakeholders. I think we have a tremendous track record of working collaboratively here to address these issues.

I think, again, when you look at some of the dynamics here, a large part that is the composition of our industry. Again, unlike the heavy concentration in the farm industry or when a single company has a patent on a molecule and they own the marketplace, the device industry is much, much different. For the most part, there are three, five, sometimes 10 manufacturers

associated with certain products. And there are a number of different sizes, features, others that patients, physicians feel the need for, and the other piece here is, again, when you have five or 10, 15 manufacturers, there's not only that focus on doing what's right for the patient, but there's an issue for the business. And so, if another competitor out there somehow falls by the wayside, they're located in a geographic area that's susceptible to a storm, and the other nine manufacturers aren't, guess what, those nine manufacturers are motivated to go in and pick up the slack and I think that is a corner stone for them to sell products out there that they have that resiliency and redundancy built in.

And that is why I think, again, prior to COVID and during COVID, there is a motivation. I can tell you, there is not a single one of our members that if they see something in their supply chain that's a vulnerability, they're gonna sit on their hands. They want to be proactive because it's the right thing to do for the patient and it's the right thing to do for the business. Again, I really want to commend FDA for the steps they have taken to help build this muscle up, to help facilitate the collaboration and move forward.

Now, as it relates to the list itself, I'm not expert in all the particulars. It's great to have the expertise of you all around the table. A couple things I'd just like to flag though. There are going to be tradeoffs here. This list, I call it “the need to have versus the nice to have.” So, I think as we consider what ultimately makes it on the list, try to have this screen in place that says okay because there's going to be cost associated for the companies to report.

There's going to be cost associated with FDA to review this. So, I think we want to have that lens of okay, let's make sure that this is the right list. Again, I think part of this has to be, again, I commend the FDA, understanding the market share, understanding how many competitors there

are, the geographic manufacturing. It was mentioned earlier, the CMDL, the Critical Medical Device List, MDMA and others were engaged in that process.

And despite multiple efforts that we made as industry to say market share and competitive dynamics should be part of considerations, it wasn't. So, that's the CMDL list that was put forth here. The FDA relied on it, took none of those considerations into play. So, again, we are looking at resiliency here. I think it would be a missed opportunity not to look at the totality here.

Couple other points I'd like to raise. It was brought up earlier about capacity. You know, you could have an issue with the components, but if you didn't have access to capacity, then maybe you don't drive and address those issues. And that's a real concern. And I think one of the things here we've seen is that, you know, capacity function of what is the market opportunity. And, again, I think for the hospitals around the table here, too, if you are looking at this and saying, these are critical medical devices that need to be on the list, our hope would be that you would also say and go back to your hospital administrators and saying we shouldn't be sole sourcing these products. We need resiliency here. We can't put all our eggs in one basket. Because if that resiliency and that opportunity for additional market opportunity for companies isn't there, they can't have lines that aren't running for the hope that something may or may not come to fruition. So, again, this is an issue where all collectively and together, I think we've demonstrated that we got through some pretty extraordinary times. I mean COVID was, hopefully, a once in a century issue. Other circumstances will arise.

I remain confident that the, you know, our industry will remain proactive and engaging with all of the stakeholders here. Again, appreciate our friends at FDA for helping facilitate, but it's all not just the FDA. There are other agencies involved that work with the supply chain, but I

can tell you too, as mentioned earlier, our companies have learned a lot from COVID. They have appreciated the importance of, you know, variations coming up and resiliency, redundancy.

So, whether it's manufacturing locations, whether it's sourcing multiple component manufacturers, this is something that our members have taken very, very seriously. I think we've learned a lot through the process but that doesn't mean there isn't more to learn. So, again, we appreciate the opportunity to be here today. All the hard work that goes into this, again, hopefully, we look through a lens here that is balanced and appreciates all the dynamics, so, thank you for your time today. Look forward to answering questions later in the afternoon.

Dr. Jarvis: Thank you, Mr. Leahey.

I would now like to invite our next guest speaker, Miss Abby Pratt, who's vice president of Global Strategy and Analysis for the Advanced Medical Technology Association to begin. You have seven and a half minutes to present.

Ms. Pratt: Good morning and thank you so much for the opportunity to speak and address this distinguished group. I'm Senior Vice President for Global Strategy and Analysis at AdvaMed. We represent, roughly, 450 manufacturers of medical devices. Since March 2020, I've also been leading our supply chain work. And in this role, I've been working with federal partners to identify supply chain risks that may impact the delivery of patient's care.

So today I'd like to highlight the med tech industry work over the last few years to address a few supply chain challenges and develop systems and collaborative partnerships to better prepare for the next crisis.

And in that context, I'd also like to offer AdvaMed's perspective on med tech supply chain resilience and factors stakeholders should consider, as policies develop, like the ones we're discussing today. Ultimately, resilience initiatives only succeed if industry, government, and

healthcare providers are working in partnership to solve problems, particularly in situations that are complex and fluid.

As we saw throughout COVID, resolving global supply chain issues requires trust among all stakeholders. And a policy environment that facilitates and fosters flexibility and agility. Now at the onset of the pandemic, the AdvaMed members jumped into action, and we've created a COVID-19 supply chain taskforce. Through this group, we worked with the government key stakeholders across the supply chain to understand the public health needs, identify barriers to rapid deployment be it on the manufacturing side, transportation side or the healthcare delivery side and come up with solutions to meet patient and provider needs in the face of the COVID crisis, but also to ensure the continuity of everyday patient care.

So, for example, our companies worked with federal partners to quickly mobilize and ramp up production of critical technology such as ventilators, diagnostic testing, syringes. Some cases involved adopting technology such as a ventilator for a wider variety of uses. When transportation became a challenge with massive shipping delays and container shortages, we engaged port authorities and terminal operators on both coasts to develop a fast pass system where shipping containers with medical products and supplies were prioritized at the ports.

As the pandemic wore on, the supply chain challenges moved further upstream due to a constellation of events, global COVID-related disruptions, severe weather, geopolitical instability, including war, created acute constraints of various raw materials and inputs. Across med tech industry, our company struggled with access to semiconductors, medical grade packaging, helium, and resins, just to name a few areas. We worked with suppliers and federal partners to ensure medical supplies and equipment were prioritized in the face of these massive constraints.

The key to understanding some of the most challenging upstream shortages was real-time coordination. Our goal was to ensure that these upstream issues, whether driven by weather, geopolitics, or public health emergency were resolved well before any impacts were seen at the delivery of patient care.

Now, today in 2024, we find ourselves in a much more stable situation with fewer upstream constraints as compared to 12 months ago. We are also better positioned because we now have enduring partnerships across provider groups, suppliers and federal partners that allow us to quickly step into action as the need arises.

Now, I heard earlier that the medical device supply chain is reintroducing vulnerabilities. Well, I have to say representing hundreds of companies over the past four years on supply chain, I have a very different view. During the COVID crisis and the subsequent shocks I was talking about, companies, providers, the government were working around the clock, relentlessly, in pure, sort of firefighting mode. I would say now, in the past 12 to 18 months, we finally do have some breathing room. Not all issues are resolved, but we have that breathing room to really focus on supply chain resilience.

And so that's what I'm seeing. I'm seeing everyone really lean into that. I'm seeing them introduce greater supply chain resilience. We're seeing partnerships with federal partners, government authorities, direct relationships with suppliers. We're seeing greater partnership within the companies that are hiring more supply chain personnel, standing up new supply chain functions. We're we seeing additional suppliers being identified and looking at alternatives; dual sourcing, multi-sourcing. We're seeing our companies use very sophisticated data to improve their analytics and improve capabilities. And, yes, onshoring and nearshoring is also something companies are looking at, but I caution that's not a panacea as we saw with the infant formula

shortage, which is exclusively produced here in the U.S. I really have to disagree with that point. I think we are introducing supply chain resilience from C-Suite on down unlike any time in the past.

Now, device shortage reporting provides to FDA, in particular is just one piece of that broader picture. Such reporting under the 506J program and FDA's efforts to take meaningful action as a result of the reporting should be tailored to those devices that are critical and in the context of a particular situation and for which FDA and the government can actually make a difference and be impactful. Most importantly, the focus of devices identified for reporting should be tailored based on how the reporting tool can be effectively used during or in advance of a public health emergency. Device types may differ. For example, for one device it doesn't make sense to consider for procurement, for stockpiling, for targeting of onshoring or nearshoring or diversifying of suppliers. It's a very complex ecosystem.

For this reason, there should not be a one size fits all approach. It's also important that these distinctions be carefully assessed. And for this reason, FDA should also consider the option of recognizing a more focused list of devices that are critical in a given emergency or a given situation. We've seen other institution around, institutions around the world take this approach.

In our experience, reporting can assist the government in having the visibility into a particular shortage issue, but the benefit of this visibility extends as far as the government's ability to intervene and help the public. This is particularly the case in a public emergency where resources are stretched. Without a focus on key devices where an impact can be made, there's further risk to straining the system and losing focus on truly critical devices for patients. Another point I want to underscore is ensuring that earnest efforts do not lead to unintended consequences. Imagine a minor supply chain disruption that could easily be addressed, but

triggers reporting and results in a shortage declaration that leads to panic purchasing and confusion, only exacerbating the issue on the road to being resolved. On the other hand, if well handled, we've observed instances where companies have come forward and flagged for federal partners an issue that could have a massive impact and worked in close partnership to resolve the issue before there are any impacts on the healthcare system. There's a lot of things happening behind scenes that you are not aware of.

So, what I'm trying to say is there's a lot of things happening behind the scenes that, ideally, you all are not even aware of, you know, hopefully. Or we have enough information and there's enough collaboration so that providers in government and manufacturers are able to navigate the ongoing issue to minimize the impact on patients.

I realize I don't have a lot of time, but I just want to say what a privilege it's been to work with our companies and federal partners on these issues and to learn from them. And I think, as I tried to, you know, point out today, it really requires a thoughtful process. I like the screen my partner, Mark, talked about, let's focus on what's truly critical and what we can actually solve for, so that we are not boiling the ocean and we're really having a targeted and thoughtful approach. So, again, thank you for your time and your consideration. And I look forward to more discussion.

Dr. Jarvis: Thank you, Miss Pratt.

Stakeholder Presentation: Healthcare Systems

I would like to invite our next speaker, Dr. Paul Biddinger, Chief Preparedness and Continuity Officer for Mass General Brigham. Dr. Biddinger, you have 15 minutes to present.

Dr. Biddinger: Thank you so much, Dr. Jarvis. To the members of the panel, again, thank you so much. It's really an honor to be able to provide a perspective from the healthcare system on this proposed 506J Device List, and in general about medical supply chain device resilience.

Just very, very briefly a word about the system that I represent, it is an integrated academic healthcare system, one of the largest such in the United States. And with admission of patient care research teaching and service to our community, we have 12 specialty, acute and specialty hospitals. Five of which are Harvard affiliated, multiple rehabilitation locations. I will not read the entire slide to you. But we serve more than two and a half million patients. So, I think we have a diverse healthcare system with a variety of perspectives. We're the largest healthcare, largest private employer in our state.

So, to put this in context from the perspective of a healthcare system, I really want to describe not just how communication is so important to the FDA, to the USG partners, that takes such great actions as described previously, but the impact it's having on healthcare systems and, actually, on our patients. Premier, which is a private national healthcare company with which I have no affiliation, just from a 2022 survey, the data indicates shortages are shifting from multi-year pervasive issues to a very rapidly revolving door of persistent new products and categories every month. That is certainly our experience that the pace of shortages, both pharmaceutical and medical devices, I recognize we will address medical devices in this discussion but is accelerating. And I think we're feeling it a lot.

I think, again, communication to FDA, to the USG, to all the partners that can affect these supply chain shortages is critically important but actually transparent to the healthcare systems themselves, to the providers is really important because we need lead time. We need to be able to adjust to minimize the impact on our patients.

It is very hard because as the vast majority of U.S. healthcare structure is private. We tend to not know how our partners are affected. Who are their suppliers? Are they having the same degree of difficulty that we are? And I would say in a significant number of shortages, it's hard for us to know when it's going to end or how much worse it's going to be. We really struggle to get access to information that I think will help us best fine tune our response either individually or with our partners. A little bit less of an issue for a system like mine, which is relatively large, but I think the smaller you get, I'll say more about this in a second, the harder it is to know what alternatives you may have access to. If you're a single nursing home provider or MS agency or a small community health center, knowing who else you can go to for alternative devices, alternative resources is hard and it's hard to navigate this world. We only have connections with a small number or single supplier.

So, there's some data again from relatively recently, this was published 2023, supply chain shortages were right up there, inflation and labor issues, things I think everyone understands, some of the biggest challenges facing healthcare, supply chain shortages are right up there, is a major concern. Our ability to procure the necessary devices, the necessary material to operate healthcare is, again, equal with the major other threats we face.

Similarly, if you look, and this was again a national survey, nearly half of healthcare organizations had to reschedule or cancel medical care at least quarterly, which I think is astounding. I think we're having a repeated and consistent effect of healthcare shortages on the delivery healthcare shortages in this country.

How much time is it taking? It takes an awful lot of time. If you see here nearly 40% said more than 20 hours per week, three FTEs just dealing with consequences of shortages and how to identify product alternatives can serve utilization, reallocate resources in other ways. So, this

is a major concern for all healthcare organizations. I'll tell you within my own healthcare organization, we only recently created a specific division in our supply chain department with three FTEs to work on shortages.

And this is a list of some of the supply chain shortages we have experienced. I recognize, again, I have pharmaceuticals on this list that are outside this discussion, but to show you how many things we've had in shortages. And, I believe, Dr. Morgan had asked in a question earlier about the definition of advance. And, I guess, one specific recommendation I would love to make to this panel and to the FDA is the broadest possible definition or understanding of that term in advance of a healthcare public health emergency.

Because these events are happening constantly, many of the events we are talking about would cause a public health emergency on no notice; and therefore, if I don't know something in shortage, and an earthquake happens or even major hurricanes of which we get a few days' notice of those before we have impact, finally knowing just when an event happens that a product is in shortage, is not nearly as useful as knowing something is in shortage all the time.

I will share with you this specific anecdote, that surgical sterile gowns were in short supply for us in early 2020. In fact, my healthcare system activated our emergency operations plan, was using the incident command system to manage a surgical sterile gown shortage, and we were not allowing certain trainees in the OR because we had so few gowns before the COVID pandemic struck. We actually transitioned from our surgical sterile gown emergency operations into the COVID pandemic as one emergency faded into the other. These things are that impactful. They affect our patient care. So many of the items on the left of that list, obviously, are affected by the 506J List we think is really important for our resilience.

Don't want to go into all of the items on the list, but again I will tell you, even something as simple as a small blue top tube –a tube we use for coagulation studies– went in shortage prior to the pandemic was enough to have us, potentially, look at needing to cancel certain kinds of surgery, particularly pediatric surgery because we did not have sufficient supplies of pediatric blue top tubes.

So, part of the reason I want to explain why I think the transparency that would come from the 506J List early reporting, is that, again, it takes us a long time as large healthcare systems, vast majority healthcare systems in the United States is integrating; and therefore, brings together large number of stakeholders, really hard to get cardiologists and neurosurgeons and anesthesiologists all together to come up with priority lists to figure out what did shortages affecting how we're best going to conserve resources, how we're going to reallocate or identify alternative products. It requires strong medical leadership.

And again, has required us to actually activate emergency operations plan, it alters healthcare systems operations significantly. The IV contrast shortage was mentioned again. And I appreciate it's outside this list, but I think it's illustrative. We had two physicians working full time to allocate IV contrast across our entire system, because imaging, interventional cardiology, interventional radiology, neurosurgical procedures are so dependent on that. It takes away care from other resources. And trying to explain to patients why we are having to change their schedule. Why do we have to delay their procedure requires good clear transmission of information. If we don't have good access to information from the manufacturers, it's hard for us to know what to share with patients, about what they can expect when we can reschedule.

I would say, again, in advocating for increased transparency, which I think this rule does and what the FDA is proposing is strongly in support of, is that trying to allocate resources on a regional basis with healthcare coalitions and others is important even though we lack authorities. I know that's not something that can be addressed in this forum, but I would like to point out the vulnerability of the smaller systems, if we don't have a little bit, both more transparency and a couple other things I would like to suggest in the next couple of slides. Those elements of the healthcare system that are small, community health centers, individual nursing homes are particularly vulnerable when medical devices go in short supply. And without lead time to start to identify alternative suppliers to make, to identify solutions with others in their regions, other collaborators, they can be left holding the bag. And I think we saw this during COVID quite a bit. They were the groups that had hardest time finding N95s, and protective gowns. They were the ones finding it hardest to get even IV fluid flush syringes. And so, I think what we never want to see is crisis standards of care, which is where we constrain our use of resources as we, differently than we would during normal care because we haven't had time to compare, we haven't had time to collaborate. We haven't had time to share.

So, these recommendations are gathered from a number of experts across my system. I offer them up as suggestions for your discussion or consideration. I think really again, creating as many incentives as possible for communication at the earliest possible moment, the healthcare system is complex. We don't react quickly. It's hard for us to identify other resources. As you well know, for most distributors, they tend to prioritize their existing customers over other customers. So, it's hard to switch. If I'm buying from vendor A, and vendor A's durable medical equipment goes into short supply, going to vendor B, I'm going to be second, third, fourth in line. It's going to be hard for me to adapt, even if a product exists.

I will say that our own supply chain and experts say that really a minimum of three months lead time is really important to know for product continuations how we can identify a product. We can't often just swap product A for product B. There is training involved. There's a lot of education to be rolled out and we don't turn on a dime in the healthcare sector. We do encourage and support standardized notification processes, similar to the recall process. We think routing through the FDA is exactly the right way to go and try and make sure that this is as transparent as possible. Again, we think it has to be mandatory, of course. But if the FDA can manage it through central websites, through one single clearinghouse where you can always find what is about to be in shortage or threatened or what's discontinued. I think makes it much easier for us.

We would love to strengthen notification of transition plans. Again, I think this is more relevant for smaller organizations within the healthcare sector. But what are alternative products or practices if something is being discontinued? I know from a commercial or business standpoint that doesn't really make sense. Yet necessary for continuity of healthcare delivery, yet it's necessary. I think for continuity of healthcare delivery.

We think this needs teeth. And I think, you know, there need to be some consequences if folks do not follow these processes. So, it was suggested within our supply chain group for potentially disallowing 510(k) approvals for a year. I had mentioned that importance of centralized information hub, it actually still is pretty hard to navigate this process to find products that are potentially threatened right now. And to know that they're threatened to be able to easily access the information to access up-to-date information so that when additional information is made available about a product that could be in shortage, that it is in shortage, that it's easy to find. And trying to help, again, identify solutions I think is very important. Leaning ahead, there's

been a lot of commentary, I think, that's well appreciated about how proactive everyone is trying to be about looking at raw materials, transportation issues that affect the supply chain.

But thinking about establishing a tool or communicating through FDA how these things might affect us all would be, might be real important. All of us now are so sensitive to supply chains, that when we see severe weather events everywhere in the world we ask, "what could be the consequence for supply chain if we see any transportation disruption in a canal?" You name it, we start thinking ahead. I think to have a centralized tool that predicts for all of us how we might anticipate supply chain shortages I think is really important.

This one is hard, but I would love to at least ask about it. You know, we have now been in circumstance where we have been in critically short supply of some very, very important, either personal protective equipment or lifesaving device equipment that is intended as single use only, but can, in fact, be safely reused.

We think that there is value in working with manufacturers to help design and, actually, promulgate these safe and sterile solutions that can be used during shortages.

It really was left to the healthcare institutions to develop their own processes, to make their own judgments, one by one during many of the shortages that we experienced. And we think we recognize that there are some raw materials, some other challenges that cannot be overcome, but when we have safe alternatives that avoid getting the crisis standards of care where we cannot use the equipment, we think is important.

So, I want to thank the panel for the opportunity to provide some commentary. I really want to thank the FDA for this extraordinary initiative. We think it's going to improve our resilience and we're grateful. Thank you.

Stakeholder Presentation: Healthcare Providers

Dr. Jarvis: Thank you, Dr. Biddinger.

I would like to invite our final guest speaker, Dr. Jacob Collen, Professor of Medicine at Uniformed Services University. Dr. Collen will have 15 minutes to present.

Dr. Collen: All right. Thank you. Just going to make sure I can keep track of the time. Cause I have a tendency to ramble. All right, so, Jacob Collen. My background Is in pulmonary and critical care and sleep. ’'m stationed at the Uniformed Services University in Walter Reed Medical Center. So, as a disclaimer for myself, I’m an active-duty officer in the U.S. Army. But the views ’'m expressing are my own and should’'t be taken to reflect official Army or DOD policy or the policy of Walter Reed or Uniformed Services University. I was’'t going to wear my uniform, but I have to do a presentation with med students in about an hour and a half. If ’'m not in my uniform, it kind of sets a bad example.

And a nice example of these shortages and supply chain is during the pandemic I gained a little weight, and the top end of my pants, you know, just kind of exploded and popped off. And there was no replacement due to supply chain shortages. [Laughter]

That is something that has still not been remedied, a few years later and ’'m still using that excuse. Another thing ’'d like to talk about is, I think for all of us involved, stakeholders, intentions are good, but anxiety is high. And this can cause a lot of conflicts, which can have big implications on the topic w’'re discussing. W’'re going to talk about the 506J List from the standpoint of critical care physician. I work at Walter Reed and our ICU is pretty low volume, actually. During the COVID pandemic, because w’'re sort of a locked-in facility, we did not have a huge volume of COVID patients. Even with that, we were kind of overwhelmed in the

beginning. I think in the first week or two we had 11 patients and found number of issues with supply chain problems that occurred.

I can only imagine my colleagues of large institutions that had probably hundreds of patients in the hospital that they were dealing with. And I also have to use, I realize a lot of civilian institutions in the community, around Maryland, kind of a COVID only hospital for a while. So, that kind of brings up some real-life perspective. An anecdote ’'d like to bring in is, at Walter Reed, when the pandemic, in the first few weeks or months or so of the pandemic, when we were anticipating this massive shortage in ventilators, I was sort of tasked with being on this guideline panel where we were going to look at different proposed ventilators, like portable ventilators that could be made by a number of major manufacturers, and even just private folks making ventilators in their garage, theoretically, like homegrown ventilator solutions like these MacGyver for different type situations. And the stakes were high.

You could get, I think, a couple hundred million dollars from this process. And it was myself and a few other critical care doctors from Walter Reed and some of the anesthesia critical care folks, we were on this panel, we were reviewing all these ventilator prototype, ’'m not an engineer, so I really do’'t know how, a lot of the intricacies of how a ventilator works other than how it applies to my patients. And a lot of time and effort was spent in looking at these, you know, proposals and, so that was sort of one process that was going on. Kind of almost like maybe an overreaction, reasonable reaction, depending on where you sit in the pandemic. Another interesting kind of aspect of this need, huge need for ventilators and anticipated shortcomings, was thinking about ethical decisions that we realize we might have to look at the mechanical ventilator as like an organ transplant sort of situation, like a precious resource. And you'd have to allocate it ethically, maybe withhold it from patients. And many institutions were

looking at developing policies for who you would like withhold therapy from and maybe say, you know, we're not going to give you the ventilator, unfortunately. And I was on another one of this kind of made up sort of panels, kind of on the fly with intensivists and interestingly, no ethicists were involved. So, after we spent weeks, you know, putting together these guidelines, the ethicists heard about it, you were like, wait a minute, why weren't we involved, and this is illegal. You can't, like, make some sort of a makeshift guideline where you're denying care to certain populations.

And, so, some of this is, all of this happened with good intentions. Maybe some of it was driven by a bit of anxiety. Maybe some overreaction. Again, hindsight's 20/20, but it highlights how some of these crisis and decision making can really impact supply chain issues, the amount of equipment that you think you're going to need. You could end up over producing ventilators. Soon after that, we realized that many patients who had COVID, had the hypoxemia phenotype hanging out, and the 85% oxygen and doing fine, and there was actually harms of putting all these people on ventilators, should be a whole separate talk. That scenario kind of, almost sort of a clumsy way, kind of highlights how implications that could happen with something that seems kind of innocuous, like supply chain issues.

So, the way I thought about bundling this talk was thinking about, first and foremost in the ICU when you're thinking about equipment for resuscitative needs, what do you need for resuscitative effective resuscitation? I polled a number of my colleagues, what is a single thing, like most important to you, that you can't do without in the ICU? Thinking about institutional needs, you know, we work with different institution sizes. I think a lot of the speakers brought this up already, considering all your stakeholders. Like, in my experience forgetting about ethicists, sometimes your stakeholders are people you've forgotten about because you haven't

maybe worked with them in a while. And in a crisis, people are going a million different directions, and you don't realize, actually, all the folks you have that could help you.

And then ability, the ability to modify lists, like the 506J List over time almost is like a living guideline to adapt to changes in technology or types of equipment you need. For sort of resuscitation must haves, as a disclosure, a lot of pictures I got from Dall-E ChatGPT program. I said can you make me a picture of an empty supply closet. I realized when I was taking pictures off Google, some of those are copyrighted or some of them have brand names. So, I tried to use this. I've also used this program to help me do my son's math homework, fifth grade math homework.

It's pretty good at that. So, airway, vascular access, hemostasis were kind of the top three from colleagues, sort of categories. Point of care ultrasound is something that comes up over and over again. These are something where a living guideline would be crucial because the ultrasound devices are becoming more and more sophisticated. Smaller footprint. They're getting cheaper. So, your idea of, that each ultrasound would cost 20 to $50,000 10 years ago is very different now, potentially.

Sterilizing flushes are critical and IO access kits. Not everyone knows how to put a central line in. Depending where you're at in a crisis, this wouldn't necessarily be in a pandemic, but at any time IO kits are a huge lifesaver. For the airway, many of us have become accustomed to using the GlideScope, which is huge. I mean it saved me.

But when I talk to colleagues, many of them express the desire don't forget about just your basic DL, older diagnostic laryngoscopy having those available for situations, like maybe you don't have electricity or something happens with the equipment that's unanticipated. And Bougies is for difficult airways, big long flexible tubing, for those not familiar where, if you can

barely see the airway when you're putting in a tracheal tube, you can throw the Bougie in, so you know you have a trach to get your tube down even though your visualization is not great.

And then disposable bronchoscopy, the image quality on these is pretty outstanding now. I mean 10, 15 years ago, anytime I heard disposable anything, I thought it was kind of junk, expensive and the image quality wasn't great, but now it's almost better than non-disposable.

For hemostasis, as a military officer, having to do a tour in Afghanistan, this is an area where there's been huge improvements with industry and so on and so forth, and creating a number of different types of devices, products help with hemostasis at the bedside. We use Surgicel all the time on fresh tracts, where there's a lot of oozing. And it provides, this is something where not only do you need hemostasis equipment, but it needs to be, have the ability to be agile and change that list over time.

Institution capability and expectations, this is something interesting with these ChatGPT programs sometimes, they can sort of hallucinate, so, which is the term when they sort of make up their own phrasing and spelling. So, it gives you a great picture, but then you'll notice a lot of the words are misspelled but better spelling than I would have done.

But this is meant to highlight, and I think a few folks brought this up, the needs in a community-based hospital are very different than the needs at a tertiary care center. On the 506 List, there's a section looking at extracorporeal membrane oxygenation, mechanical device support, continual renal replacement therapy. Some of those you probably wouldn't need in a community-based hospital in a metropolitan area that can send people to a tertiary care center easily. So, you wouldn't want to allocate that type of equipment to a small place. And all the second order stuff, like all extra IV fluids are going to need tubing, and lab capability, and blue top tubes and all these things.

But if you're a community hospital in a remote rural area where weather could impact, you know, impact your supply chain or some other unanticipated crisis could impact your ability to get there. You may need to have a little bit of a more robust footprint of mechanical device support. So, thinking about kind of the second or third order of implications of these devices like ECMO, CRD, you are going to need a lot of Heparin at these facilities and a lot of lab capability, that, you know, for renal replacement therapy to check your electrolytes every four hours. So, there's everything that goes with these technologies that has to be considered. Imaging transport and portability, we sort of talked about every IC needs to have the ability to be portable, chest x-ray for verifying tube placement and central lines and endotracheal placement and all these sorts of things.

Another one that I have not seen around much lately, but portable CTs, so probably in around 2010, 2009 at Walter Reed was a portable CT scanner for all the head trauma that was coming back. Because many of these patients were too unstable to transport down to radiology. And so, having the capability to get a head CT in the ICU with portable capability is huge. That is something that can be considered. Space constraints, there's never enough room in the ICU. I've coded a patient before and then realized at the end that someone who is doing CPR was standing on the patient's chest tube or kneeling on it on the bed, and so that probably, you know, we were coding a patient who is getting tracheal deviation hemothorax through our team or, you know, ventriculostomy, has been yanked out and transported so, space constraints, anything that improves portability and reduces the amount of space in ICU is crucial.

And when you think about equipment that’s on 506J List, part of a living document or process of being able to revise things over time is if you can get a smaller ultrasound, or a

smaller x-ray machine, smaller CRT, ventilators, that improves more bed space around the patient.

We talked a little bit about the disposable devices. This another sort of ChatGPT one that I got because all of the other ones we used had brand names on them. Point of care lab testing is something I had not thought about much until I worked in an ICU that had it. This is something that's kind of a growing literature base on your ability to improve patient care with this, reduced delays in getting labs back. I think this would be something that would be important to have on that list and have the capability to revise over time. Reimagining stakeholders.

In my example we talked about this, you know, how the ethicists were sort of forgotten about. That really could have come in handy in safety a lot of times. Thinking about relationships in a different capacity with our colleagues and your patient population. So, if you are maybe in a rural area where there's a lot of super morbid obesity, that's going to impact supplies that you need. You're going to need more central line kits and lumbar puncture kits that can, with more reach, to go through more soft tissue but you may not have considered in a more metropolitan area where you don't see quite as much of that.

In the COVID pandemic, there was a big uptick in alcohol use, and so if you're going to be in population where there's potentially a lot of alcohol use withdraw coming in, you may end up with an Ativan shortage, which is something that already has happened, kind of recently and is ongoing. And finding sort of other supplies, so you have to think carefully about your supplies and adjuncts to those depending on the population. Thinking also about if you are in an institution that has obstetric care, like some institutions don't have obstetrics and they ship it somewhere else if you're in a place that deals with obstetrics, very low frequency. It's a kind of no fail sort of situation, so you need to be properly outfitted.

And transport is another kind of aspect of agility. Not just the ability to the equipment for transporting patients in general, but equipment for transporting a patient safely from bed to transportation or around the hospital and thinking about those equipment needs was another challenge during COVID. Being able to sort of reduce waste. Are there things we can remove and is there equipment that probably should be revised over time? So, any questions, or we can save those for later. That's the end of my talk. Thank you.

Dr. Jarvis: Thank you, Dr. Collen and all the guest speakers for their presentations. And now do we have any members of the panel who have brief questions for any of the guest speakers?

Dr. Beavis: I want to thank all the guest speakers, Dr. Biddinger, in particular. Your talk focused on discontinuation of a product. We're continuing to run into back orders, and I don't know how that can possibly solve it. I do want to bring that to the attention of this panel, whether that stays at the institution supply chain or whether there should be a more centralized way of addressing back orders.

Dr. Biddinger: Thank you. I think from my perspective, back orders, obviously are a shortage that needs as much lead time as discontinuation of a product. And I think it s historically been very variable about how much lead time we get for notification of a back order. I think the points made about the unintended consequences, when something goes on back order, how everyone adjusts and sort of rushes for the alternatives are valid. I think we still need to do this. And as much lead time as possible is absolutely critical. I think, again, try to standardize back orders, think of them the same way as we think of discontinuation, is just really important for the adaptation. I don't know if that's helpful, that answer.

Dr. Siddiqui: Hi. Quick question for all of you guys. Thank you, again, for presenting. It sounds like, when there was scarcity, lines of communication open between manufacturers, suppliers,

consumers, are those lines hardwired now or is that going to be every time there's an issue you have to come back to reinvent the wheel?

Ms. Pratt: Yeah, it's a great question and our expectation, our plan, is the latter. This is why we're working so closely with FDA and their supply chain resilience program. We're also a part of AHA Supply Chain Council that meets on a monthly basis with 60 hospital systems, maybe more. Yes, there's White House level supply chain resilience groups that are convening in meeting. There're groups convened by FDA and other parts of HHS. And then there's sort of, you know, voluntary partnerships that emerge, but I think the idea and what we've learned is that these need to be enduring, so we might get a little complacent, but they need to exist there, so we can quickly spring into action. [Off mic]

AUDIENCE MEMBER: FDA is important, other folks in the White House ask for Department of Congress, this is kind of all government effort and also with hospital, again, we can do everything about reporting here, but if we still have two large GPOs, you are not addressing resiliency. So, part of this is a holistic solution to ensure that we don't find ourselves repeating the same issues as before.

Ms. Pratt: Supply chains have gotten closer and tighter, so I find better communication between the manufacturers and their customers, the hospitals, then our upstream better communication with suppliers cutting down the number of tiers of suppliers and going more direct. So, when we find those getting tighter and closer and more efficient, but it's not perfect. It's a work in progress. Thanks.

Ms. Sauer: I was a little surprised to hear of discontinuations and customers not receiving any information about it, but I've been working in environments I don't think are that unusual where we are sending outreach on the order of a year. Before any product is discontinued, there's

always discussion, right, of what the alternatives would be, so I'd love to hear some commentary, the regular, something that should be probed, right, why those communications may not be reaching everyone who should be hearing them. I think industry would welcome understanding how to do this more effectively.

Dr. Tjoumakaris: Thank you for your presentations. This question is for Dr. Biddinger. I really enjoyed and I was intrigued with the suggestion to have a centralized information hub. And if you could elaborate a little bit more, that could be a great solution, not just for medical device supply chain, but for other issues. Do you perceive such hub to be institutional, institution based national hub, should patients have access, as you can imagine sometimes anxiety can shift the pendulum against us. What are your thoughts on that? It was very interesting.

Dr. Biddinger: Thank you. I think the suggestion, at least as far as we've gotten so far, is something may be curated by FDA as the recipient of the 506J notifications. But is a living hub again where not just the initial notification, but further updates, it's about the expected length of shortage, alternatives that could be suggested or any progress either acceleration or delays in the return to normal timeline.

I think having it be public is really good. I think the healthcare system is too diverse to sort of have a behind the firewall kind of portal that would be useful. I think it's an interesting point about patients, but I think the first thing most patients–at least I would expect–might do is turn to their physician or their provider and say what does this really mean? And then as long as we have access to the same information, then I think we're good.

It's been my experience that sometimes, and perhaps not regularly, but sometimes people have very different access to different information, there are rumors and people start hearing one

thing and, you know, a lot like the stock market, if we all have access to equal information, we all do better, so, yeah. Thank you.

Dr. Dominitz: Jason Dominitz, University of Washington, and the VA. I have a question for Mr. Leahey and Miss Pratt. When I look at the product codes, they can be quite broad; for example, endoscopes and accessories and, you know, the number of accessories is quite broad. There's hemostatic clips, there's cauterizing devices, there's, even it mentions the lubricating jelly for the outside of the endoscope, and the brushes that we use to clean the scopes.

So, you know, this is incredibly broad. I wonder if you can comment on your perspective of how this might be implemented and how the manufacturers would interpret these codes.

Mr. Leahey: I'll start and let Abby respond.

As Suzanne noted, I think one of the issues here is maybe what Congress put in the procode here. There's a statute piece, that may, I'd like to hear the FDA's perspective, that may provide some limitations on how targeted you could be. But as you noted, I mean right now, to procode, and there's so much variation in place. And Nancy said earlier, this, we're creating a lot of noise here without, I think, getting the key information to the patients, to the providers, to hospitals, so, I think this is something maybe we can work with the collective group here to maybe find a way. If there's too much noise, the current way the statute requires things to be reported, it can be refined, again, as was noted. It doesn't make sense to add a lot of reporting requirements for things that are noise and wouldn't provide value.

Dr. Dominitz: Thank you.

Dr. Jarvis: A question for Dr. Biddinger. Many, if not all hospitals, have contracts, and those contracts are sometimes with specific companies that make a specific device, how do you deal with the problem with one manufacturer that you have a contract with who has a shortage or a

problem that they foresee where your contract basically prevents you from going to another manufacturer?

Dr. Biddinger: I'm going to be a little bit out of my depth in this one. I'll speak from experience than direct knowledge. But I believe that once a supplier's unable to provide the device that we require, according to the terms, we then have pop off provisions where we're allowed to seek alternatives. I can double check that and I can reply to you and the committee, the panel, on this. But we, from experience I know, when we have been contractually obligated to use one supplier, and they can't meet the needs that are specified in the contract we then do go find an alternative. That has not caused a problem previously.

Dr. Allen: Keith Allen from Kansas City. So, there's no question that supply shortages occur, but there's also a component of the artificial creation of supply shortages. And by that, I mean it was not uncommon during the pandemic, for example, in Kansas City they have one health system have an overabundance of a product and another health system had none of it, and in desperate need. So, I don't know whether it's the FDA or regulations or manufacturers or hospital systems, but how do you prevent that hoarding mentality that artificially creates shortages?

Dr. Biddinger: I think it's a great question that I definitely don't have a complete solution to. I would offer the argument that more information and more lead time prevents the hoarding. I think often when these things are last minute that we see panic reactions and sort of attempts to react to uncertainty. The more that I know how big a shortage is going to be, how long it may be, I think the more likely that my systems response will be more measured. I don't think that's a complete solution. I think, to your point, there is a role for public health at both state and federal levels for this. I think that there are other opportunities for collaboration on a regional scale.

But I do think that increased access to information and greater assurance of detail on the magnitude of some of these shortages would help limit, not eliminate, but limit, some of the panic.

Dr. Van Der Pol: My question sort of goes back to one that was raised a moment ago, but it is for Mr. Leahey and Miss Pratt, and that is contracts actually are a real problem. And is there a way that the partners that are the suppliers can start addressing that issue when they create contracts? Because, for example, I work at University of Alabama in Birmingham, and Alabama, which is a smaller state, and our local health department could not get gloves during the COVID pandemic because they could only buy from a single supplier by contract and the health department is not horribly flexible.

So, in that instance, UAB started donating gloves because we were not hoarding, and we recognized the shortage. But the problem comes back in these contracts. So, what can industry associations do to help make these contracts more flexible during shortage situations?

Mr. Leahey: That's a great question. I'll actually read from a 2021 White House report. It was entitled, "Building Resilient Supply Chains Note." This GPO contract practices may lead to limits on diversification of supply. GPOs may contract with certain manufacturers that are willing to pay to become sole supplier. GPOs may also discount to hospitals sole source supplier contractual arrangements, these two-practice business can lead to one or two manufacturers serving the entire regional or national supply chain. So, I would say it's not the manufacturing driving this, it's the GPO because they get a higher fee for having a sole source contract.

Dr. Jarvis: Are there any other questions? If not, thank you, again, to our guest speakers. [off mic] We will now proceed with open public hearing portion of the meeting. Public attendees are given an opportunity to address panel, at this time, I'm sorry, at this time, are there any public

attendees who wish to address the panel at this time? Oops. Sorry. At this time, are there any public attendees who wish to address the panel? Okay. Please.

Ms. Melendez: Good morning.

Dr. Jarvis: Before you begin, I'm going to give it to Mr. Collier here.

Open Public Hearing

Mr. Collier: Yes, good afternoon. I'm going to give the open public hearing statement prior to you speaking. Both the Food and Drug Administration and the public believe in a transparent process for information gathering and decision making. To ensure such transparency at the open public hearing advisory meeting, FDA believes that it is important to understand the context of an individual's presentation.

For this reason, FDA encourages you, the open public hearing speaker at the beginning of your oral or written statement, to advise the committee of any financial relationship you may have with any company or group that may be affected by the topic of this meeting. For example, this financial information may include a company's or a group's payment of your travel, lodging, or other expenses in connection with the attendance at this meeting. Likewise, FDA encourages you, at the beginning of your statement, to advise the committee if you do not have any such financial relationships. If you choose not to address this issue of financial relationship at the beginning of your statement, it will not preclude you from speaking.

I will turn it back over to Dr. Jarvis. Thank you.

Dr. Jarvis: Please, go ahead.

Ms. Melendez: Thank you. Good morning, everyone. My name is Joan Melendez, I'm President and Founder of Xcelrate UDI. To clarify up front, I have no financial interests to disclose.

We inadvertently compromise patient safety in several ways. For instance, patient harm occurs not only through direct device failures, but also from systemic issues such as inadequate identification, delays in issuing recalls, and the continued sale of devices officially removed from the market, including those on 506J.

These problems are further aggravated by our reactive response to device shortages and to disruptions in manufacturing. To address challenges of device shortages and disruptions is essential that we elevate the safety of our patients by enhancing our ability to manage medical devices more effectively.

A key strategy involves establishing a link between the 506J Device List and the global unique device identification database, the GUDID. This link is crucial for improving device identification, ensuring device availability and safety from the time of manufacturing to the final disposition of the medical device.

Embedding the implantable device framework, the GUDID and medical devices, unique device identification, also known as the UDI, offers an example of a proactive approach ensuring comprehensive device tracking and patient safety. Consider the FDA's recall –I'm sorry– consider the FDA's call to action to be recall ready. The challenges managing recalls underscores the need for precise identification and labeling, including the IFU.

Incorporating a 506J flag into the GUDID is vital to ensuring a medical device is appropriate for sale, proof of sale, and to quickly identify and address issues with devices, especially in times of shortages and health crisis. A move towards immediate access to complete device data through the use of medical devices UDI and the GUDID can help facilitate the identification of suitable replacements or a product code is too broad a classification.

The GUDID associates the global device, the medical device nomenclature and appropriate replacement should a product on the 506J be in shortage. The GUDID combined with the IFU offers critical guidance for a device and can help determine an appropriate substitute. Or if a device merely a part listed under the same classification code. The IFU contains every detail about devices from shipping restrictions and storage temperatures from cleaning to prep steps including the manufacturer's contact in the event of a shortage, need or failure. Fundamental elements for patient care and device safety.

In summary, creating a 506J device flag in the GUDID and linking the exact medical devices UDI and the IFU is fundamental to achieving a comprehensive medical device management system. This system not only ensures device safety and availability, but also strengthens our healthcare system resilience against challenges paving the way for a proactive stance for device shortages and manufacturing disruptions and ensuring pandemic preparedness and patient safety.

Thank you so much for your time and attention and for the opportunity to share these important considerations today.

Dr. Jarvis: All right, thank you. Is there anyone else from the public who wishes to address the panel? If not, I now pronounce that the open public hearing to be officially closed.

We will now take a break for lunch. Panel members, again, please do not discuss the meeting topic amongst yourselves or with any members of the audience during lunch. We will resume with the FDA questions to the panel at 1:10 pm. Thank you.

Dr. Jarvis: Welcome back. I'd like to call the meeting back to order. At this time, I'd like to focus the discussion on the FDA questions to the panel. Panel members, copies of the questions have been sent to you electronically and posted online for the public.

I would ask that each panel member identify him or herself each time he or she speaks to facilitate transcription.

I will now turn the meeting over to Linda Ricci who is going to read the FDA questions to the panel for discussion. Thank you.

Working Session 1 – FDA Questions to the Panel

Dr. Ricci: Thank you. Good afternoon. My name is Linda Ricci, I'm the Deputy Office Director of the Office of Strategic Partnerships and Technology Innovation.

We have three questions today. I'm going to go through questions one at a time and several questions have subparts and we'll stop at each subpart for discussion.

Question one: Do the device types, by product code, on the proposed 506J Device List, meet the requirements for critical device as outlined in Section 506J of FD&C Act?

Part A, are there device types, by product code, on the proposed 506J Device List that are not critical to public health during a public health emergency and should be removed from the list?

Dr. Jarvis: Questions?

Dr. Van Der Pol: Barbara Van Der Pol, University of Alabama at Birmingham. I'm not super familiar with product codes, are there subcategories, because I think that someone mentioned, and I agree that the broadness of these codes may become problematic and some subsets may be important others may not, or meet the criteria, I should say. So, are there subcodes that we could subdivide any of these by?

Dr. Ricci: As was discussed earlier this morning, because the legislation that directs us to create this list specifically talks about product codes. We made this list by product codes.

In order to facilitate review, because we do understand that there can be some challenges associated with the broad nature of some of the product codes, we try to describe the types of products that would be of most concern in each of the product codes to facilitate that discussion. We also try to list more general product, by panel, and general name for those product codes. And if you need specific, in order to best answer this question or any of the following questions, if you have specific questions on specific product codes, we can do our best to get you a response.

Dr. Dominitz: Jason Dominitz, University of Washington, and VA. Just to expand on that a little bit. Is there, does the regulation restrict you to these specific codes or I think there might be a necessity to have some subcodes? Because, you know, code ODG endoscopic ultrasound system, gastroenterology, urology, it goes on to describe general endoscopes more than ultrasound endoscopes. There's a little bit of a problem with the naming, matching the description that's in the document we have.

But it goes on to, you know, include cleaning accessories for endoscopes, photographic accessories, non-powered endoscopes, on and on and then there's a lubricating jelly for surgical instruments. It's very broad. And I think you may need to have some kind of subcategorization in order to identify those elements that are not critical to public health. You know, when I look at the list, I'm thinking we need to have all the hemostatic devices, all the foreign body removal devices, you know, the ERCP devices for dealing with stones and whatnot.

I just don't know, for a fact, I know that gets into part B of your question of what needs to be added. I just can't tell what it means by saying accessories. How broad is the definition of accessory and is it too broad?

Dr. Ricci: Understood. And we might be able to get a response from some of our SMEs with regards to, if you have a specific device that you can't tell if it falls into one of these product codes, that we might be able to, we will do our best to get you that answer to make sure, so that you can make that assessment.

Dr. Van Der Pol: Can I just follow-up quickly? I just want to be clear, there are no subcodes is what you're saying?

Dr. Ricci: There are no subcodes.

Dr. Van Der Pol: Thanks.

Dr. Petersen: Paul Petersen, Department of Health. [off mic] One question. So, when you look at, thank you, something like insulin pumps, open to others feedback here, too, but there seems like there could be suitable alternatives, right? And are we talking inpatient care or are talking outpatient care? I'm open to other thoughts, but it seems like if you have insulin drips, insulin you can administer, do you need an insulin pump on this list?

Dr. Ricci: I think that's a great question for the panel to deliberate.

Dr. Siddiqui: Maybe this is a little bit too granular. Under dressings we have general gauze and tape and then hydrophilic dressings, separate category. I guess I would say I'm not sure we need any special dressings, that maybe that whole category can be removed if we have tape and a Band-Aid or gauze to go over that might be better.

Dr. Beckham: So, I did want to mention that one of the items that should be in your panel pack is the device list that is listed by, to your point, Dr. Van Der Pol, by device type and then the product code falls under that we [off mic] Okay. Just wanted to make sure.

Dr. Van Der Pol: Great. The problem is it's not clear to me how we can have a conversation about which ones of these do we leave in or leave out. Or we want to say part of this code and not part

of that code. I understand your constraint with the way that the regulation was passed, so I'm not really sure what the real solution to that is, but maybe some of the bright minds around the table can come up with a solution that is still within your regulatory remand.

Dr. Ricci: I think it would be great feedback for us on all of these subparts to know if there are, you know, critical devices that do not appear to be within the broad categories. Or when looking at these broad categories you know that there might be a device that you would not want on there. I think that would be important feedback for us.

Dr. Cassiere: Hugh Cassiere. Just a step off on the insulin pump conversation, I want to get back to that. We're talking about inpatient or outpatient? And if we're talking about inpatient, we have plenty of patients who come into the hospital with an insulin pump that can transition to other forms of insulin or therapy and then transition them back on their way out. So, if the intent is for hospital and inpatient, I think I agree with our gentleman over there, Dr. Petersen, about, that may, in my mind, could be removed from the list.

Dr. Fischer: Gwenyth Fischer. In a crisis situation, I see high frequency ventilators listed, my understanding is that my adult critical care colleagues no longer use those for ventilation, so if we could limit that down to the probably neonatal infant use.

Dr. Cassiere: Hugh Cassiere again. I'll step off on that, too pretty much it's contraindicated in adults, high frequency ventilation increases mortality, so, I'm going to agree with that, that comment about maybe focusing on the neonate population and not so much the adult population.

Dr. Tjoumakaris: And I just wanted to clarify that during the public health emergency, the insulin pumps we would be looking outpatient as well. Can we address question B or are we still on A adding device to the list or you just want to remove?

Dr. Ricci: Are there more clarifying questions or discussion that needs to happen on question A? If not, I'm happy to move to question B, but I'll defer to the chair.

Dr. Morgan: Charity Morgan, UAB. My question is for these devices that might be like the high frequency ventilation, not critical for one population, but possibly critical for say neonates, is the device list going to specify the populations that the device is considered critical for?

Dr. Ricci: So, with regards to the device list, we will be somewhat constrained by what Congress has indicated that we need to do. But the points that you are all making and the deliberation you are all having about specific populations for which a device may be more critical than another population are going to be valuable for us to understand.

Dr. Van Der Pol: So, while we're on Part A, Barbara Van Der Pol, also UAB, as I mentioned earlier, I think that the media and transport devices, it's unclear if those are broadly enough encompassing. I don't know if there are other product codes that also, because I don't see swabs on here, for example, and the things that we would need to collect things for molecular-based diagnostics, so things that are missing, I think that's the area I would have a concern about.

Dr. Jarvis: Any other questions on A? Then B.

Dr. Ricci: All right. Thank you.

Question B, one B, are there device types by product code that are not on the proposed 506J List that are critical to public health during a public health emergency and should be added to the list?

Dr. Siddiqui: So, one product called negative pressure wound therapy is used in a lot of open wounds, I think that would be a, I don't see it specifically listed and I try to see would it fall under other categories, but it's something that use regularly, and I think it should be included.

Dr. Tjoumakaris: I think I mentioned that a little bit earlier. That doesn't just apply to neurology and neurosurgery, but also cardiology, interventional radiology, geographic closure devices. So,

when we go intravascular, we have to exit safely. So, they probably need to be listed. And there's also, under the retrievers' catheters category, so for a stroke mechanical thrombectomy to remove the clot in the brain.

Aspiration is one mode of removal were you basically place a catheter and apply negative suction pressure to remove the thrombus, more often than not, adjunct devices that are stent retrievers they're called, need to be utilized. It could either be an old catheter thrombus retriever device, I think that may be a little more prudent cause next year when we have a different form of thrombus removal specifying to one particular like catheter, so I would perhaps change that as well.

Dr. Jarvis: What was the name of the clip?

Dr. Tjoumakaris: I'm sorry? It's not a clip, for the first part the closure device. There are different types of closure devices. I don't want to use specific industry mentions, but they would seal the arteriotomy that we would create with a technique. There's an array of them. We need to ensure we have at least the best basic ones so that we can safely exit. And it depends if your femoral, if your [indiscernible] wrist band device. Femoral, obviously, because there's greater concern because if you have any bleeding from the site that could be a life-threatening consequence with retroperitoneal hematoma. And then the other device is, again, for the thrombectomies. There's so many, so I think just keeping it general here would be best.

Dr. Dominitz: Jason Dominitz from the University of Washington, and the VA. I got a few items to consider. Again, I'm not sure if these fall under some of these other broad categories. One would be carbon dioxide regulator and its accessories we use for the insufflation of the colon. And the OR uses CO2 regulators as well. I didn't see that, maybe I missed it. I don't know if this is a drug or a device, but, you know, there's talk, there's a section on automated high level

disinfectant device, category LDS. But alcohol we had shortage of isopropyl alcohol during the pandemic for drying the endoscopes. It may fall under that category.

There's a section KDQ, product called KDQ, talks about vacuum power, body fluid suction apparatus, but it specifically states that it's powered by an external source of vacuum, large vacuum bottles that we use for abdominal paracentesis have been in short supply in the past. And it, you know, the first line of that category sounds appropriate, but when you say it's externally powered, that negates, I don't know if that is falling under some other product code. The accessories endoscopy, I know I mentioned before, hemostatic devices, there's a broad array of those, so we need to make sure we have devices, including now, hemostatic powders that I think the gentleman from NY he showed in one of his slides. And then older tubes may be an endoscopic accessory we use for the safe intubation of the esophagus and foreign bodies and other types of procedures.

Dr. Jennings: Lisa Jennings, University of Tennessee. I mentioned these earlier, and I certainly yield to my physician colleagues to make comments. One that the stakeholder mentioned, in particular, was the oxygenation, the CPAP and supplies associated with that. I didn't see the MRI, so I question that. For surgical, whether there needs to be some sort of surgical mesh on the list regarding patients and staff. Stretchers were there, but wheelchairs were not.

So, we talked a little bit today already about being able to mobilize patients for relocation or for healthcare. And then for either the pathology or clinical chemistry, there's really nothing associated with complete blood count, such as, automated hematology analyzers or any way of coagulation status, other than PT and aPTT. So, a coagulation analyzer should be considered as well.

Dr. Siddiqui: Sorry. Aamir Siddiqui again. There's only two sutures listed, both braided. One is silk. I would say that most of us don't use that regularly, so we probably need a broader menu of suture material. And the other thing I noticed was, for long bone fractures there's no plating. A mass casualty would be important to have some way to stabilize patients.

Dr. Cassiere: Just a question about the CPAP. It has here, under mechanical ventilators it has a QBY positive airway pressure system. Do we have any more granular detail than that? Does that include BiPAP and CPAP home machines, hospital machines?

Dr. Ricci: I do not believe that that includes CPAP and BiPAP specifically for the home use machines, but we will clarify.

Dr. Cassiere: Because if not, I would venture to say that any bi-level blood pressure machine should be on the list. And that could go, we can use that for BiPAP and as a CPAP and kill two birds with one stone, so to speak.

Dr. Jarvis: Let me just mention several items, I don't know if they are considered under a cardiopulmonary bypass, it doesn't seem like it –devices there with bypass surgery and bowel surgery are an essential item. With the intravascular catheters, we talked a little about this earlier, about kits. But needleless connectors don't seem to be on the list and that's a pretty integral part of most intravenous catheters these days.

I wonder, in terms of the automated, it seems like automated machines actually may cross a lot of different areas here. And I notice that you, under colectomy and other types of testing, you literally are limited to 11 chemistry tests, that's it. So, there's a lot that are left out. And if there was a reason why some are in and some are out, in of terms of chemistry, also already talked about hematologic and coagulation, but I would think also for microbiology a lot of

automated machines, responsible for organism identification, what's included what's not included.

Dr. Dominitz: Jason Dominitz. I have a couple more. In terms of kits, we do large volume paracentesis where, you know, is it critical to have a kit or not? I think it's a bit of a judgment call. There's issues of sterility where it would be nice to have maybe really important to have, so, something for you to give some consideration to.

And then, categories MQR and MUM are respectively stent colonic metallic expendable and stent metallic expendable to adenylyl. But then descriptions that are in a separate document we got, not the simplified document, they both talk about esophageal parenthesis, when one is colonic, one's duodenal. I don't know exactly what that annotated document means to the, you know, the market, what they're going to see, but I think we need to have a whole array of stents from the esophageal to the duodenum to the colonic tract to lumen-apposing stents. We need to make sure we include all those various types and that the annotation matches whatever product codes you have.

Dr. Tjoumakaris: Stavropoula Tjoumakaris again. A few more that I notice that are missing for neurosurgery and neurology, a cranial fixation system, so after we perform a craniotomy, we need to replace the bone flaps, we need the plates and screws for that.

And also, I'm trying to find under general surgery drains, I don't see simple or complex drains, whether it's bulb suction and, too, for plastic surgery. Obviously, they have different vacuum suction, et cetera, so we should probably include those as well.

Dr. Fischer: Gwen Fischer from U of M. Just to add to the drain list, thoracostomy tubes might be included in one of these more general terms. But chest tubes are meant to stay in place for a few days or weeks. Pericardial drains, same thing. Interosseous needles and interosseous drill

kits and just, and bubble CPAP, which is specifically used in neonatal ICU for long term respiratory support for infants.

And just a general comment about the generality of these codes not reflecting sizing. So, basically, anything that has a lumen or tube would have to be downsized. As for pediatrics, considering a relative shortage of something that might be pediatric size.

Dr. Cassiere: Just a couple of items. There's a device called an ACT, a device that measures the activated clotting time for patients on cardiopulmonary bypass, ECMO I think would be required. And for my coagulation colleagues, some centers rely on the thromboelastography, which is a separate device for measuring complex coagulopathies, especially with liver and cardiac cases to put that on for consideration. And the other thing that I notice, there's a section on pacemakers, but in cardiac surgery when patients have valves done, especially dual valves and reops, there's a specific type of pace, epicardial wires that get sewn to the heart that come out externally pace patients. Those are truly life requiring, especially with surgery.

Dr. Beavis: Kathleen Beavis, University of Chicago. For microbiology collection devices, swabs have been mentioned a few times. They need to be swabs compatible with the FDA cleared and approved items that are on the market. I also didn't see blood culture bottles mentioned. If it could be expanded to that. And for a lot of microbiology we're moving from traditional culture techniques to what I'm going to call multiplex panels and they certainly need to be available. Multiple manufacturers, but it's for rapid PCR identifications of organisms causing problems in the CSF, the GI tract, respiratory, joints, infections and so forth.

Dr. Tjoumakaris: Along the same lines with the ACT machines, I would add on antiplatelet, devices to measure the potency of an antiplatelet. We do it for Aspirin, we do it for Plavix and a lot of the other antiplatelets out there. They are really defining the way we can check for the

potency of the medications prior or after stenting, whether it's intracranial, cardiac, carotid, et cetera, but they need to be included.

Dr. Ricci: Can I ask a clarifying question on some of the chemistry tests that we, that you all have discussed and brought up and indicated that there is a set that are included in our list? What I think I heard, and I may have misheard is that it is unclear if that set is adequate or are there specific additional chemistry tests that you think would be helpful to add on to the list? I just want to make sure that I get as specific feedback as we can get.

Dr. Jennings: This is Lisa Jennings. I don't think you have listed like the hematology analyzer or the coagulation analyzers that would be necessary to conduct the tests that are needed. You've got some certain tests listed like PT and EPPT and activated clotting time, but these would not, you know, provide a full picture such as a complete blood count or some of the needed tests for understanding clotting status, for example.

So, I think you are missing some of the analyzers from that perspective. And the antiplatelet function test, certainly for patients who may be on certain medications that target platelets, some information about platelet function would be important.

Dr. Cassiere: To get a little more granular, we need a test called the P2Y12 assay, and we also need anti-factor Xa activity. A lot of health systems have transitioned from EPPT to that measure to check the therapeutic range of anticoagulants. Those are two specific things. And patients on medical devices such as Impella, ECMO, it's Fibrinogen would be invaluable to have that level as well.

Dr. Jennings: Fibrinogen levels and D-Dimer.

Dr. Jarvis: I guess a more general question, on your device list you have the device type, the product code and the product code preferred names. I suspect within FDA you have another

column that would be listing all of the things that are under each of those code names. Is there any way that the manufacturers, our committee, if you put this out to Federal Register, that that is going to be provided so that I would know under product code BYX, product code preferred name tubing pressure and accessories what is included in that and better be able to tell you get rid of this, keep this rather than you asking us all under a category and we don't know what's in the category, which makes it very difficult to answer A, B and C.

Dr. Ricci: Very fair point. I do understand that procodes are broad for sure. The information that we have provided is the description of what is in that procode. There are examples of devices, of specific devices that are cleared under those procodes, cleared or approved under those procodes that we can do searches of in our database and that would bring up like every 510(k), for example, that has been cleared under a particular procode that sometimes can help with the specificity of the types of devices that are in that procode.

But we provided you all the information that we use internally as well in the description of procodes.

Dr. Beckham: Can I make a clarifying comment, too? So, there are some items that have been mentioned, specifically, hematology analyzers, coagulation analyzers, so some of the testing of equipment that are, that is the equipment itself, we agree that, obviously, those are critical to performing the test, but we also, just so the panel is aware, we looked at other items as well. So, are those machines more likely to be resilient from a supply chain disruption?

And so, when we created the list, we looked at various different factors, so that we were able to scope, which has been mentioned earlier in the list, so, while we agree that there are analyzers and other types of testing equipment that would be critical, we also felt that those were

more resilient to supply change disruptions. So, I just wanted to mention that, because that also carries over to other things, like other types of capital equipment and so forth.

Dr. Jarvis: Can I follow-up just with a question to that? Earlier we heard from the manufacturers. I guess a couple of times market share came up, and I'm wondering, does FDA actually have information on market share for different medical devices? For instance, you know, when I think about the issue of heater, cooler devices, micro bacterial infections, I think a factor in FDA's response was the fact that the problem was with the device. It had 60% market share.

So, if you said take that off the market today, there would be a problem. Do you have that information for all of these devices, so for instance, the speaker from Mass General Brigham raised going from you have a contract with X company. You have to stick with them. They have a problem. You need to get it somewhere else. Does FDA know that that company has 80% of the market share and you're going to have trouble getting it?

Dr. Beckham: Yes. So, we do evaluate market share. We have access to data sources that provide market share for these devices. We understand. That's part of our impact assessment as well, what I was talking about earlier. So, if we know that there's going to be an issue with the supply chain's specific manufacturer, we are able to look and see across the market share who else produces, right and who else would be able to maybe fill that void during that time. We do a lot of work in that, in our impact assessments, and that's part of our mitigation strategy as well. That was factored in, by the way, those types of things were factored in. Because I said we ran it against a set of strict criteria first. Then we looked at a variety of resiliency factors. That was one of the resiliency factors was market share, geographic diversity, as well as increases in demand. All of those things were taken into account.

Dr. Jarvis: Thank you.

Ms. Diaz: I have a quick question. So, is there a system in place with the FDA for devices on the list that may be recalled or discontinued?

Dr. Beckham: Manufacturers under 506J must report the discontinuances as well. We post those as well as the shortages. We do evaluate, you know, medical product recalls for potential shortage issues and shortage impacts. We do the same kind of impact assessments as well. Not on every recall, but, again, going back to that market share, what does that look like and how is it going to impact the supply chain and availability to patients.

Dr. Schwartz: Suzanne Schwartz, FDA. I do want to expand a little bit on what Tammy mentioned right before and we're going to get into this with question number two. So, I'm jumping ahead a little bit but asking panel members, as you have mentioned, a sizeable number of other products and devices that would be considered critical, life sustaining, lifesaving or needed in surgery, were you to be aware that there are not particular vulnerabilities with respect to, again, market share or other issues that there is sufficient resilience in the supply chain, would that in any way alter your decision in terms of whether they belong or not on the 506J List?

This is kind of what we we're going to be asking you to overlay or think about in terms of ultimately where we want to get to on the 506J List. It's not merely just the definition provided in this, in the statute, but also, we do need to scope down this list, otherwise, it will be ultimately almost every single device out there. We need to be able to identify other factors that would make, in particular devices, it absolutely necessary for life sustaining, you know, lifesaving and, you know, critical for surgery, critical care patients, but in addition to that, where there may be, you know, vulnerabilities associated with the supply chain. Those vulnerabilities were not on the table, would you consider the particular products that you mentioned here not necessarily needing to be on the 506J List?

Dr. Jarvis: I guess a question for you related to that. If we think back to COVID, the biggest problems were N95s. Multiple companies make them. I don't think there's one that has a huge share. Gowns, the same issue. How do you deal with that, you know? You wouldn't have predicted that. That would have been a problem.

Dr. Schwartz: Suzanne Schwartz, FDA. Our understanding of the market on the PPE side, particularly around respirators, was that it was a pretty consolidated market to begin with, particularly around the domestic side. There was a lot of efforts towards industrial based expansion when that was recognized. And we actually had a number of emergency use authorizations to allow bringing in a lot of respirators from outside of the country for that reason while industrial based expansion domestically was being built up.

But, you know, I'm not sure that that is an example, specifically, I would point to. What I would say though is, as Tammy mentioned, we are trying to kind of factor in other considerations in terms of availability, what the ability to supply, to meet demand, particularly during a public health emergency. So, those factors become, you know, critical to the calculus of what we are putting together in the 506J List.

Dr. Beckham: Can I just add. Sorry, Tammy Beckham, FDA. You know, when you take a look at that how are we, geographically, reliant on other countries. Suzanne brought this up, but we are, we are experiencing, even today, and this gets back to some things that were said earlier, shifts of domestic manufacturing back overseas, so, how does that make our supply chains vulnerable? And would you consider that as well? Those are some of the things that we look at. Because we saw, during the beginning of public health emergency, there were export resurgence and that impacted our ability to have access to those materials and products.

Dr. Ricci: Would it be beneficial if we switch to that question now to discuss the resilience and the vulnerabilities in the supply chain?

Dr. Jarvis: Two more, then we'll move on.

Dr. Van Der Pol: Barbara Van Der Pol, University of Alabama at Birmingham. Quickly to say something about C before we leave this one, because I doubt we'll get back to where we are. I think that this has sort of been mentioned and I know I'm an ID person, so I harp on infectious diseases but, if you look at the COVID thing, you know, how critical were those diagnostics to management of every single procedure that happened in your facility.

So, I think that's an overarching supply that's very limited on this list. And so, when it comes to when additional devices would be needed, I think we need a universal transport device that can handle any kind of nucleic acid testing, so that it's not specific to any one particular company that's out there and it takes away some of that vulnerability if that company has supply chain problems.

And so, I mean, I think there are solutions that we could put in place that would help with our preparedness. I don't quite have the capacity yet, I'm still blond, not quite all gray, I can't wrap my head around where that falls into all of this. So, I'm not sure if there's a specific product code that's missing or if that's a device that needs to be created. I'm not really sure where that goes, but I'll throw it in.

Dr. Ricci: Thank you.

Dr. Carrino: Hi, John Carrino, Weill Cornell. So, FDA mentioned then in terms of understanding what we should suggest in knowing supply chains we're not really aware of the supply chain piece on the medical side, because we can certainly make recommendations on the medical side, and I thought it was the FDA's job to figure out the resiliency part or which are the

manufacturer's parts. So, on imaging side, so with question C, I see MRIs are not on the list and I thank other panelists for adding that. And that would certainly be something we would want to be, should I presume that it wasn't on the list because the FDA feels MRIs are resilient enough devices that don't need to be on this 506J list?

And, you know, how would I have known that a priority to the meeting and I should just make, make a recommendation to see if we should include MRI and given other discussion, MRI compatible support devices, which are different than the ones you would use in general environment, things that are safe for magnetic environment, they would then have to be on that list, whether those devices are made here, there, somewhere, if they're resilient or not, I would have very little idea other than we purchase them, but we don't know all that other stuff.

Dr. Ricci: That's a fair point. So, this first part of this question really is trying to understand which devices, you know, really meet definitions that we have described. And then when we get to question two and we start talking about the resilience, that will allow us to understand from the panel's perspective, how we would do that overlay.

Dr. Dominitz: So, the distinction between a device and a drug sometimes alludes me. You guys talked about saline flushes, which sounds like a drug to me, but could be a device. And so, you know, we've had our share of water shortages recently that has impacted us and, you know, I don't know if that's a drug or device. We've had many drug shortages, for example, Midazolam. So, I just wonder, so two questions, is it water or a drug or a device? And so, two, is there a similar process for drugs that's being undertaken by the FDA?

Dr. Ricci: So, there is a similar CEDR drug shortage effort, drugs have longstanding authorities in the drug shortage arena. So, are they convening a panel like this, I do not believe so. Their

authorities are a little different than ours. With regards to sterile water, we will get a direct answer for you on sterile water.

Dr. Jennings: Lisa Jennings, University of Tennessee. I think your question about some of the analyzers that were mentioned, I think that my experience, at least, the laboratory has been that, you know, there's not a huge inventory of these types of analyzers. And the other issue with that, though, is that you may have the analyzer, but you may not have the reagents to do particular tests that you would like to do.

Second thing with platelet function testing, you may have the machine to test, but the cartridges that you need may be on limited supply. So, that's something, I think, to tease out. It's very, a lot of detail to work through.

Dr. Beckham: Tammy Beckham, FDA. You're spot on and we do have many of the reagents and carcinogens, but going back, also sometimes they're for proprietary purposes of it, analyzers, so that's where it's not [off mic].

Dr. Van Der Pol: Can I throw one last comment in here before we leave this whole topic of question number one? And that is it sounds to me like part of what I hope you are all hearing at the FDA is that product codes need to be revamped so they're not so broad. And I know that's, I'm not saying, if there's 284, where there need to be product code, you know, A, B, C point one or point two or point three, things that fall under that. Otherwise, this decision making is next to impossible to do.

Ms. Sauer: Thank you for that. This is Nancy Sauer, industry representative. That's akin to what I wanted to; this discussion has been interesting to hear the medical colleagues struggling with the codes as much as we are in industry. As a regulatory person, I understand how these came in to be and how products proliferative underneath them through the regulatory process. So, I fully

appreciate that Congress handed you this structure. So, our initial efforts are going to have to work through this. But I think there would be great value, right, with FDA industry and the medical professions working together.

First of all, going to Congress and get this ramped up in a different way and then work together to identify those items, whether it's a pediatric size, whether it's a specific piece of surgical equipment or et cetera, so that when, when an emergency does arise, right, you are able to prioritize appropriately, right, and manage that noise to signal ratio. Because I'm just very concerned about the ability for this to be effective, right, with such a population, or even with some of the exemptions that you have already put in place through your own analysis.

Dr. Tjoumakaris: If I could add on to that, Stavropoula Tjoumakaris, Thomas Jefferson University, equally important to the 506J Device List is perhaps an adjunct list of necessary and vital devices to operate on an emergency basis that don't have the high resilience, they don't have the issue, potentially, because a lot of devices that you're lacking on the list perhaps have been investigated by the FDA and deemed resilient. And so, we need to, A, ensure that we have that list. And B, that it's a dynamic list. It is updated, you know, perhaps on a weekly basis, as we know, that was quite optimistic. [Laughter]

Updated frequently, right, so just to ensure resilience, right, can change overnight depending on geographic locations and everything that was mentioned in the presentations today.

Dr. Beavis: Kathleen Beavis University of Chicago. And I'm going to come back to my least favorite topic again, which is swabs. Dr. Van Der Pol mentioned the possibility of universal transport device. Many of us use BTM. But some of the challenges with swabs, is that many of them are proprietary to the particular manufacturer. And when we encounter shortages during the pandemic, I had lots of people bringing me swabs that I was trying to do an off-label validation

in my laboratory from 3D printers to cotton on sticks, to things you wouldn't want to stick up anyone's nose. It was very challenging. So, you know, I like Dr. Van Der Pol's suggestion of uniform transport material, but if we could have a swab that would work with all the different vendors, that would be great, too. Thank you.

Dr. Van Der Pol: [off mic] I include that in word device.

Dr. Morgan: Charity Morgan, UAB. Just to sort of piggyback something that was just brought up about the device list needing to be a living list, does the FDA, at this time, have an idea how frequently the list will be updated? Because, as noted, if we're basing inclusion on the list, it's critical to public health but how resilient it is, that is going to be, today, this is resilience, this is the market share, making something completely different a month lately, so how quickly does the FDA anticipate being able to update the device list?

Dr. Ricci: That is definitely a great point. You know, we don't anticipate that this list would be developed once and never revisited and it is something that we will need to work out with regards to what is the right cadence for reviewing and updating this list. You know, I heard one vote for weekly.

Dr. Tjoumakaris: At neurosurgery, we tend to be pretty high-strung.

Dr. Ricci: I'm trying to see, I don't know that there's a better place to address that. If there are, if other panelists have suggestions on frequency of update, you know, what would be too long of a period? I mean I know it's difficult to say and we would all like it to be up to date as often as possible. What would be a time period that is, perhaps in your opinion, too long to go without revisiting?

Dr. Tjoumakaris: Since I started this fire, Stavropoula Tjoumakaris from Thomas Jefferson. I think definitely biannual, quarterly would be really great. [Laughter]

Dr. Ricci: Probably a little off topic here, so I apologize for that.

Dr. Beckham: We've seen, can I also, Tammy Beckham, FDA, so we've seen, I mean depending on the supply chain issue, we've seen market resilience taking up, you know, up to a year or even more, depending on the supply chain issue, right. So, if you take a look back at what happened–I mean that had a long tail on it, right, a couple of years probably. There are other ones where you have more immediate constraints that will resolve themselves. And I think that, those are all the things that we take into consideration when we're looking at that.

Obviously, those types of things need to be weighed in too, how often, in addition to the resources to do that. Do we need to be flexible? Do we need to be agile? I would say. And our updates, but that was just a point I wanted to make about resiliency.

Dr. Dominitz: In terms of upping, this may be off base, would it be possible during the 510(k) clearing process to have a consideration of whether or not devices should be added to the list as they're cleared, so that prospectively they're easier moving forward?

Dr. Ricci: Thank you for that feedback. We can certainly take that back.

Dr. Allen: Keith Allen from Kansas City. I'm going to take a contrarian view. So, I think it's fascinating to see at a 30,000-foot level to hear what we are asking the FDA to do and what we're asking industry to do. It's impossible. It's not realistic. So, what the FDA wants is a concise list of what is essential if we had a thermonuclear war.

What is essential if we had, you know, some horrible plague that was killing people? We don't need ECMO devices to put people on ECMO, because we are going to triage those people and they are not going to get care? Do I, as a vascular surgeon, do I need a closure device? No, I need suture and scalpel to cut down and fix that artery.

We really have to think about you are not going to be doing elective cases where you're using biologic mesh to fix elective hernias. That isn't realistic. And we can't ask the FDA, and we certainly can't ask industry to have a list like that. So, we need to be realistic about what we're asking for and what really is mission critical to care for patients in a national emergency.

Dr. Morgan: Charity Morgan, UAB. A couple things about the issue of feasibility. I think that it was mentioned earlier that there are different mitigation strategies for the devices. So, this list is just which ones get the notification that there is a shortage or possible shortage coming up. It doesn't mean that the FDA is going to take action because something is, another issue pops up, it may be deemed that this is the current public health emergency, this the critical device is as important for this in healthcare emergencies. So, we don't have to ring the alarm bells just yet. We can notify hospitals that shortages may be coming.

But I think that every device on this list would have to be treated equally in terms of how it would be used during public health emergency or how the FDA would respond to this possible shortage. And then the other thing I would say is that it sounds like the clinicians on here, the ideal timing for upping the list is something that's completely not feasible for industry and for FDA.

In that case, I would say that when deciding which devices should go on the list, that we don't weight it so much by these factors that can change. So, if a device is critical, but it has the idea what the market share it says, well, the market share is fine, so it's, we think it’s resilient. Since resiliency can change faster than this list can be updated, maybe don't make resiliency such an important aspect of whether devices get included or not.

Dr. Carrino: If I could follow up on her statement. Hi, John Carrino, Weill Cornell. Yeah, so there's a master list that's going to be parsimonious and really critical what's needed, then that list

will have attributes that might include an attribute would be resiliency, and therefore, if it's resilient, then you can filter that out as not being the concern for resiliency.

Dr. Tjoumakaris: I can actually answer, Dr. Allen, because I think that's a great point. I believe, and I'm not sure, forgive me for my ignorance, whether there has to be a graded process of these devices. To answer, we have a thermonuclear war, all I need is a scalpel. It would be nice to have an aneurysm clip, but I may not have that, right? So, I can coagulate. My point being, that's a great idea, should we grade, not to add more complexity, but devices for these extreme catastrophic situations versus devices early in the pandemic and, Charity, I loved your comment, a lot is to be transparent and giving that time, the latency, so that supply chain health systems device manufacturers can respond.

Can we grade these somehow into an absolute necessary, you know, down to, you know, it would be nice to have a closure device. Again, not an extreme public health emergency. Are they graded within the FDA or...

Dr. Ricci: Currently, the list is not graded. Currently, it is a list that where we follow the statutory criteria, overlay it a little bit with some resiliency factors. So, thinking about, you know, how we could grade a list, we'd have to certainly take that back, think about it.

Dr. Tjoumakaris: Because then a lot of devices, perhaps 80% of this list, again making it manageable, perhaps we should address level three dire situation and then move down. Yeah, it would be great to have a PY12 assay. We may not have that. And you know what, we still did intracranial stents and cardiac stents without it 20 years ago. It's less safe for sure, but in the setting of a catastrophic event what do we really need? Perhaps that's what we should be asking.

Dr. Jarvis: Can I get a show of hands of the panel members, following up on Dr. Allen's issue, who would prefer to have a very, I'm not going to let manufacture vote, because I know what your answer is, relatively small list of really critical essential devices, versus, okay.

Dr. Carrino: Is that the end of the question? [Laughter]

Dr. Jarvis: No. No. Part two is, and I'm not going to see very many, apparently, a large list like we have now, which has everything that, well not everything that everybody can think of, because we've added another 50, at least here at this meeting. Bacause I think that the smaller the list, the easier it is for FDA as well. If you have this huge list, it's, obviously, an enormous burden on the manufacturers and on you. You're going to have to keep adding to that list, assessing what comes off that list, what goes on that list. And dealing with all of the little shortages that come up that are nothingness. Start here and we'll move this direction.

Dr. Morgan: I think we heard from Dr. Biddinger, the guy from Mass General, that they are dealing with shortages all the time, constantly. One shortage ends another one starts. So, I think that we have a broad scope of possible public health emergencies. They're not all going to be COVID. Sometimes it's an earthquake or a train derails carrying toxic chemicals, hopefully not thermonuclear war. But I think I vote for the broader list, just because it seems like that's the world we're in, where the shortages are happening. They pop up quickly. Industry and health industry has to deal with it and by the time they fix one emergency something else is coming up.

So, I think having a list that's too narrow doesn't help as much as a list that's too broad would slow FDA industry down. I mean it's going to be a tradeoff either way. I think a broader list with expectation that FDA will have to decide for themselves when an earthquake comes in what sort of level of response is required so you are not going, you know, red alarm each time a shortage pops up, but you want to know what the shortages are happening so that healthcare

systems can be notified, even if their response is going to be just keep an eye on your stock and that's all we're going to do about it right now.

Dr. Allen: Keith Allen again. I'm going to frame it a little differently. So, a broad list allows you to try to conduct business as usual in the setting of a national emergency, and that is not possible. That isn't what we should be trying to do. We should have a very narrow focus list that can be executed and implemented that's reasonable, that allows us to survive and care for patients, not the way we would normally do it in a non-emergency, but to get the most people to the end of the day and have fewer deaths with mission critical items. It doesn't do us any good to come up with an elaborate plan that nobody can implement.

Dr. Beavis: Kathleen Beavis, University of Chicago. There’s two challenges. One is the one that Charity and the others, the gentleman from Mass General were describing, we daily get a list of things that we're short of, whether it's erythromycin or whether it's blood plates, but our charts here, at least according to these questions, is during public health emergency and to me that's biological, it's chemical, it's thermonuclear.

So, I'm very much in favor of putting together a shorter list that will be manageable. That if we were to be in that situation, resources could be, hardest to actual meet those ends. Thank you.

Dr. Cassiere: Hugh Cassiere. I think we are being asked to look for a spectrum of response. We put plenty of patience on ECMO during COVID and saved a lot of lives. We were limited by supplies of CVH machines, supply issues and all the equipment that goes with it. So, we're not, we shouldn't look at this as a thermonuclear war. What do you do after that? Who cares who goes on ECMO? We're talking about a national emergency, COVID, where we were limited by supply.

And again, I'll restress, we did not do care as usual, we gave the best care we could. The limiting factor was supply. So, again, I will be contrarian to the contrarian that we should keep the list broad. And it's the FDA's duty to look at what that list is. We're recommending what's critical for my care of my patient. I'm not worried if it's a nuclear war or if it's the next virus that comes out. You're asking me what I think needs to be on that list to take the best care of my patient and that's why I think we need to keep the list broad.

Dr. Jennings: I don't think there's been really too many things suggested that are out of the maybe realm of need. I think that maybe some certain tests were identified that can be done without during an emergency, but many things that were offered I think probably belong on the list, it's just a matter of understanding what each code really represents.

I think it's a clarification of the codes, as well as what fits under those codes, as well as the things that have been mentioned today, some of them do belong on the list and others can be eliminated based on the criteria that, for example, that Keith and others have stated.

Dr. Petersen: I would just say also being really clear on what our charge is, if the charge is to communicate with the provider community what you are not going to get then we need to have a plan on how to make this actually operational. We have to do something that can actually be executed on. I think having a list of however many hundreds of devices makes that very difficult for FDA, for this group to discuss. So, whether it's typing or doing some sort of scenario-based listing of each of the devices, there needs to be some way of stratifying these things. But you know, kind of epi mind, you don't want to lose the data, right. You don't want to lose all these device types. But you have to be able to filter that down to be able to know what to focus on in the emergency that's before you.

Dr. Van Der Pol: I'm sort a middle of the road person here. Again, I think the most critical point is to say exactly what the point of the list is. Because like we were talking about the person from Mass General talked about the shortages he was dealing with prior to COVID and shortages he's dealing with now, that's not the charge of this group. This group has focused, according to my understanding, on what things are critical during a public health emergency.

And you are right, Dr. Allen, it depends on what that emergency is. And it depends on if we are trying to survive or thrive, so, that's why I'm kind of in the middle. But I think if anything is too broad, everybody looks at it and just goes, I can't cope with this. So, either nobody is compliant with it, or nobody reads it when it hits their inbox. So, we need to find a happy middle ground. God bless you at FDA. I wish you luck.

Dr. Dominitz: Jason Dominitz, University of Washington. I just want to build on that a little bit. I'm really struggling with this. I voted originally for the very narrow list. I think about what Dr. Biddinger said about the gowns. You know there's things we can do with mitigation strategies, keep the fellows out of the endoscopy, saves gowns and gloves and we can do that whether there's a public health emergency or not. Now the manufacturers of gloves and gowns may not want to tell us that they're having supply chain issues, because then we'll look at their competitor's supply.

So, you know, do you make it voluntary reporting, or do you make it mandatory reporting? It's quite a challenge. It would be great if they all voluntarily reported they are having supply chain issues so we can start conserving and not get into the trouble that we got into.

Dr. Jarvis: Any other questions or issues? I'm supposed to summarize what we said.

[Laughter]

Dr. Jarvis: I guess the easiest was, is to say A, B and C. Good luck. I think a broad issue, at least for, if you're going to ask outside experts, whether it be this committee or others, is to have that next level after the product code preferred name because otherwise we're all picking things out of the dark and have no idea what you decided to exclude and what you've decided to include and what the reasons are for those.

If I go to A, I don't think there were a whole lot of items I have written down, about six, which you'll have in the transcript to be eliminated. And with B about 40 items added to the list. And then C, kind of gets back to a little bit to Dr. Allen's point of what it is critical in a national emergency. I think one of the things that's clear from this, or at least clear from COVID is, you are not going to be able to predict is it going to be a thermonuclear war, chemical attack, or a biological attack or a pandemic the next time a public health emergency arises.

But as time goes close to that, you are going to know what it is, be able to go to this list and identify what really are the critical elements for that particular public health emergency. So, with that, why don't we move to question number two.

Dr. Ricci: Thank you. Question two, how should supply chain resilience and vulnerabilities be considered when determining device types by the dreaded product code, for inclusion or exclusion on the 506J Device List?

Dr. Allen: I don't think resilience should play a role, it's not, shouldn't be a factor because resilience can be as simple as a company goes bankrupt and they are out of business and that resilience disappears and it can disappear in a heartbeat. So, it's either mission critical or it's not mission critical. If it's mission critical, it needs to be on the list. If we happen to have great resilience, great. You don't need to pay as much attention. But it still needs to be on the list.

Dr. Carrino: I agree.

Dr. Allen: Hallelujah. [Laughter]

Ms. Sauer: Nancy Sauer, industry representative. It depends. So, I think it depends a little bit on do we send her on that, those pantry essentials, right. Must, must have in the hospital versus, that we would love to keep everything going. Or again, for, and then I think also very much how we are defining supply chain resilience. I would say that any product type where one company going out of business causes a significant dent, that that's not a resilient supply chain, right. I think if there is a breadth of manufacturers and alternatives available, even within categories, product codes or otherwise, where there are multiple substitution opportunities, I think those, we really can think about setting some of those aside. I think maybe when we get into the capital equipment and other things, that's a little bit of a different topic.

But I think if it's publicly available information and something really is broad and a lot of geographic or a variability and ability to bring product in, again, needs to be revisited so that does add a burden to constantly revisit at some frequency. But I think it is a reasonable factor, but we would need to be careful about how that is defined.

Dr. Beckham: I want to make one comment, could be another group to consider, there could be multiple manufacturers. Supply chain may not be resilient, they source from same raw materials supplier. Throwing that out when looking at resilience, just because they are spread across the market doesn't mean it's [indiscernible].

Dr. Cassiere: Hugh Cassiere. Should we be discussing whether it's these devices or tests that we're looking at in terms of resiliency or domestic or international, threshold when something is majority coming from international community versus domestic should be weighed as factor throws it out there for other panel members to comment on that.

Dr. Allen: So, not to be argumentative, doesn't really matter what international or domestic, if mission critical, we need to pay attention to it. If it's not mission critical and it's coming in for international who cares? If it's not mission critical, who cares?

Dr. Cassiere: Say not mission critical coming international that supply stops should that be on list of 100% product A comes from country B, that country B is not, we can't get it from country B should that be on list even though it looks like it's 100% resilient?

Dr. Beavis: I'm going to suggest little more nuance, we have domestic producers output committed to international doesn't matter if they are in this country or not. Name.

Dr. Tjoumakaris: Going to get so complex, we're trying to solve two million things. Nancy mentioned this, how do we define resilience? What's fluff two suppliers, three, how do you define that? I'm in agreement when it comes to considering allocation of resources and human capital, this, to me is a luxury. Sticking to the "what we need to function with or without" resilience, I agree with Dr. Allen, needs to be here and then if there's a red flag, if we're good resilient at the time keep an eye. Alert, be transparent, and be watchful. But it's going to get so complex with local versus, how do you define export versus import? So many moving pieces to define this, sometimes device specific not just division specific whether neurosurgery or cardiology, so, I think it will be very tough to manage although luxury to have that would be great.

Dr. Van Der Pol: Barbara Van Der Pol, UAB. I think what this question asks people to do know unknowable because it's the future. Nobody had a test for COVID before COVID existed in our world. So, until these things happen, we have no idea what we need, what's mission critical. If you are talking about what's mission critical based on what we know right now, we have to recognize we don't know how resilient any of these things have capacity to be. We don't know

who we are going to lose, what capacity what's going to lose. So, for example, if all manufacturing for molecular diagnostics moved to COVID, all other molecular diagnostic we used that doesn't mean molecular diagnostic weren't in good supply three weeks before COVID, right? So, you cannot know this.

Trying to guess right is not always in your best interest, forgive my grammar. So, I would be with Dr. Allen, we need to recognize, if it's important it's important. We really cannot guess what impact may be to manufacture in the future.

Dr. Jarvis: How many items of products were eliminated you considered they were not vulnerable, or supply chain was resilient? How big would this list become if you put those all back on the list?

Dr. Beckham: 1700 start with when we developed the list so literally started from everything and then using information that we had from previous public health emergencies, previous shortages, we narrow that down against the statute.

Dr. Ricci: Would be challenging to specify exactly if there were any discern removed from this initial draft list purely because of resilience, I think we were looking for panel input on how to use the vulnerabilities and resilience to limit any procodes.

Dr. Morgan: Charity Morgan. I don't think any procode should be removed solely because they are considered resilient that is because, I think realistically this list is not going to be updated often enough to keep up with changes for the supply chain.

Dr. Petersen: One question. Something we ran into during COVID is product quality as well. Does that create vulnerability in itself? Public health vaccinating, hundreds of thousands, millions of people, and we start getting to bottom of barrel of needles and syringes have needle failures. These kind of things, because they are coming from manufacturer that's way down the

line on the list of folks who we normally buy from. So, pontificating that vulnerabilities out there can be from products just not being the best either.

Dr. Jarvis: Raise of hands how many feel that supply chain resilience should not be considered? Okay. Thank you.

Dr. Carrino: John Carrino. Yeah, so, we're putting together list of must haves, resiliency kind of dynamic attribute potentially attribute that is again where FDA can focus their energy saying this is what doctors think they need, right now this is what we're good on, this is something we need to maybe work on that might direct government to put incentives for that, domestic activities incentivize domestic companies, what have you. Yeah, the list is the list you can have other attributes you can then work off of and not have to say okay now the list is bigger, or smaller, blah, blah, blah, you can filter it on. We got to work on these things heard, we heard number of them masks, PPE, et cetera.

Dr. Jarvis: Anything else on C or question two, rather? Okay. Question three.

Dr. Ricci: Yes, for question three how should following device types be addressed with regards to proposed 506J Device Lists? Single use disposable versus –convenience consists, capital equipment such as imaging?

Dr. Carrino: John Carrino. We already answered it right with the last one. The list is the list, but, and on the imaging devices, so, you have device on there, again could be made from multiple manufacturers may be very resilient, you don't need x-ray machine, radiograph machine for using vendor X, Y may be able to ramp up production in U.S. if coming from somewhere else, so, I think categories themselves are important. I'll let surgeons speak to those things.

I heard surgeons say I need to be able to do this, be able to do this activity one level requires scalpel, more sophisticated level requires specific device, but that would be

accomplished by surgeon in any event depending which device. Levels of what they, what's essential, what is desired, and what is required might be another, hate to add it, another attributes to these types of things. Thank you.

Dr. Dominitz: Jason Dominitz, University of Washington. Fascinating. A lot of single use devices that are reusable, blood pressure cuffs we throw away after single use, you could reprocess them, manufacturers don't have, don't relabel them as such in crisis it's, you know, no brainer. There are more complicated devices, biopsy forceps, reuse reusable devices until forever, until few years ago people started using disposable, seems like it might be, may be safer. May be cheaper, but not really.

Could you reprocess biopsy forceps? Dr. Biddinger had comment, could there be requirements for safe reapproving of these devices, how does FDA regulate that? So, it's a fascinating question not sure there's an easy answer to multiple use devices, there are many that are able to be used multiple times, they're just not labeled as such.

Dr. Van Der Pol: Barbara Van Der Pol. Clarifying questions, so are you asking if multiple patient reusable devices should not be on the list because they have higher level of resilience? Question one. Question two, when talking about capital equipment, only about equipment or talking about all of the consumables required to run that equipment? For diagnostic we ran out of tips that run on instruments, right all kind of little plastic wear that aren't devices and you guys don't necessarily have control over, but we can't use that equipment without, how does that all roll into your thought process here?

Dr. Ricci: To start with first question, capital equipment yes, we were talking about that, machines themselves and not disposable or pieces parts that are needed to run the tests, run the imaging or do whatever you need to do.

Dr. Van Der Pol: Barbara. Parts?

Dr. Ricci: Yes, device, so that the parts, if they are regulated as a device themselves, they may be, they could be considered separately. Many parts may not be independently regulated. So, there may be no way to separate capital equipment from replacement parts.

Dr. Tjoumakaris: Stavropoula Tjoumakaris. To attempt to answer your question, I know it's a very complex answer, I think most of us would agree single use –truly single use, disposable– and obviously, everybody needs to take charge within their own specialty what can be multi-patient usable, et cetera, should be addressed at higher level of scrutiny rather than multi-patient reusable. Another piece of information would be helpful volume, how many single use disposable masks we need in case of public emergency. Hundreds of thousands? Millions? As opposed to reusable blood pressure cuffs, we need them at much, quantities also important here.

I think B, anything that has word convenience next to it kind of alerts one that perhaps we can deduct Dr. Allen's point, state of emergency nice to have these kits, where we can figure things out without them. And again, capital equipment, I think you just answered the question.

Ms. Sauer: Nancy Sauer, industry representative. Agree with most of what I've been hearing disposable most vulnerable, some multi-patients reusable may have their place on the list. Completely, convenience kits I also like convenience, and they are only as vulnerable as their components again to try to be keeping in mind practicality, signal to noise, talking about information, we want to minimize and keep this an effective process. Having hard time seeing value of majority of kits, having separate requirements.

Capital, I have a question back to those working in healthcare facilities. In my experience, replacement of capital devices that is largely done on very scheduled basis rather than an emergency basis. Repair is a different thing. Many of these devices are still very

functional, able to do their essential jobs at the time they were being replaced by something with more features or because it's going to have warranty coverage, et cetera. Capital, I think in terms of entire system is really quite different right from what's in category A.

Dr. Cassiere: Hugh Cassiere. Company A says we're going to start making this MRI, okay. I think much more important that if companies in capital, capital equipment parts that go along with that more than equipment itself is much more critical. I want imaging colleagues to kind of weigh in, because you could have imaging equipment if you don't have accessory equipment to work with it it's like not having it. Government gave us ventilators but didn't give us connections, that's nice I have hundred ventilators I can't use them anyway I don't care about that. Convenience kits, word "convenient" sound convenient but when you are used to putting in catheters with a kit that has everything in it, that's necessary to do it, don't have to scrounge around or try to put things together that aren't meant together, they are not convenience they are kits that help me put in something safely in sterile manner which is why I'm not sure why neurology bladder catheters made it others didn't.

We're asking for pie in the sky, been involved in companies stopped making central lines, we have to scramble how to get around that, whether through emergency or whether now. Emergency highlight that and I think I'm going to vote for those convenience kits should be included as well, and I'll make mention what my colleague said about single use disposable category single that can be used and singles that cannot. I'd like to hear imaging colleagues weigh in about capital equipment as well.

Dr. Carrino: John Carrino, on imaging side, imaging devices are resilient in the sense you can run them longer. If you are running MRI eight hours, go to 24 hours so you don't need to buy more capital equipment during a crisis, just need to increase utilization of that, as long as you

have supplies you need modality specific for things like raid or fee equipment. Same thing, MRI we only change every three or four years, CT more critical to have x-ray tubes available cause they can burn out you know sometimes months or years, so that's how they are going to be more resilient, other ways need to understand other characteristics of what pieces you need. Thank you.

Dr. Jarvis: I would second the comment on convenience kits, seems illogical to me at least, what I heard was urinary catheter kit was considered essential for meeting 506J criteria because closed system CDC insertion kits does not, that's closed system. If the system being closed or open was reason why one chosen, I would say both of them should be chosen.

Dr. Ricci: Thank you. That's helpful. Just probing little bit on convenience kits to make sure that we have as much specificity as we can. Are there specific types of convenience kits or convenience kits that are used in specific situations that are more important than others? Because the reason I ask is that there are kits for I don't need to tell all of you but everything under the sun; is there any distinguishing factors that the panel can --

Dr. Cassiere: I'm going to use Dr. Allen's I don't need pleural, I can put chest tube in, I think pleural catheter kits probably shouldn't be on that list in terms of, again paracentesis kits, think should be on that list, central line kits and serial capital kits, at least in my mind, those are go to procedures in ICU that need to be done meticulously, flawlessly sterile technique not having so-called convenience kits would be detriment. Those are two I would add. I'll leave the neurologic LP kits for other colleagues to comment.

Dr. Jarvis: I would add with urinary catheter, if you don't do it right, you get urinary tract low mortality.

Dr. Tjoumakaris: Stavropoula Tjoumakaris. Second line kits, in particular, they are sized for pediatric patients, wires dilators made for that particular size having to piece together different sizes would be time consuming, you don't want to find out you have the wrong wire halfway through your procedure. Add to central line kit code, which also involve multiple dilators making sure have proper set of instruments.

Dr. Jarvis: Umbilical line kit as well.

Dr. Fischer: Yes, thank you for bringing that up.

Dr. Tjoumakaris: Stavropoula Tjoumakaris. Convenience kits is an all catch term, what's truly convenience kits, what's central access, et cetera, and placement of intracranial pressure monitor, lumbar puncture kit, again, those are not necessarily convenience kit but access kit, so, perhaps that is defining and decisive factor whether critical or not, sounds like example mentioned earlier for pleural catheter that's a true convenience to have the specified catheter for that.

Dr. Cassiere: Hugh Cassiere. Just to give an example we call them convenience kits in hospital, we put central line kit together with sterile gloves with sterile gown and mask and hat and, that's convenient. These kits aren't convenience kits.

Dr. Van Der Pol: Barbara Van Der Pol. I'm not going to pushback, I don't have a horse in this race. I'm just going to so say one of the things my lab has to do, put together all different devices that provide, provider doesn't want to stop what they're doing to find out "do I need this device or that device?" We do that internally, as long as I can get devices, I can put my own kit together. I think that might be the question being asked here, if you can get your hands on a device your world doesn't stop, it's just a pain in the behind. At what point does it need to be on your list? Again, I can't speak to procedures you are doing, I'm saying I think that might be the question.

Dr. Ricci: Yes, yes, that's exactly the question. Understanding the kit is several devices together and I think we have gotten very nice feedback about inclusion or exclusion of, specific, what's called convenience kits.

Dr. Jennings: Lisa Jennings, capital equipment. I think one of the messages is that capital equipment is a capital expenditure and these pieces of equipment do supposedly last for number of years, it's the parts and its reagents and the supplies needed to run the equipment that becomes short supply. So, many places might have equipment sitting there but not operational without all components.

Dr. Jarvis: Any other questions. Or comments? If not, I'm actually going to let you continue with the next session rather than taking a break since I know we have a number of people who have very tight connections.

Dr. Ricci: Working session one and working session two? Are we done with panel deliberations as well? We're super-efficient.

Working Session 2 – FDA Questions to the Panel

Dr. Jarvis: I'd like to call the meeting back to order. So, at this time we'll now begin what we just finished, actually, continuation of panel discussions. I don't know that there's anybody from public still here, this portion is open to the public observers, public attendees may not participate except specific requests of panel chair. Additionally, we require all persons who are asked to speak again, identify yourselves before you have any comments. This, basically, any remaining questions that anybody has or comment that you have, particularly regarding questions that we just finished with.

Dr. Carrino: John Carrino, during break I had a chance to reflect on a situation and I think come to like framework to me would seem that what we're looking for is, we have one of these

emergencies, what is desired, what is required, what's resiliency, what's contingency and then, that might be something FDA can use to work with. So, maybe take example not from imaging I wasn't able to think of one we heard about convenience kits. Desired to have convenience kit to do X maybe pleural chest tube, placement, what's required chest tube and scalpel and whatever, and gauze or then resiliency you can determine based on what you know, those are pretty resilient, we can have those different pieces you don't need contingency, so, that's my, that's what I had a chance to think about during the break. Thank you.

Dr. Jarvis: Thank you. Any other comments?

Dr. Fischer: Gwen Fischer from University of Minnesota. That type of emergency matters to Dr. Allen's, emergency mass trauma may want to limit ECMO. In respiratory pandemic key to survival for a lot of our COVID patients, so I think that might need to be taken into consideration as well.

Dr. Tjoumakaris: Combining two comments perhaps, rate devices to absolute configure around it public health emergency you know, dire catastrophic emergency different peers to guide you as to we can give you master list and then based on the absolute necessity of devices and type of emergency, you can figure out you know which one to focus on. Maybe more manageable.

Dr. Jarvis: Anyone else? If not, go ahead.

Dr. Petersen: Paul Petersen. FDA website the place you would focus people to go to for this list?

Dr. Beckham: Tammy Beckham FDA, yes.

Dr. Petersen: It would be hard to work with, it is searchable, I need to practice.

Dr. Jarvis: Anything else, if not, we'll hear summation from Dr. Tammy Beckham from FDA.

FDA Summation

Dr. Beckham: Thank you all for your time, truly really appreciate it. We appreciate dialogue and feedback; we also appreciate difficulty of the topic area that we put in front of you, and we realize difficulty challenges providing recommendations by product code to us as well.

So, what I heard, and you guys summarized a lot when you came back after the break, was clearly we need to think about what you 50 said: framework, mission critical versus national, and national public health emergency and think about it at that level.

We also heard from you today that, you did not believe resiliency should factor into whether or not a device was on 506J List. Then, we heard conversation around convenience kits as relates to critical access and most important devices on the list whether packaged as part of that kit, perhaps there's two types of convenient truly for convenience but then obviously those that are not convenience need to provide care.

So, we also heard again thought around updating frequency or cadence with which, consideration as well. And then conversation you had about, we were just having actually, about prioritization, so, like offering of end here about framework, desired, required, kits can you configure around that, around the prioritization, tiering, think about tiering, think about specific types of emergencies are ways to group this that would make it easier to digest and to comply with, so clearly heard that.

And then I just wanted to let you all know that as we work towards finalizing this list, guidance will allow us, based on your feedback today, to further elaborate some specifics that we heard, whether it was around thoughts on pediatric, different sizes as well, we will be able to elaborate on some of that in the guidance as we finalize guidance, I just wanted to let you know that as well. Again, I want to thank you, I hope I summarized that and thank you for your time

today. Again, I realize it was a challenging topic, we realized that coming into this that it was a challenging topic, we do appreciate thoughtful comments and discussions today. Thank you.

Adjournment

Dr. Jarvis: Thank you. That concludes our meeting, I want to thank all panel members for great input and discussion today, our guest speakers, and FDA for doing a lot of work and we've given you a lot of work to continue.

For all of your contributions to making this successful meeting. Meeting General Hospital Personal Use Devices Panel meeting is now adjourned. Have good flights home. Thank you all very much.