SUMMARY MINUTES

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

GENERAL HOSPITAL AND PERSONAL USE DEVICE ADVISORY COMMITTEE MEETING

FEBRUARY 6, 2024
9:00 a.m. EST

Attendees

Chairperson
William Jarvis, MD
President, Jason and Jarvis Associates LLC
Hilton Head, SC

Members
John Jordan, MD, MPH, MS, MBA
Director of Clinical Informatics
Central Health
Austin, TX

Charity Morgan, PhD
Professor, Department of Biostatistics
University of Alabama at Birmingham
Birmingham, AL

Aamir Siddiqui, MD
Plastic and Hand Surgeon
Henry Ford Hospital Michigan State University
Detroit, Michigan

Member/ Industry Representative
Nancy Sauer, RAC
Senior Director of Regulatory Affairs Medtronic, Inc.
Golden, CO

Consumer Representative
Teresa M. Diaz
Patient Safety Advocate, Global Patient Advocacy Coalition
Orlando, FL

Consultants
Keith Allen, MD
Director, Surgical Research Surgical Director Structural Heart
St. Luke's Hospital of Kansas City
Kansas City, MO

Kathleen Beavis, MD
Professor of Pathology University of Chicago
Chicgo, IL

John Carrino, MD, PhD
Vice-Chairman Radiology and Imaging Professor of Radiology
Weill Cornell Medical College
New York, NY

Hugh Cassiere, MD, FCCP, FACP
Director of Critical Care Division
Cardiac Services South Shore University Hospital
Bayshore, NY

Jason Dominitz, MD, MHS
Executive Director National Gastroenterology and Hepatology Program
Veterans Health Administration
Seattle, WA

Gwenyth Fischer, MD
Assistant Professor of Pediatric Critical Care
University of Minnesota College of Medicine
Minneapolis, MN

Lisa Jennings, PhD
Professor College of Graduate Health Sciences
University of Tennessee Health Science Center
Memphis, TN

Paul Petersen, PharmD, MPH, CEM
Director Emergency Preparedness Program
Tennessee Department of Health
Nashville, TN

Stavropoula Tjoumakaris, MD, FAANS, FACS, FAHA
Professor of Medicine and Public Health
University of Alabama at Birmingham
Birmingham, AL

Barbara Van Der Pol, PhD, MPH
Associate Professor of Medicine
Director of Data Science and Machine Learning Research
Rutgers Robert Wood Johnson Medical School
Calla, AL

FDA Participants
Kellie Kelm, PhD
Acting Office Director Office of Office of Gastrorenal, ObGyn
General Hospital, and Urology Devices
CDRH - Silver Spring, MD

Suzanne Schwartz, MD, MBA
Director Office of Strategic Partnerships and Technology Innovation
CDRH - Silver Spring, MD

Tammy Beckham, DVM, PhD
Associate Director Resilient Supply Chain Program Office of Strategic Partnerships and Technology Innovation
CDRH - Silver Spring, MD

Jarrod Collier, MS
Designated Federal Officer
Office of Management
CDRH - Silver Spring, MD

CALL TO ORDER & INTRODUCTIONS

Dr. Jarvis, the panel's chairperson, called the meeting to order, advised that the panel members participating in today's meeting have received training in FDA device law and regulations, and announced the agenda for the meeting: to 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 as part of the Consolidated Appropriations Act, and how it relates to medical devices used and pandemic preparedness.

Dr. Jarvis asked committee members and the FDA attending virtually to introduce themselves.

CONFLICT OF INTEREST STATEMENT

Upon completion of introductions, **Jarrod Collier,** the Designated Federal Officer, read the conflict-of-interest statement and made general announcements, noting that based on the agenda for today's meeting and all financial interests reported by the panel members and consultants, no conflict-of-interest waivers have been issued.

Miss Nancy Sauer is serving as the industry representative, acting on behalf of all related industries, and is employed by Medtronic Incorporated General Surgical Technologies. **Jarrod Collier** reminded all members and consultants that if the discussions involve any other products or firms not already on the agenda for which the FDA participant has a personal or imputed financial interest, that participant needs to exclude themselves from such involvement, and their exclusion will be noted for the record.

Jarrod Collier advised that for the duration of the general hospital and personal use devices panel meeting on February 6, 2024, **Dr. Gwenyth Fischer** has been appointed to serve as a temporary non-voting member. This individual is a special government employee or regular government employee who has undergone the customary conflict of interest review and has reviewed the materials to be considered at this meeting.

The meeting was handed back to **Dr. Jarvis**, who asked **Dr. Schwartz** to make the opening remarks.

Dr. Schwartz began by providing background on CDRH's work to mitigate medical device shortages, the recently published 506J guidance documents, and the aims of the meeting. **Dr. Schwartz** noted that the COVID-19 public health emergency demonstrated the fragility and complex nature of the medical device supply chain. While the disruptions from acute COVID-19 disease have mostly ended, the underlying supply chain vulnerabilities remain. The CDRH has strengthened public health supply chains by establishing the Office of Supply Chain Resilience or OSCR, which monitors, assesses, and communicates risks and vulnerabilities to prevent shortages of medical devices.

Dr. Schwartz provided an overview of the history of the OSCR and its roles. One role is to identify and communicate shortages under Section 506J of the Federal Food, Drug and Cosmetic (FDNC) Act. 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.

Dr. Schwartz also discussed the Prevent Pandemics Act, which directs the FDA to issue guidance on notifications outside public health emergencies; issue or revise guidance on Section 506J requirements and include a list of devices that apply to Section 506J; and convene panels of the Medical Devices Advisory Committee at least once a year to provide advice to the secretary. **Dr. Schwartz** stated that the latter two are the reason for this meeting.

Dr. Schwartz provided a high-level overview of two guidance documents issued to address Section 506J, which included the 506J Device List to assist manufacturers in providing timely notifications to the FDA. **Dr. Schwartz** added that this list needs to be finalized and that the purpose of the meeting is to discuss the proposed 506J Device List, which includes 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. **Dr. Schwartz** added that in making recommendations for the list, the panel should consider if the device types on the proposed 506J Device List meet the requirements for a critical device and how supply chain resilience should be considered when determining which devices should be included on the 506J Device List.

FDA PRESENTATION – MEDICAL DEVICE SUPPLY CHAIN RESILIENCY, SHORTAGES, AND PROPOSED 506J DEVICE LIST – DR. TAMMY BECKHAM

Dr. Tammy Beckham presented information regarding the FDA's medical device shortage reporting authorities and the legislation that led to the creation of the proposed 506J Medical Device List. She advised that the FDA is looking for thoughts and recommendations on the appropriate inclusion of devices on the 506J Device List.

Dr. Beckham provided an overview of the recently elevated OSCR within CDRH. The OSCR is responsible for building supply chain resilience and preventing shortages that impact healthcare delivery. This is achieved by working with stakeholders, including suppliers, manufacturers, group purchasing organizations, distributors, transportation companies, healthcare systems, and the United States government.

Dr. Beckham discussed the history of the FDNC Act, which directs the FDA to develop and publish the 506J list. **Dr. Beckham** also noted that devices that require notification under 506J 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. The FDNC 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 is likely to lead to meaningful disruption in the domestic supply of that device.

Dr. Beckham also discussed the FDA's obligations from this Act, including establishing and maintaining a publicly available list of medical devices that the FDA determines to be in shortage, distributing this information on device discontinuances and interruptions to appropriate organizations, issuing and publicly posting failure to notify letters should manufactures fail to comply with their requirements, and expediting premarket reviews or facility inspections that could mitigate potential shortages. The FDA must also develop and publish a 506J Device List by product code, for which manufacturers of such devices are required to notify the FDA. When finalized, the list is meant to assist manufacturers in providing timely, informative notifications about changes in the production of certain medical device products. Once finalized, the FDA will periodically reevaluate the list, following the FDA's good guidance practices.

Dr. Beckham provided an overview of how the FDA uses this list to help prevent and mitigate medical device shortages. The list is used to develop impact assessments to determine if a medical device is in shortage or shortage is imminent. This is then used to inform on the need for implementation of both regulatory and nonregulatory mitigation strategies, such as enforcement discretion, expediting premarket review, conservation strategies, or defense priority rating.

Dr. Beckham reminded the panel that the FDA's ability to prevent and mitigate shortages depends on timely notifications. The earlier the FDA receives notification of a supply interruption, the greater its ability to mitigate or prevent a shortage.

Dr. Beckham then discussed how the proposed 506J list was developed. This was initiated by an internal FDA working group with representatives from the Office of Strategic Partnerships and Technology Innovation, the Office of Product Evaluation and Quality, and the Office of Policy, who used a multi-step process. Experts from the Office of Technologies within OPEC and the Center for Biologics Evaluation and Research were consulted as needed.

Dr. Beckham explained each step of the development of the proposed 506J Device List:

1. An initial list of product codes was developed using a broad and diverse set of inputs, including lessons learned and external information such as information published by the World Health Organization and SMI—spell out name first time used critical products partners advocates framework.
2. The initial set of product codes was evaluated against statutory criteria, such as devices critical for public health emergencies, life-supporting devices, and devices used in emergency medical care.

3. The device characteristics and resiliency of the device supply chain were also considered, and the proposed 506J list was finalized.

Dr. Beckham also provided details on the structure of the list. The product codes on the proposed list were organized by the FDA medical specialty panel. The proposed 506J Device List contains 284 product codes organized under 16 medical specialty panels. Most of the product codes fall under anesthesiology, cardiovascular, clinical chemistry and clinical toxicology, and general hospital panels. Product codes and device types used to visualize and maintain airways and facilitate intubation were also proposed for inclusion.

Dr. Beckham provided examples of devices classified under the cardiovascular panel, such as those required for maintaining adequate profusion to tissues and organs with oxygenated blood; those used for extracorporeal membrane oxygenation procedures; ventricular assist devices; those used for physiological monitoring; electrocardiographs (ECGs); and those used to maintain vessel patency such as stents, angioplasty catheters endovascular grafts, and automatic electronc defibrillators (AEDs).

Dr. Beckham provided examples of devices classified under the clinical chemistry and clinical toxicology panel, such as those used to measure chemical balance and metabolism, collect specimens, and deliver and maintain appropriate glucose levels.

Dr. Beckham also listed examples of devices classified under the gastroenterology and neurology panel, such as those used to treat life-threatening instances of intestinal obstruction, deliver peritoneal dialysis and hemodialysis, and diagnose and treat life-threatening situations such as acute gastrointestinal bleeding. **Dr. Beckham** explained that devices classified under the general and plastic surgery panel include those used to perform general surgery, control bleeding, and for incision and wound care. Inclusion on the list under the general hospital panel included devices needed to support nutrition, deliver food, provide other essential physiological functions, protect wearers from spreading infections, and disinfect and sterilize medical devices.

Dr. Beckham added that devices under the hematology and pathology panel included devices used to test for coagulation abnormalities, collect and transport patient specimens, culture and identify microorganisms, and test for sensitivities and direct resistance. The obstetrics, gynecology, and radiology panels included those used to monitor fetal heart rate and oxygenation, those used to treat post-partum hemorrhage and imaging devices.

Dr. Beckham ended her presentation by reminding the participants that their feedback on the proposed 506J Device List was required.

Q&A FOR FDA PRESENTERS

Dr. Carrino asked **Dr. Beckham** a question about whether the list included support components or parts. **Dr. Beckham** answered that the list was only for devices and not raw materials or components. **Dr. Carrino** clarified that he meant parts on a device that are not part of the main device that need to be replaced, for example, x-ray tubes or contrast materials. **Dr. Beavis** added that the biggest microbiology shortfalls were collection swabs and wanted to

confirm that these were included on the list. **Dr. Siddiqui** asked how the system would work to prevent shortages of gloves, masks, and personal protection equipment (PPE). **Dr. Schwartz** explained that during a public health emergency, based on 506J notifications and other information sources, the FDA worked with partners and manufacturers to increase raw materials and components supply to increase manufacturing. The FDA also mitigated some regulations and conducted impact assessments.

Dr. Morgan asked for a clarification of the FDA definition of the conditions in advance of a public health emergency. **Dr. Beckham** explained that a public health emergency is the time period when the Health and Human Services (HHS) secretary declares a public health emergency under Section 319 of the Public Health Services Act, which includes any renewals made by the HHS secretary in accordance with Section 319. For the purposes of this guidance, the 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.

Dr. Van Der Pol asked about collection swabs and why they were not on the list and stated that providing further raw materials when the manufacturers were at full capacity would not solve shortage problems. **Dr. Van Der Pol** also asked about products that are not approved and gave an example of nucleic acid amplification testing, such as primers and probes for DNA and RNA sequencing. **Dr. Beckham** acknowledged these comments.

Dr. Cassiere asked if convenience kits were not included, and **Dr. Beckham** confirmed that they were not but would appreciate feedback on this issue. **Dr. Jennings** stated that nucleic acid PCR testing devices were limited to partial thrombplastin time (PPT) and activated PTT (APPT) and activated clotting time and that the list should be upgraded to reflect other needs in the clinical chemistry area. She also stated that continuous positive airway pressure (CPAP) and supplies associated with that for diagnostic magnetic resonance imaging (MRI) and surgical mesh for incisions and wound care were missing. She also asked why wheelchairs were not listed but stretchers were. Finally, she asked if devices for laboratories and pharmaceutical developments, such as for developing vaccines, would be included. **Dr. Beckham** acknowledged the comments and added that while the FDA wanted to hear about resilience, the focus is on medical devices and finished medical devices.

Dr. Tjoumakaris asked about angiographic closure device shortages, why they were not listed, and how to increase resilience when there is only a single plant manufacturing a particular device. **Dr. Beckham** provided an overview of the FDA's approach to working with industry to reduce the risk of shortages and increase resilience. **Ms. Sauer** commented about the product codes and how they cover a wide variety of devices. She stated that industry would welcome an examination of whether product code is the most appropriate mechanism. She also mentioned that maintaining continuity and infrastructure links between industry and hospitals are necessary. Finally, she added that there needs to be an emphasis on protecting facilities in areas vulnerable to natural disasters.

PANEL QUESTIONS AND DELIBERATIONS

Dr. Jarvis called the meeting back to order after a break, made a few announcements, and asked **Dr. Schwartz** to make some clarifications. **Dr. Schwartz** clarified that the FDA regulates imaging contrast agents as drugs under CEDR and not CDRH and that under the Prevent Act, the list must be developed using product codes. **Dr. Jarvis** introduced the guest speaker, **Dr. Mark Leahey,** from the Medical Device Manufactures Association (MDMA).

Dr. Mark Leahey explained that MDMA represents 300 primarily small-size medical technology companies, and their relationship with the FDA predates COVID-19. He stated that the device industry is a very specific industry, where three, five, and sometimes ten manufacturers are associated with one product. He stated that the industry is proactive toward supply chain vulnerabilities and works with the FDA collaboratively. **Dr. Leahey** commended the FDA for understanding the needs of the industry and engaging the MDMA in the process of developing the Device List. However, he also stated that market share and competitive dynamics were not considered even though industry had argued that they were necessary. He also added that capacity, resiliency, and market opportunities are all important and that lessons have been learned from COVID-19, such as sourcing from multiple component manufacturers and manufacturing locations.

Dr. Jarvis introduced the next guest speaker, **Miss Abbey Pratt**, Vice President of Global Strategy Analysis for the Advanced Medical Technology Association (AMTA). **Miss Pratt** explained that the AMTA represents 450 manufacturers of medical devices and works with federal partners to identify supply chain risks that may impact the delivery of patient care. She highlighted the work of the medical technology industry over the past few years to address supply chain challenges and develop systems and collaborative partnerships to better prepare for the next crisis. She stated that the AMTA believes that resilience initiatives only succeed if industry, government, and healthcare providers work in partnership to solve problems, particularly in situations that are complex and fluid, such as public health crises. It also requires trust among stakeholders and a policy environment that facilitates and fosters flexibility and agility.

Miss Pratt added that AMTA works with government and key stakeholders across the supply chain to understand public health needs, identify barriers to rapid deployment, and develop solutions to meet patient and provider needs. AMTA works with federal partners to mobilize and ramp-up the production of critical technology such as ventilators and diagnostic testing syringes. Some cases involved adopting technology such as a ventilator for a wider variety of uses, and when transportation becomes a challenge, the AMTA engages with port authorities and terminal operators to prioritize medical equipment. **Miss Pratt** stated that the key to understanding some of the most challenging upstream shortages was real-time coordination, and their goal was to ensure that upstream issues, whether driven by weather, geopolitics, or public health emergencies, were resolved well before any impacts were seen at the delivery of patient care.

Miss Pratt also stated that there is a focus on supply chain resilience, and AMTA members are identifying additional suppliers, looking at alternatives, using dual and multi-

sourcing, increasing partnerships, using big data to improve analytics, investigating onshoring and nearshoring, and developing new supply chain functions. **Miss Pratt** argued that rather than vulnerabilities reemerging, the industry is more resilient than at any other time in the past. On reporting device shortages, **Miss Pratt** suggested that this be tailored to the context to focus on impact, and the reporting tool should also be made more effective, especially for public health emergencies. She also suggested that a Device List be developed specifically for emergency situations and argued that without a focus on key devices where an impact can be made and specific lists for emergencies, there is a risk of straining the system.

Dr. Jarvis introduced the next guest speaker, **Dr. Paul Biddinger**, Chief Preparedness and Continuity Officer for Mass General Brigham. He began by explaining that he represents one of the largest integrated academic healthcare systems in the United States. He provided an overview of the healthcare system's perspective and stated that the key issue is communication. As shortages are shifting from multi-year pervasive issues to a very rapidly revolving door of persistent new products and categories every month, the importance of communication is more evident. Most of the U.S. healthcare structure is private, so information is difficult to access. **Dr. Biddinger** stated that this made it difficult for small providers to access alternative resources from different suppliers. Subsequently, supply chain shortages are a major concern. He provided an overview of recent surveys of healthcare organizations on supply chain problems, which highlighted their challenges.

Dr. Biddinger recommended that the definition or understanding of advance in healthcare public health emergency be as broad as possible. He also advocated for increased transparency, which the FDA is proposing, and allocating resources on a regional basis with healthcare coalitions, which is important and would assist smaller healthcare system providers. **Dr. Biddinger** also emphasized the importance of communicating at the earliest possible moment and strengthening notification of transition plans. He suggested a centralized communication tool for stakeholders and the FDA, which could then be used to predict supply chain shortages and stakeholder responses to these shortages.

Dr. Jarvis introduced the final guest speaker, **Dr. Jacon Collen**, Professor of Medicine at Uniform Services University in Walter Reed Medical Center. **Dr. Collen** began by informing the panel that while he was an active-duty officer in the U.S. Army, his presentation should not be taken to reflect official army or Department of Defense (DOD) policy or the policy of Walter Reed or Uniform Services University. **Dr. Collen** stated that his presentation was from the perspective of a critical care physician. During COVID-19, he was tasked with being on the guideline panel looking at proposed ventilators, and this process highlighted how decision-making processes impact supply chain issues and how important it is to consider all stakeholders, including ethicists.

Dr. Collen stated that having a list that could change over time and be adjusted was essential. He gave examples of how this would impact the work of critical care physicians. **Dr. Collen** pointed out that different types of hospitals and healthcare centers require different medical devices and this should be considered and this should be evident in the Device List. He

provided more examples, such as alcohol use increasing during the COVID-19 pandemic, that changed the types of shortages that emerged.

Dr. Jarvis then asked if anyone had any questions for the guest speakers. **Dr. Beavis** asked **Dr. Biddinger** about the best way to manage backorders. **Dr. Biddinger** replied that back orders require as much lead time as possible, which is variable. They should also be standardized.

Dr. Siddiqui asked a question about lines of communication between manufacturers, suppliers, and consumers. **Ms. Pratt** replied and said that industry is working closely with the FDA and their Supply Chain Resiliency Program and the White House-level Supply Chain Resilience groups. She agreed that the lines of communication need to be enduring and robust. While supply chains have tightened, communication has improved and become more efficient. **Ms. Sauer** was surprised to hear about customers not receiving information on discontinuations, as there is always communication from industry on this matter.

Dr. Tjoumakaris asked **Dr. Biddinger** to elaborate on the idea of a centralized information hub. **Dr. Biddinger** replied, stating that the FDA should curate this as the recipient of the 506J notifications but that this should be a living hub open to the public. This would create access to equal information, which would reduce the spread of ambiguous information. **Dr. Dominitz** asked **Mr. Leahy** and **Miss Pratt** about how the product codes could be improved and how manufacturers should interpret the codes. **Mr. Leahy** stated that while there is a statute, it would be good to hear the FDA's perspective on refining the product codes.

Dr. Jarvis asked **Dr. Biddinger** how hospitals deal with contracts with suppliers. **Dr. Biddinger** stated that from his experience, if they are contractually obligated to use one supplier and they cannot meet the needs that are specified in the contract, they then find an alternative, and this has not caused a problem previously.

Dr. Allen asked a question about how the FDA prevents hoarding that artificially creates shortages. **Dr. Biddinger** answered that there is no complete solution, but more information and time can reduce this problem. Refining the reporting requirements would also reduce this problem. **Dr. Van Der Pol** asked **Mr. Leahy** and **Miss Pratt** about how suppliers can address contract issues by creating contracts that address the problem. **Dr. Biddinger** answered by reading from a 2021 White House Report, "Building Resilient Supply Chains Note." This stated that as the Group Purchasing Organization (GPO) receives a higher fee for having a sole-source contract, they are driving the contracting problem.

Dr. Jarvis asked for any final questions before proceeding with the open public hearing portion of the meeting.

OPEN PUBLIC HEARING

Jarrod Collier read the open public hearing disclosure process statement and turned the meeting back over to **Dr. Jarvis**, who then invited **Ms. Melendez** to speak. **Ms. Melendez** introduced herself as the President and Founder of Xcelerate UDI and had no financial interests

to disclose. She stated that 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. She suggested that a key strategy involves establishing a link between the 506J Device List and the global unique device identification database, the Good ID.

Ms. Melendez stated that embedding the implantable device framework, the Good ID 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. She also provided an overview of the benefits of creating a device flag in the Good ID framework, which she argued is necessary for achieving a comprehensive medical device management system.

Dr. Jarvis then asked if any other members of the public wanted to address the panel. As there were no other comments, he closed the open public hearing.

WORKING SESSION 1 – FDA QUESTIONS TO THE PANEL

Dr. Ricci opened the meeting after the break. She began by introducing herself as the Deputy Office Director of the Office of Strategic Partnerships and Technology Innovation. She then read out the first question for the panel discussion: Question 1: Do the device types, by product code, on the proposed 506J Device List meet the requirements for critical devices as outlined in Section 506J of the FDNC 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. Van Der Pol began the discussion by asking about how product codes can be organized. **Dr. Ricci** answered by reminding the panel that the product codes were required by the legislation but recognized that their broadness can be challenging. **Dr. Dominitz** asked if the legislation restricted the use of codes and if sub-categories could be included.

Dr. Ricci assured attendees that efforts would be made to provide specific device categorizations from SMEs to aid in assessments. **Dr. Van Der Pol** sought clarification regarding subcodes, which **Dr. Ricci** confirmed do not exist. **Dr. Petersen** questioned the necessity of insulin pumps, suggesting potential alternatives and considering the context of inpatient versus outpatient care. **Dr. Siddiqui** proposed reconsidering the need for special dressings, suggesting standard options might suffice.

Dr. Beckham reminded attendees to reference the device list provided in their panel packs for guidance. **Dr. Van Der Pol** expressed uncertainty about how to determine which devices should be included in specific codes, acknowledging regulatory constraints. **Dr. Ricci** welcomed feedback on critical devices not fitting into broad categories or devices that may not belong in certain categories. **Dr. Cassiere** discussed the potential removal of insulin pumps from the list, particularly in the context of inpatient care where alternative therapies are available. The discussion revolved around clarifying device categorizations, assessing the necessity of specific devices, and considering contextual factors such as inpatient versus outpatient care.

Dr. Fischer and **Dr. Cassiere** suggested focusing high-frequency ventilators on neonatal use due to contraindications and increased mortality in adults. **Dr. Tjoumakaris** sought clarification on the inclusion of insulin pumps for outpatient use during public health emergencies. **Dr. Morgan** inquired about specifying device criticality for specific populations in the device list. **Dr. Van Der Pol** expressed concerns about the inclusivity of media and transport devices and suggested considering missing items like swabs for molecular-based diagnostics. The discussion moved to Part B of Question 1, regarding critical device types not included in the proposed 506J List: Are there device types by product code that are not on the proposed 506J Device List that are critical to public health during a public health emergency and should be added to the list?

Dr. Siddiqui highlighted negative pressure wound therapy as essential and missing from the list. **Dr. Tjoumakaris** recommended including geographic closure devices for various medical specialties and modifying the listing for stroke mechanical thrombectomy devices. **Dr. Jarvis** requested clarification on a specific device mentioned during the discussion. The conversation addressed the need to specify device criticality for different populations, including essential devices not currently on the list, and refine listings for various medical specialties.

Dr. Tjoumakaris clarified the need for closure devices and thrombectomy tools across various medical procedures. **Dr. Dominitz** highlighted several items potentially missing from the list, including CO_2 regulators, alcohol for endoscope disinfection, and vacuum-powered devices. **Dr. Jennings** raised concerns about the absence of CPAP devices, surgical mesh, stretchers, and blood analysis equipment. **Dr. Siddiqui** suggested expanding the variety of sutures and including long bone fracture stabilization equipment. **Dr. Cassiere** sought clarification on the inclusion of CPAP and BiPAP machines.

Dr. Jarvis highlighted the need for intravenous catheter components and a broader range of automated medical devices. **Dr. Dominitz** proposed the inclusion of large-volume paracentesis kits and a comprehensive array of stents. **Dr. Tjoumakaris** emphasized the need for cranial fixation systems, surgical drains, and interosseous needles. **Dr. Fischer** added thoracostomy tubes, interosseous needles, drill kits, and bubble CPAP devices for neonatal care to the list of suggested inclusions.

Dr. Fischer suggested including thoracostomy tubes, interosseous needles, interosseous drill kits, and bubble CPAP devices for neonatal care on the list. **Dr. Cassiere** recommended including devices for measuring activated clotting time, thromboelastography, and epicardial wires for pacing patients undergoing cardiac surgery. **Dr. Beavis** emphasized the need for FDA-approved swabs, blood culture bottles, and multiplex panels for microbiology testing. **Dr. Tjoumakaris** proposed including antiplatelet devices and P2Y12 assays for platelet function measurement.

Dr. Jennings highlighted the absence of hematology analyzers, coagulation analyzers, and antiplatelet function tests. **Dr. Cassiere** added specific tests like P2Y12 assays and anti-factor Xa activities to the list of suggested inclusions. **Dr. Ricci** clarified that while product codes are broad, the FDA provides descriptions of devices cleared under those codes to aid specificity. **Dr. Beckham** mentioned that some critical testing equipment was excluded from the

list due to resilience to supply chain disruptions, considering factors like market share. **Dr. Jarvis** inquired about the FDA's knowledge of market share for medical devices, citing instances where market dominance could impact supply chain disruptions and device availability.

Dr. Beckham confirmed that the FDA evaluates market share and other factors like geographic diversity and increases in demand to assess supply chain resilience and potential shortages. **Ms. Diaz** inquired about the FDA's system for managing devices on the list that may be recalled or discontinued. **Dr. Schwartz** elaborated on the FDA's approach to assessing vulnerabilities in the supply chain and considering factors beyond market share. **Dr. Jarvis** raised the example of PPE shortages during COVID-19 and questioned how the FDA deals with unpredictable problems like those. **Dr. Beckham** highlighted the challenges posed by shifts in domestic manufacturing and export restrictions on supply chain resilience.

Dr. Jarvis suggested transitioning to Question 2 for the panel. **Dr. Ricci** read out the question to the group: Question 2: 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. Van Der Pol emphasized the importance of universal transport devices for nucleic acid testing to mitigate vulnerabilities in the supply chain. These discussions underscored the complexity of evaluating supply chain resilience and the need to consider various factors beyond market share when determining the inclusion of devices on the 506J List.

Dr. Carrino raised concerns about the absence of MRIs on the 506J List and questioned whether it was due to their resilience. He emphasized the difficulty in understanding the supply chain from a medical perspective. **Dr. Dominitz** inquired about the distinction between drugs and devices, particularly regarding saline flushes and sterile water shortages. He also asked about the FDA's approach to drug shortages. **Dr. Jennings** highlighted the challenges associated with analyzers and platelet function testing due to limited reagents and cartridges. **Dr. Van Der Pol** suggested revamping product codes to be more specific, making decision-making easier.

Ms. Sauer emphasized the importance of collaboration between the FDA, industry, and medical professions to address challenges in the 506J List and improve its effectiveness. **Dr. Tjoumakaris** proposed the creation of a dynamic list of necessary devices for emergency use, which should be updated frequently. **Dr. Beavis** emphasized the challenges with swabs during shortages and suggested the development of universal transport material compatible with various vendors. **Dr. Morgan** inquired about the frequency of updates to the Device List, considering the dynamic nature of supply chain issues. **Dr. Ricci** acknowledged the need for periodic updates to the list and highlighted the varying timelines for resolving supply chain issues. **Dr. Beckham** underscored the importance of considering the duration and nature of supply chain issues when determining the frequency of updates to the list. These discussions highlighted the complexity of managing the 506J List and the importance of considering various factors, including supply chain resilience, inclusions of devices, and updating the list accordingly.

Dr. Dominitz suggested considering the inclusion of devices on the 506J List during the 510(k)-clearance process to streamline the process. **Dr. Allen** expressed a contrarian view,

emphasizing the need for a concise list of critical devices essential for patient-care during national emergencies. **Dr. Morgan** highlighted the challenges of managing constant shortages and advocated for a broader list to address a variety of public health emergencies. **Dr. Tjoumakaris** proposed grading devices based on their necessity in extreme catastrophic situations versus less critical scenarios. **Dr. Jarvis** polled the panel on whether they preferred a smaller, essential device list or a larger, comprehensive one.

Dr. Carrino suggested creating a master list of critical devices with attributes that could include resilience, allowing for a more targeted approach to shortages. **Dr. Beavis** emphasized the need for a manageable list focused on resources during public health emergencies, aligning with the statutory criteria. Overall, panel members expressed differing opinions on the ideal scope and nature of the 506J List, with some favoring a concise list of critical devices and others advocating for a broader approach to address various emergency scenarios.

Dr. Cassiere emphasized the need to consider a spectrum of responses and suggested that the list should cover devices critical for patient care during emergencies like COVID rather than focusing solely on extreme scenarios like thermonuclear war. **Dr. Allen** argued against considering resilience as a factor, emphasizing that if a device is mission-critical, it should be included on the list regardless of its resilience. **Ms. Sauer** from the industry suggested that resilience could be a factor depending on the definition and context, but caution should be exercised in its consideration. **Dr. Beckham** highlighted the complexity of resilience assessment, mentioning that resilience does not necessarily equate to a diverse supply chain.

Dr. Van Der Pol expressed skepticism about predicting future resilience and suggested that the focus should be on including mission-critical devices rather than trying to anticipate resilience. **Dr. Jarvis** raised concerns about the potential size of the list if items were added based on perceived resilience, highlighting the challenge of balancing inclusion and exclusion criteria. **Dr. Ricci** clarified that the focus was on gathering panel input on using vulnerabilities and resilience to limit the product codes on the list.

Dr. Morgan emphasized that no product codes should be removed solely based on their perceived resilience, considering the challenge of updating the list frequently to keep up with supply chain changes. **Dr. Petersen** raised concerns about product quality affecting vulnerability, especially during public health emergencies like mass vaccination campaigns. The panel generally agreed that supply chain resilience should not be a primary factor in determining device inclusion on the list. **Dr. Carrino** highlighted the importance of distinguishing between single-use disposable devices and reusable devices, noting that specific multi-patient reusable devices may have a place on the list.

Dr. Jarvis then asked **Dr. Ricci** to read out the last question. **Dr. Ricci** read out question 3 as follows: Question 3: How should different device types, such as single-use disposable devices and capital equipment, be addressed with regards to the proposed 506J Device Lists,

Dr. Dominitz discussed the complexities surrounding single-use disposable and multi-patient reusable devices, suggesting that safe reprocessing standards need to be considered. **Dr. Van Der Pol** raised questions about how to define and categorize resilience, highlighting the

challenge of predicting future supply chain disruptions. **Dr. Cassiere** emphasized the critical role of accessory equipment and replacement parts for capital equipment, suggesting that they should be considered separately. The panel discussed the significance of convenience kits, with **Dr. Cassiere** and others advocating for the inclusion of kits essential for critical procedures like central line placement and lumbar punctures. **Dr. Jennings** highlighted that while capital equipment may be resilient, the availability of parts and supplies needed to operate the equipment could be a vulnerability during emergencies. **Dr. Ricci** sought clarification on specific types of convenience kits and their inclusion criteria. **Dr. Jarvis** concluded the discussions by acknowledging the efficient progress made and prepared to move on to the next session.

WORKING SESSION 2 – FDA QUESTIONS TO THE PANEL

Dr. Carrino proposed a framework for considering device inclusion based on what is desired, required, resilient, and contingency planning, with examples like convenience kits for specific medical procedures. **Dr. Fischer** emphasized the importance of considering the type of emergency when determining device necessity, citing the critical role of extracorporeal membrane oxygenation (ECMO) during respiratory pandemics like COVID-19. **Dr. Tjoumakaris** suggested combining comments to create a master list of devices with a focus on the absolute necessity for different types of emergencies, providing a more manageable approach. **Dr. Petersen** inquired about the accessibility and usability of the FDA website for accessing the device list, expressing the need for clarity and searchability. Following the discussions, **Dr. Beckham** from the FDA is expected to provide a summary or summation of the meeting, likely addressing key points raised during the discussions.

FDA SUMMATIONS, COMMENTS OR CLARIFICATIONS

Appreciation: **Dr. Beckham** expressed gratitude for the time, dialogue, and feedback provided by the panel members, acknowledging the difficulty and challenges of the topic area.

Framework: **Dr. Beckham** highlighted the importance of considering a framework that distinguishes between mission-critical devices and those necessary for national public health emergencies.

Resilience: **Dr. Beckham** noted the panel's consensus that resilience should not be a factor in determining whether a device is included on the 506J list.

Convenience Kits: There was discussion around convenience kits, particularly distinguishing between those essential for critical access and those not purely for convenience.

Frequency of Updates: The panel discussed the frequency or cadence of updates to the list and the need for clarity in prioritization.

Elaboration in Guidance: **Dr. Beckham** assured the panel that their feedback would be taken into consideration as they finalize the guidance, particularly regarding pediatric considerations and tiering of devices.

Gratitude: **Dr. Beckham** expressed gratitude once again for the thoughtful comments and discussions, acknowledging the challenging nature of the topic.

Dr. Jarvis thanked the panel members and the FDA and adjourned the meeting.

I approve the minutes of this meeting as recorded in this summary.

William Jarvis, MD
Chairperson

I certify that I attended this meeting on February 6, 2024 and that these minutes accurately reflect what transpired.

Jarrod W. Collier -S

Digitally signed by Jarrod W. Collier -S
Date: 2024.02.22 16:42:35 -05'00'

Jarrod Collier
Designated Federal Officer

Summary Prepared By:
Sam English
Translation Excellence
3300 South Parker Road, Suite 200
Aurora, CO 80014
(720-325-0459)
February 20, 2024