UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

MEDICAL DEVICES ADVISORY COMMITTEE

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PATIENT ENGAGEMENT ADVISORY COMMITTEE

+ + +

October 6, 2021
10:00 a.m.

Via Zoom Videoconference

PANEL MEMBERS:

PAUL T. CONWAY	Chair
CYNTHIA L. CHAUHAN, M.S.W.	Voting Member
BENNET R. DUNLAP, M.S.	Voting Member
NECIE L. EDWARDS	Voting Member
AMYE L. LEONG, M.B.A.	Voting Member
MONICA PARKER, M.D.	Voting Member
RITA ROY, M.D.	Voting Member
SAMPRIT BANERJEE, Ph.D.	Temporary Non-Voting Member
SHELBY D. REED, Ph.D., R.Ph.	Temporary Non-Voting Member
RUTH M. PARKER, M.D.	Temporary Non-Voting Member
RACHEL BRUMMERT, M.S.	Consumer Representative
JIJO JAMES, M.D., M.P.H.	Industry Representative
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Visiting Professor
University of Paris School of Medicine
Former FDA Associate Commissioner

RICH KUCERA
CEO
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TERRIE REED
Director, Partner Relationships
Symmetric Health Solutions

MARIA GMITRO
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BETTYANN CONNORS
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Former Executive Director, Breast Cancer Action

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President
National Center for Health Research

CAROL SMALL
Patient

JAMEE COOK
ALCL in Women with Breast Implants Facebook Group

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M E E T I N G

(10:00 a.m.)

MR. CONWAY: Good morning. I'd like to formally call this October 6th, 2021 meeting of the U.S. Food and Drug Administration's Patient Engagement Advisory Committee, or PEAC, to order. My name is Paul Conway and I have the distinct honor to serve the public, the FDA, and my fellow Advisory Committee members as Chair of the Committee. The Committee extends a warm welcome to all who are participating virtually and to those who are watching our proceedings today from across the nation.

The PEAC is a very unique FDA Advisory Committee. In fact, we are the only FDA Advisory Committee composed solely of patients, caregivers, and patient advocates. The PEAC is one of the most direct ways that the public can provide comments and key recommendations to the FDA. The FDA relies on the Committee for independent expert insights and advice on scientific, technical, and policy matters. We operate within a well-established body of law and regulation that determines how expert insights and recommendations are gathered by the federal government. We follow all appropriate safeguards to ensure public trust between citizens and their government is maintained, and that any appearance or actual undue influence or the perceived advantage to any person or entity is avoided.

The establishment of the PEAC by the FDA was both a historic and pivotal moment in the ongoing development of substantive patient engagement and advancements in the science and utilization of patient insight data. The creation of the Advisory Committee sends a very strong and powerful message to all stakeholders involved in the medical device development life cycle and ecosystem. And most importantly, to patients and caregivers, it sends a very strong signal that their lives and the burdens that they've managed matter and

have substantive value to decision makers.

Beyond my service as Chair of this Committee, I bring both personal and professional insights. I'm a kidney patient and I've managed kidney disease for 42 years, including 13 years of chronic kidney disease, 3 years on home dialysis, and for nearly 25 years as a kidney transplant patient. The gift of life that I have enjoyed came from a young man who was killed in a car accident who made the decision to help others and through his gift, I've been able to serve the public, including in this role with my fellow Committee members.

In terms of my background, I serve as the chair of Policy and Global Affairs for the American Association of Kidney Patients, the largest kidney patient organization in America. I have a background in federal and state policy and policy implementation and particularly, the role of stakeholders in successful policy solutions.

The FDA decision to create the PEAC has reinforced the efficacy of patient-led and patient-centered efforts across the federal government. Today, in nearly every single agency that touches health care and health policy, patients are at the table advising federal decision makers, both appointed and elected, on specific issues including precision medicine, patient-driven quality measures, patient-reported outcomes and real-world evidence. This is a tribute to the leadership of the FDA, which broke new ground with the creation of the PEAC and many other efforts that are conducted by the Agency.

Over the course of the past 5 years, this Committee has covered a substantial portfolio of issues ranging from those in our inaugural meeting, which focused on patient engagement in medical device clinical trials, through to social media in the following year and the role of e-platforms in collecting scientific evidence generated by patients, cybersecurity and medical devices, and last year, artificial intelligence and machine learning.

The content of our in-person meetings, combined with the additional insights that we've provided through homework assignments, have given the FDA a very deep and rich research background and set of data that they have used and incorporated in many of their decisions and across their priorities. Most recently, we've been involved in giving the FDA advice on COVID-19 communications, and the work of our inaugural meeting led to 2019 draft guidance on patient engagement in the design and conduct of medical device clinical trials, the posting of videos about how medical device trials encourage underrepresented groups of Americans to participate, and in 2020 FDA posted communicating cybersecurity vulnerabilities to patient considerations for a framework. All of these things are a substantive inclusion of the insights of this Committee and the members of the public who have come forward to offer their expertise and their own experiences.

My fellow commissioners and I are very proud of the work that we've conducted on behalf of the FDA and most importantly, the citizens across the United States who have a strong view that must be included in FDA decision making. On behalf of the Committee, I'd like to thank the FDA and in particular, those public servants who have the courage to meet patients where they are to bring them into the Agency decision-making process and give substance to the PEAC.

I'll now read into the record the exact purpose of the PEAC, which is available online. I think it's very important to set the record initially when we do these meetings so that everyone understands clearly what the PEAC is and what it is not.

On the objective scope and activities and duties:

The Patient Engagement Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective devices for human use and, as required, any other product for which the FDA has regulatory

responsibility. The Committee provides advice to the Commissioner or designee on complex issues relating to medical devices, the regulation of devices, and in use by patients. The Committee may consider topics such as Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient-reported outcomes, and device quality of life or health status issues and other patient-related topics. The Committee will provide relevant skills and perspectives in order to improve communication of benefits, risks and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It will perform its duties by discussing and providing advice and recommendations in ways such as identifying new approaches, promoting innovations, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

At this point I'd like to note for the record that the non-voting members constitute a quorum as required by 21 C.F.R. Part 14. I'd also like to add that the Committee members participating in today's meeting have received training in FDA device law and regulations.

For today's agenda, the Committee will focus and make recommendations on medical device recalls. Once a medical device is available in the U.S. marketplace and in widespread use, unforeseen problems can sometimes lead to a recall. When a device is defective or potentially harmful, recalling that product, removing it from the market or correcting the problem is the most effective means for protecting the public. A company may recall a device after discovering a problem on its own or after FDA raises concerns. In rare cases, FDA may require a company to recall a device.

When a device is recalled, FDA reviews the company's strategy for resolving the problem by assessing the relative degree of risk associated with the product and making

sure the strategy effectively resolves the problem with the device. FDA provides transparency and communicates information when the public needs to be alerted to a serious hazard, as well as once the recall has been appropriately resolved. The recommendations provided by the Committee will address factors FDA and industry should consider to effectively communicate medical device recall information to patients and the public, including, but not limited to, content, format, methods used to disseminate the message, and timing of communication. The Committee will also consider concerns patients have about changes to their device in response to a recall and will discuss ways patient perspectives could be incorporated in FDA and industry benefit-risk decision making, as well as the healthcare provider and patient decision-making process related to a recalled medical device, including implanted devices.

Now I would like to lay down a few ground rules. If a panelist would like to discuss a question, please physically raise your hand and I will get to your question as we proceed throughout the day, and I'll make a really sincere effort at getting everybody included here. We want to prevent multiple persons from speaking over one another as we proceed since this entire meeting is being transcribed for the official record.

Before we begin, I would like to ask our distinguished Committee Members and FDA experts identified on the meeting's roster, attending virtually, to introduce themselves. Committee members, please turn on your video monitors if you have not already done so and unmute your phone before you speak. I will call your name and when I do, please state your area of expertise, your patient and/or caregiver role as it pertains to the PEAC so that the public is well informed about your role, your position, and professional affiliation. And now I'd like to go ahead and begin with Dr. Jijo James, our Industry Representative.

DR. JAMES: Good morning and thank you so much for the opportunity. Jijo James,

Chief Medical Officer of Johnson & Johnson Medical Devices and Global External Innovation. I am in charge of overseeing patient monitoring and safety surveillance practices across the entire product portfolio. I am also the chair of the Medical Devices Innovation Consortium, which is a first-of-its-kind partnership between industry, academia, and regulators to advance regulatory and safety science for patient benefit. Thanks again.

MR. CONWAY: Great. Thank you very much.

Rachel Brummert.

MS. BRUMMERT: I'm Rachel Brummert, I am the communications lead for the American Society of Pharmacovigilance. I'm a harmed patient by medication and by medical devices, and I'm here to serve as the Consumer Representative.

MR. CONWAY: Great. Thank you very much, Rachel.

Cynthia Chauhan.

MS. CHAUHAN: Good morning, I'm Cynthia Chauhan. I am a heart failure and kidney failure patient with multiple comorbidities. I also have implanted devices. I am an active research advocate in cancer research and in heart failure research at both the national and international levels.

MR. CONWAY: Great. Thank you very much, Cynthia.

Bennet Dunlap.

MR. DUNLAP: Hi, good morning. Thanks, Paul, it's a pleasure to be with you again. I'm Bennet Dunlap, I'm a parent of four, two of whom live with Type 1 diabetes and have done so for 15, 20 years. I'm a Type 2 diabetes patient myself. I'm proud to work with families, a lifeline of living with diabetes through patient advocacy organizations, and I'm thrilled to be here and to contribute what I can. Thank you, Paul.

MR. CONWAY: Thank you very much, Bennet.

Necie Edwards.

MS. EDWARDS: Good morning, Paul. My name is Necie Edwards and my specialty is healthcare advocate and pain management. I'm the founder and organizer of Fibro Patient Education and Support. We empower you beyond the journey of chronic pain. I have Type 2 diabetes as well as several other conditions, as well as a few implanted devices. Thank you.

MR. CONWAY: Thank you, Necie.

Amye Leong.

MS. LEONG: Good morning. I'm greeting some dark in Santa Barbara, it's still very dark here. I am a patient advocate, I have served for 15 years for the United Nations initiative called the Bone and Joint Decade. I have a couple of bone and joint disorders including rheumatoid arthritis and osteoporosis and as a result of those two diseases, I am the official owner of 22 joint replacements, wires, stents and everything else that goes with that. I have worked tirelessly at the international level in a group called Outcomes Measures in Rheumatology Clinical Trials to bring the patient perspective in a systematic way across clinical trials throughout the globe. I'm delighted to be part of the PEAC. I have served as chair of the Arthritis Foundation and recently, a couple years ago, got married and am enjoying good married life. Great to be here.

MR. CONWAY: Thank you very much, Amye.

Dr. Parker.

DR. M. PARKER: Good morning, everybody. Thank you for the invitation to be here to be a part of this very important committee. In my professional life, I'm a family physician and geriatric primary care provider. I now serve as director of the Goizueta Alzheimer's Disease Research Center's minority engagement corps and outreach, recruitment and

education corps, where my main job is educating community persons about the opportunities to be volunteers in clinical research, longitudinal clinical research in Alzheimer's and related dementias.

Personally, I am the sole primary caregiver of a 95-year-old mother living with Alzheimer's for about 10 years now and her sister, age 93, who similarly is affected but we recently lost to a cerebella stroke, and now I deal with that on a regular basis. So I think I'm in a great position to inform about the needs of families living with persons with dementia, particularly if you have multiple persons living with you.

MR. CONWAY: Great, thanks. Good to see you, Dr. Parker.

Dr. Roy.

DR. ROY: Good morning, everybody, it's a real honor and privilege to be here and it's a privilege to serve our great nation in this way. I am a physician by training, I trained in general surgery and then went into patient education as a career after leaving my residency, and I recently, in the last 5 years, became a spine patient. I have a fusion at L4/L5 with a very straightforward spondylothesis and realized that there was not great patient education or advocacy in the spine area.

And so I dove into bringing my professional experience to a patient advocacy group, which is now the National Spine Health Foundation. We primarily focus on patient education, clinical research outcomes, so we do a lot of patient-reported outcomes, research evaluating various treatment options, and then we are very involved in advocacy and supporting other organizations in healthcare legislation that is favorable to raising awareness of the need of advocacy and education for spinal health care. And so we are very -- I'm very pleased to be here. I have a device in my spine and I also had a knee replacement, so I've been through that journey and as a patient, really understand the

needs of education and advocacy. Thank you.

MR. CONWAY: Dr. Reed. My apologies, Dr. Reed.

DR. REED: Good morning, everyone, I am very appreciative of having the opportunity to work on this Committee. I'm serving as a consultant. I am a professor in the Department of Population Health Sciences at Duke University. I'm also a faculty leader in the Duke Clinical Research Institute, where I lead the patient preference research group. We apply methods to try to elicit patient preferences, and so I'm serving in that role today to provide my expertise in that area. So, I look forward to today's discussion, thank you.

MR. CONWAY: Great. Thank you very much.

Dr. Banerjee.

DR. BANERJEE: Hi, I'm Samprit Banerjee. I am an Associate Professor of Biostatistics in the Weill Cornell Medical College of Cornell University. I'm in the Department of Population Health Sciences. I have worked on medical devices, particularly in understanding the comparative effectiveness of devices using real-world evidence, and I've also worked on the scope of postmarket surveillance and how devices can be tracked over time, particularly in the context of registries. Like Dr. Reed, I'm also a consultant in this meeting and hoping to extend my expertise in this area. Thank you.

MR. CONWAY: Great. Thank you very much.

Dr. Ruth Parker.

DR. R. PARKER: I'm the other Dr. Parker, also a consultant. I'm recently Emeritus Professor at Emory after over 3 decades of working as -- where I was a Professor of Medicine, Pediatrics, and Public Health. I've spent the last 3 decades working on health literacy, on defining it, looking at its associations, advancing interventions and policy to make what we do in health and health care align with patients' abilities to get it,

understand it, use it for their health. A pleasure to be here, great to be a part of the Committee, and look forward to listening and learning and contributing anything I can from the lens of health literacy. Thank you very much.

MR. CONWAY: Thank you very much for joining us.

Kathryn Capanna.

MS. CAPANNA: Good morning, Committee members. Good morning, everyone. My name is Kathryn Capanna, I'm a deputy division director here at FDA's Center for Devices and Radiological Health, and I oversee the Patient Science and Engagement Program.

MR. CONWAY: Great. Thank you very much.

And Erin Keith.

MS. KEITH: Good morning, everyone. I'm Erin Keith, I am the Associate Director for Compliance and Quality in CDRH's Office of Product Evaluation and Quality, and part of the programs that my area oversees is the recall program, and so we're looking forward to your help in that area today.

MR. CONWAY: Great. Thank you very much. And thank you all for giving your backgrounds and especially as it relates to the PEAC. I'm certain that the public is quite interested in the operations of the Committee, but most importantly, those who have been selected to serve. So thank you very much.

At this point I'd like to turn it over to Letise Williams, the Designated Federal Officer for the Patient Engagement Advisory Committee, and she'll make some introductory remarks.

Go right ahead, Letise.

MS. WILLIAMS: Good morning. I will now read FDA's Conflict of Interest Disclosure Statement for the October 6th Patient Engagement Advisory Committee (Particular Matter

of General Applicability).

The Food and Drug Administration (FDA) is convening today's meeting of the Patient Engagement Advisory Committee under the authority of the Federal Advisory Committee Act (FACA) of 1972. With the exception of the industry representative, all members of this Committee serve as special Government employees and are subject to Federal conflict of interest laws and regulations.

The following information on the status of this Committee's compliance with Federal ethics and conflict of interest laws covered by, but not limited to, those found at 18 U.S.C. 208 are being provided to participants in today's meeting and to the public.

FDA has determined that members and consultants of this Committee are in compliance with Federal ethics and conflict of interest laws. Under 18 U.S.C. 208, Congress has authorized FDA to grant waivers to special Government employees or regular Federal employees who have financial conflicts when it is determined that the Agency's need for a particular individual's service outweighs his or her potential financial conflict of interest.

Related to the discussions of today's meeting, members and consultants of this Committee who are special Government employees or regular Federal employees have been screened for potential financial conflicts of interest of their own as well as those imputed to them, including those of their spouse or minor children and, for purposes of 18 U.S.C. 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 Committee will discuss and make recommendations on the topic of patient input into medical device recalls. Once a medical device is available in the United States marketplace and in widespread use, unforeseen problems can sometimes

lead to a recall. When a device is defective or potentially harmful, recalling that product — removing it from the market or correcting the problem — is the most effective means for protecting the public.

Based on the agenda for today's meeting and all financial interests reported by the Committee members and consultants, a conflict of interest waiver has been issued in accordance with 18 U.S.C. 208(b)(3) to Dr. Shelby Reed. Dr. Reed's waiver addresses her stock holdings in affected firms. The combined holdings are currently valued between $50,000 to $70,000.

The waiver allows this individual to participate fully in the Committee deliberations. FDA's reasons for issuing the waiver are described in the waiver document which is posted on FDA's website at http://www.fda.gov/advisorycommittee/default.htm. Copies of the waiver may also be obtained by submitting a written request to the Agency's Division of Freedom of Information, 5630 Fishers Lane, Room 1035, Rockville, Maryland 20857.

Dr. Jijo James is serving as the industry representative for communication of benefit and risk to patients and is acting on behalf of all related industry. He is employed by Johnson & Johnson.

We would like to remind members and consultants that if the 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 other participants to advise the Committee of any financial relationships 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. Thank you.

For the duration of the Patient Engagement Advisory Committee meeting on October 6th, 2021, Dr. Ruth Parker has been appointed to serve as a Temporary Non-Voting Member. For the record, Dr. Parker serves as a member to the Nonprescription Drugs Advisory Committee in the Center for Drug Evaluation and Research. Dr. Parker is a special Government employee who has undergone the customary conflict of interest review and has reviewed the material to be considered at this meeting.

The appointment was authorized by Russell Fortney, Director, Advisory Committee Oversight and Management Staff, on September 22nd, 2021. Thank you.

Before I turn the meeting back over to Mr. Conway, I'd like to make a few general announcements.

In order to help the transcriber identify who is speaking, please be sure to identify yourself each and every time that you speak.

Transcripts of today's meeting will be available from Free State Court Reporting, Incorporated.

The press contact for today's meeting is Lauren-Jei McCarthy.

For the record, FDA has received 13 written comments.

Individuals that are confirmed participants for the Virtual Breakout Session have already received Zoom access for this portion of the meeting. Virtual Breakout participants will be instructed by the Chair to log out of the webcast and into the Zoom platform to be placed in Virtual Breakout rooms during the 11:45 a.m. break.

Due to limited technology capacity, participation in the Virtual Breakout scenario discussion will be limited to a hundred and fifty participants. Once capacity reaches a hundred and fifty participants, the Virtual Breakout Session will be closed to additional participants.

Please note that the Virtual Breakout Session will not be webcast. The webcast will close at approximately 11:45 a.m. The webcast will remain closed during the lunch break. The webcast will reopen at 12:55 p.m. to allow the general public, as well as those that participated in the Virtual Breakout Session, time to rejoin the webcast before we begin the Virtual Breakout Summations at 1:00 p.m.

Thank you very much. I will now turn the meeting over to the Chair.

Mr. Conway.

MR. CONWAY: Thank you very much, Ms. Williams.

Before I ask the FDA to begin with opening remarks, I want to provide a brief overview of how today's meeting will actually run. During the morning we will have presentations from FDA and industry followed by a 10-minute break. When we return from break, we will continue with healthcare and patient presentations followed by open committee discussion. Once the open committee discussions conclude, we will break for approximately 10 minutes. During the break, I ask that those confirmed as participants for the Virtual Breakout Session log into the Zoom link they were provided so the Virtual Breakout Session can start promptly at 12:00 p.m. Once the Virtual Breakout Session participants are logged into Zoom, they will be automatically placed in their assigned Virtual Breakout rooms. The Virtual Breakout Session participants will be asked to participate in the scenario discussion questions that were provided to them and posted on the FDA website along with other materials for this meeting. It is very important to note that this portion of the meeting will not be publicly webcast.

FDA staff will serve as moderators and note-takers during these discussions and will provide the Virtual Breakout participants with the ground rules for the discussion. FDA staff will not be providing their thoughts or comments during the Virtual Breakout Session.

Instead, they will summarize the discussion and report back to the Committee the comments made by Virtual Breakout participants. The Committee members and the webcast will not be available during the Virtual Breakout discussions.

The Virtual Breakout discussions will conclude at 12:30 p.m. At 12:30 p.m. the public will have a lunch break for 30 minutes. The webcast will reopen for public viewing at 12:55 p.m. Just to be clear, I want to reiterate that I will ask the AV team to close the webcast for public viewing during the 11:45 break and the webcast will remain closed through the 12:30 p.m. lunch break. The webcast will reopen for public viewing at 12:55 p.m. Those that participated in the Virtual Breakout Session will no longer have access to the Zoom platform and will also need to rejoin the webcast to continue viewing the meeting.

When the Committee returns from lunch, we will proceed with the Virtual Breakout Summations. FDA moderators will then summarize the Virtual Breakout discussions for the Committee. Once the Virtual Breakout Summations conclude, we will proceed with the Open Public Hearing. After the Open Public Hearing concludes, we will proceed with open committee discussion. During this time, the Committee will have an opportunity to discuss the comments from the Virtual Breakout Session, as well as the comments shared during the Open Public Hearing. Afterwards, we will break for 10 minutes and return for a committee discussion of the FDA questions. Following our discussion of these questions, I will give closing remarks.

Now it is approximately 10:30 and I'd like to go ahead and proceed with the opening remarks of FDA's Dr. Jeff Shuren, Director of the Center for Devices and Radiological Health at the FDA.

Dr. Shuren, you can go ahead and begin your remarks now.

DR. SHUREN: Thank you, Ms. Williams. Good morning, everyone and thank you for

joining us today for our 2021 Patient Engagement Advisory Committee meeting. I'm Jeff Shuren, Director of the Center for Devices and Radiological Health. I want to thank all the members of the Advisory Committee for being willing to serve in this capacity. I also want to thank our CDRH team for planning this meeting and developing the materials to guide the discussion.

Our focus for today's PEAC meeting is on how medical device recalls are communicated to patients and the public. Over the past year you may have heard about certain medical device recalls from manufacturers, FDA, as well as the press. What is critical is that the communication is accurate, clear, accessible, and actionable. We are looking forward to hearing from our Committee members, the speakers, the public, and the audience during our discussion today, of ways we can accomplish that goal when communicating medical device recall information to the public.

Before we dive into today's topic, I would like to share with you some highlights of the work being done at CDRH, especially around patient science and engagement and accomplishments resulting from or informed by prior PEAC meetings.

Many of you have seen this slide in presentations by many and others across CDRH. It is unchanged because our north star is unchanged. We remain focused on patients in all that we do. Our vision is that patients in the U.S. have access to high-quality, safe and effective medical devices of public health importance first in the world. Patients is the first word because they are our most important customer, and improving the health and the quality of life for the patients is a focus of our public health mission.

We continue to foster a culture of patient engagement seeking to bring in the patient voice into important activities that inform and shape our work. We look for opportunities to better understand patient perspectives about the medical devices they

use, what is important to them and their needs, preferences and concerns. The benefits of hearing the patient voice can be realized across the total product life cycle of medical devices and across a range of diseases and conditions.

To that end, this year we held several patient engagement events. We held a CDRH Town Hall on the role of medical devices in COVID-19 patients with lingering symptoms. CDRH staff had an opportunity to hear firsthand patient experiences with post-acute COVID-19 symptoms, including the role medical devices played in their journeys. This panel discussion informed us about the challenges COVID-19 patients with lingering symptoms have faced and are still battling, in some cases, well over 1 year after being diagnosed. The event was well attended by CDRH staff and generated very positive feedback about the value and impact of patient engagement events like these.

We also held an adolescent idiopathic scoliosis workshop and a congenital heart disease in pediatric patients webinar. In addition, our commitment to demonstrate reciprocity in our engagement with patients, CDRH staff gave the panel as keynote addressors at the International Children's Advisory Network virtual summit to share FDA work of interest to children. These are just a few examples of our ongoing commitment to continue to assure that engaging with patients is part of our daily work at CDRH.

To facilitate patient engagement, the Patient and Caregiver Connection provides a readily available resource for our staff to learn about patients, about their experiences with their medical condition and the devices they use to manage them. Presently, the PCC includes 19 partner organizations with patients and caregivers across a range of conditions that utilize a spectrum of devices overseen by all seven of our offices of health technology.

To date, we have received over 4800 responses from patients through the PCC on a variety of pressing medical device issues. And we are already leveraging these relationships

to hear more about patient experiences with medical device recalls, including the ongoing Philips Respironics recall, which is impacting millions of patients who rely on certain CPAP and BIPAP devices, as well as ventilators.

Through conversations, we are already learning more about the experiences, key concerns, challenges and questions that these patients have. We will also launch a survey of PCC groups with affected patients that we hope will provide further insights from a larger group of respondents. We continue to work collaboratively to expand patient science and share the value of including the patient voice, not just internally, but also externally.

After a successful event last year, we held another boot camp to train medical device and digital health companies about the ways digital health technology can be leveraged to measure clinical outcomes, including patient-reported outcomes. This year's boot camp was hosted by the Yale University and Mayo Clinic's Center for Excellence in Regulatory Science and Innovation, and included interactive sessions designed by CDRH staff to help smaller companies understand approaches they can use to develop these technologies for supporting clinical investigations as well as other uses.

Not only do we have ongoing efforts to cultivate patient engagement and the generation of robust patient science, we are committed to involving patients directly in the regulatory process through this Patient Engagement Advisory Committee. The PEAC members you will hear from today have discussed complex scientific topics during these meetings, ranging from clinical trials to patient-generated health data to medical device cybersecurity to artificial intelligence and machine learning. And the recommendations from these Advisory Committee meetings lead to actions taken by FDA and others.

For example, following the PEAC's recommendations at our 2018 meeting on patient-generated health data, or PGHD, this year FDA hosted a virtual public meeting on

PGHD throughout the total product life cycle of medical devices. We specifically explored the critical elements of PGHD and how it could be integrated and used throughout the healthcare ecosystem. We also discussed the importance of building trust and building bridges to facilitate collecting and sharing PGHD, and considered disparities in access and use of sensors and smartphones to collect PGHD. This public meeting was a collaboration across CDRH efforts in patient science and engagement, real-world data and evidence, and the Digital Health Center of Excellence.

As a result of the Committee's recommendations at our 2019 meeting, last October we released a discussion paper laying out considerations for a framework for communicating cybersecurity vulnerabilities to patients. Since then, FDA worked with industry stakeholders, federal partners, to assess the best approaches to communicate with patients and caregivers about specific and relevant cybersecurity vulnerabilities that may affect public health. I am pleased to announce the release of the white paper "Best Practices for Communicating Cybersecurity Vulnerabilities to Patients." This resource incorporates feedback received from the public on the earlier discussion draft.

In addition, for Cybersecurity Awareness Month, I'm pleased to announce the upcoming release of the first episode of the cybersecurity miniseries designed for patients and healthcare providers. We encourage you to stay tuned for this release and view our short video to learn more about how cybersecurity hygiene can protect you. By providing clear and actionable information, we seek to empower the public to be active agents in protecting public health.

The 2020 PEAC meeting on devices with artificial intelligence and machine learning, or AI/ML, gave us insights about the factors that impact patient trust in these technologies. This year we published an AI/ML action plan that reflects the Agency's commitment to

supporting the patient-centered approach to these devices, including the need for transparency to users to ensure they understand the benefits, risks, and limitations of these devices. The action plan also includes a diversity plan to support regulatory science efforts in the identification and mitigation of bias in AI/ML algorithms.

In addition, in another example of how we are leveraging the Patient and Caregiver Connection, we disseminated a survey that will give us insight on patient experiences with and perspectives on AI/ML technology and medical applications specific to their disease states and/or medical devices. These perspectives are being used to shape our upcoming meeting on October 14th, entitled "Transparency of Artificial Intelligence/Machine Learning-Enabled Medical Devices." We hope you register and tune in to this workshop.

We applaud the insights gleaned from the PEAC meetings, which continue to shape the work we are doing at FDA. And that brings us to the topic of our meeting today, medical device recalls and specifically, how to effectively communicate important recall information to patients.

Today you will hear from FDA speakers about why recalls occur, the role of FDA and others in medical device recalls, including communicating with patients and the public. You will also hear perspectives from the medical device industry, healthcare providers, and patients. And in a popular feature that has become the custom for PEAC meetings, participants who registered in advance will have the opportunity to dialogue in roundtable breakout sessions to walk through a hypothetical scenario involving a challenging medical device recall, which will then be summarized to the Committee. We look forward to the discussion and recommendations from the PEAC members on how we can enhance our patient-focused communication about medical device recalls.

Today's meeting builds on the discussions and comments we heard from patients

and others at a public meeting last November about ways we might improve our safety communications. We are committed to continued enhancements in the way we communicate about medical device safety, so our stakeholders receive the information they need in a timely, clear, and consistent manner so they can make well-informed decisions when evaluating the benefits and risks of a medical device. You'll hear more about this meeting and other ongoing improvements from Angela Calman, who leads our communication and education strategies at CDRH.

In other efforts to promote clear and effective communication to patient audiences, last fall we collaborated with the Medical Device Innovation Consortium, or MDIC, on a patient engagement forum. This forum included patient panels, interactive learning sessions, and other virtual engagement with patients and others across the medical device community to learn about challenges, shared best practices, for communicating to patients about benefit, risk, and uncertainty around medical devices.

Lastly, our meeting today builds on a virtual public workshop we held this June on orthopedic device postmarket review. This meeting sought to improve public understanding of regulatory requirements and programs related to orthopedic devices, including recalls, medical device reporting, and related topics. We shared information with stakeholders, including members of the orthopedic community, device manufacturers, clinicians, patients and the general public, on orthopedic device postmarket activities and challenges commonly faced in this area.

Our mission here at CDRH has dual aspects, to protect public health by assuring that devices are high quality, safe and effective, and to promote public health by facilitating device innovation and timely patient access. As you can clearly see, the recommendations from the Patient Engagement Advisory Committee lead to actions taken by the FDA and

others.

We continue to encourage all members of the healthcare ecosystem to strive to understand patients' perspectives and proactively incorporate them in medical device development, evaluation, and use. So today I encourage you to listen intently as we hear from our esteemed Patient Engagement Advisory Committee members and members of the public.

To kick off the presentations, I will turn it over to Erin Keith, Associate Director for Compliance and Quality in the Office of Product Evaluation and Quality here at CDRH.

MR. CONWAY: It's now 10:45 a.m., we'll proceed with FDA's presentations. I'll remind public observers at this meeting that while the meeting is open for public observation, public attendees may not participate except at the specific request of the Chair.

FDA will have 20 minutes to present. FDA will start their presentation with an overview on medical device recalls by Erin Keith, and then Angela Calman will present on medical device recall communication.

Ms. Keith, you may begin your presentation now. Thank you.

MS. KEITH: Good morning, panel members. I'm Erin Keith, the Associate Director for Compliance and Quality in the Center for Devices and Radiological Health's Office of Product Evaluation and Quality, and I'll be providing you with a brief overview of medical device recalls. We'll talk through what a recall is, the purpose of a recall, key stakeholder activities, and the major steps in the recall process.

We all had a lived experience with recalls. I suspect many of you have received a recall notice from a car company about a defect in your car and what you can do to address that defect. A medical device recall is a similar event, it is intended to address the risks

associated with a medical device when, for whatever reason, the device does not meet all the requirements to be in use.

Recalling those devices can be the most effective means of protecting the public. Recalls can occur as corrections in the field or removal of the device, the key distinction being where the remediation actions take place. Removals involve sending recalled devices back to the manufacturer to be repaired or replaced, and corrections can be fixed without removal of the device, for example, through a software patch or an updated set of instructions for use.

A recall is a voluntary action that takes place when the manufacturers carry out their responsibilities to protect the public health and wellbeing from products that present a risk to injury, gross deception, or are otherwise defective. While manufacturers may voluntarily recall devices at any time, the FDA can request and in exceptional cases require that a manufacturer recall a product, such as when there is an unreasonable risk of substantial harm posed by a device.

Once a product is available on the marketplace for widespread use, the unexpected can sometimes lead to violative products being used by the American public, necessitating a recall to address the risks to health presented by these violative products. FDA categorizes risk to health by evaluating how severe the health consequences may be, as well as how likely they may be to occur along with some other factors.

Ultimately, the purpose of conducting a recall is to contain and control the risks to health, correct the issue in the field or remove the device from use and prevent the issue from recurring.

Before we move on to a high-level description of the medical device recall process, let's cover some of the roles and activities performed by the major stakeholders during a

recall.

Manufacturers' responsibilities are to

- Monitor devices postmarket to detect the device safety issues that may trigger the need for a recall;
- Assess the scope and risk to health of the device at issue;
- Develop and implement a recall strategy;
- Notify customers about the recall problem, as well as what they need to do about that problem;
- Notify the FDA of actions that have been and are expected to be taken and any related illnesses or injuries that may have occurred with the use of the device.

FDA's responsibilities are to

- Request or require recalls when it's appropriate;
- Classify recalls based on the level of risk;
- Oversee the company's recall strategy and how effective that strategy is, including any recall communication sent by the manufacturer; and
- Intervene when the risk is not adequately mitigated.

Healthcare providers may be the end user or the intermediary between the manufacturer and the patient. Healthcare providers should evaluate the benefits and risks associated with the continued use of the recalled device in the patient's care, and they should communicate with their patients regarding this assessment in the context of the patient's specific situation. When an implanted medical device, for example, an artificial hip, has the potential to fail unexpectedly, companies often tell healthcare providers to contact their patients to discuss the risk of removing the device compared to the risk of

leaving it in place.

And patients, patients are the end users of many recalled medical devices. Essentially, patients need to know if a recall affects them and if so, what they should do. Patients face decisions about whether to continue or stop using a recalled device. In some cases there are adequate alternatives and in other cases there are not. Patients often discuss the benefits and risks of this choice with their healthcare provider. In the case of a direct consumer device, patients may rely on other sources to become aware of a recall and obtain information needed to make their decision.

Most recalls follow a process, as described on this slide. It begins when a manufacturer detects a postmarket issue. The manufacturer assesses the problem to determine if a recall is required. Within 10 days of deciding to initiate a voluntary recall, the manufacturer must notify its direct customers and the FDA. In many cases, the direct customer is a distributor or a hospital manager rather than the patients or the individual healthcare providers. The direct customer is then expected to notify their customers downstream to the extent that it's recommended by the manufacturer in their recall strategy. Healthcare providers and end users then respond by correcting or removing the device and also sending a confirmation back to the manufacturer.

Upon being notified, the FDA assesses the risk to health and the manufacturer's recall strategy, then classifies the recall and posts public information. Sometimes the manufacturer or the FDA puts out additional public communications in this space, which you'll hear more about from subsequent speakers. The manufacturer confirms their communications and actions to remedy the recall issue are effective and then implement changes to address the root cause of the recall to prevent it from recurring. Meanwhile, the FDA monitors the recall activities and the effectiveness.

Some common causes for initiating a recall include:

- General medical device or a specific component failure such as a resistor or capacitor;
- Design flaws including human factors issues;
- Inadequate instructions for use;
- Package integrity problems for medical devices marketed as sterile; and
- Not obtaining the required FDA authorizations prior to marketing the product.

FDA requires that manufacturers operate under a quality management system. In a healthy quality management system, the manufacturer looks for evidence of issues and then takes appropriate actions when it becomes aware that there is a problem. A voluntary recall would be an appropriate action to take if the manufacturer learns that it has distributed a product that does not meet the requirements.

The FDA is responsible for ensuring the manufacturer is taking the necessary steps to adequately mitigate the risks to health in a timely manner. This includes assessing whether the manufacturer's recall communications to customers are appropriate and effective. The recall scope, classification, and strategy all play a role in determining what the appropriate communications are to inform the public and mitigate the risks to health.

If the recall involves hundreds of thousands of devices, an urgent public communication may be warranted. Alternatively, if the recall risk is low, a direct communication to the affected customers may be more effective.

In overseeing a company's recall strategy, sometimes the FDA will issue its own communication to raise public attention about the risks of using the recalled device. For example, the FDA is more likely to do so for recalls associated with a higher risk, like a Class

I, when the issue is more urgent, when the scope is broader, or when the effectiveness of the manufacturer's communication is questionable.

The FDA has another regulatory requirement that when utilized may increase the effectiveness of a recall. The FDA's unique device identification requirement involves placing a human and machine-readable code on most medical devices to make it easier to identify specific medical devices. This system may also facilitate rapid identification of medical devices affected by a recall and help healthcare providers and patients get the information they need.

So in summary, recalls are an effective way of addressing unexpected issues that emerge with products on the market.

FDA, the medical device industry, and others share responsibilities for informing patients and the public about medical device recalls.

The FDA is engaging stakeholders to identify opportunities to inform patients and the public more clearly and effectively, in a timely fashion, and in ways that are relevant and of most benefit to patients.

Next, you will hear from Angela Calman about FDA's current efforts to communicate important recall information to the public.

MS. CALMAN: Good morning, my name is Angela Calman. This is my first PEAC meeting as the new director of CDRH's Office of Communication and Education. Before I begin my overview of our communication vision and process, I would like to take time to first define what communication can and cannot do. Understanding this is critical to successfully communicating about the risks of medical devices.

While there are many things communication can do, there are some particularly relevant to recalls, to include:

- Prompting an individual to take an action, like to update a device or stop using it;
- Reinforcing knowledge or behaviors; and
- Refuting myths or misconceptions.

What communication cannot do includes:

- Compensating for inadequate health care or access to healthcare services;
- Producing sustained change in complex health behaviors without the support of a larger program for change; and
- Being equally effective in addressing all issues or relaying all messages.

These are the various communication vehicles we use to disseminate information to the public, though we must consider data about barriers to information, including some of these channels and formats we currently use. To address barriers, we must understand the factors that create them. For example, not all populations get information from smartphones. There are significant numbers of people over the age of 65 and in rural communities that can only receive information through their phones, through SMS text delivery. While the digital divide is shrinking, it must still be considered in recall communications.

Sixty million Americans age 5 and over speak a language other than English at home and 7% of Americans don't speak English at all. But to reach all Americans requires an understanding that not all people can be reached the same way.

In the U.S., 46% or nearly half of the U.S. has limited health literacy. Health literacy is defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. This means we need to be intentional about using evidence-based approaches

such as visual aids and user comprehension testing. These barriers are often compounded by each other, creating complex challenges for the communicator and the recipient.

We've covered what communications can and cannot do. With recalls, the challenge and responsibility to communicate and inform is even greater. We shared the vehicles we use for communicating but noted that the ones we use may also have multiple barriers for some in receiving information.

Patient populations are each unique, that is why it is so important that we are clear on our vision, as well as our methodology as to understand how people are impacted differently by information as well as how they receive it. In the next few slides I will share how our vision drives our strategy to build and deliver a better communication product, a product that overcomes these challenges and provides the impacted patient with the information they need.

Our vision is simple, it is a patient-centric approach using qualitative and quantitative data points that include empathy, creativity, and critical thinking to solve problems.

There are best practices in communications and ways to effectively deliver information that will be discussed throughout this meeting, but I'd like to highlight where we are focusing now for our work in recalls. We cannot solve the problems we don't understand, which is why an empathetic approach to data collection is so important.

Adopting social science best practices is the next step in our efforts to build stronger communications and improve how we deliver recall information. Social science skills and methodologies will be applied to communications through message testing and evaluation of distribution channels.

Through understanding the challenges of specific intended audiences, we are better

prepared to address these roadblocks and develop content that is communicated more effectively. This should result in clear information that reaches its intended audience, which may also include audiences that support patients such as healthcare providers and healthcare facilities.

We are focused on three core competencies. The first is message testing to better understand our intended audience's comprehension and preferences for communication and educational content.

Audience segmentation helps us better serve our intended audiences by acknowledging that different subgroups have different needs. By organizing groups into segments of people who have shared characteristics, challenges, and needs, we can align message testing and other means of research to ensure better representation of the needs of the population.

Personas are a fictional depiction of a person who represents the characteristics of a larger population. Based on qualitative and quantitative research such as individual patient feedback, personas provide a much deeper understanding of the expectations, concerns, and needs of a specific audience segment and helps answer the question, "Who are we developing this recall communication for?"

For example, a persona may be Sue, a married 50-year-old female with two grown children. She has Type 1 Diabetes and lives in a rural community. She lives 40 miles from the nearest hospital, which limits her access to care. She gets most information from cable and local TV, radio, and print news, cell phone texts, and regular e-mail. She attends church weekly and volunteers at the local library where she occasionally checks the Internet. She does not have a computer at home. She trusts the information she receives from her pastor and the nurse practitioner at the local diabetes clinic.

Personas provide a more empathetic representation of the patient experience but it is informed by real patients. Personas can also be caregivers, nurses, physician assistants, and others who have roles in informing or caring for patients.

Our focus is on continued feedback, iteration, and improvement. We have an ambitious list of goals for the office, but your input is essential. CDRH is committed to bringing the best practices of message testing, audience segmentation, and other data-driven methodologies to our work. We have started to engage on some small projects to assess the viability and scalability of enhancing our writing and design capabilities. Specifically, we work with writers who are trained to take complex scientific concepts and communicate them in clear and simple ways that resonate with the intended audience. We also evaluate design and production capabilities across various modalities such as animations, graphics, video, and audio communication for viability in a safety communication environment, especially as it relates to recalls.

It is essential that we can incorporate real-time data to address relevant concerns and the unique needs of each audience. We must develop processes and test them to assure we can develop these products with the quality and timeliness that recall communications require.

CDRH's dedication to a patient-centered approach is an example of how we continue to foster the Center's culture of patient engagement throughout the organization. We are humbled by the mission and grateful for the opportunity to serve. Thank you for your time today.

MR. CONWAY: I'd like to go ahead and thank the FDA representatives for their presentations.

We will now proceed with an industry presentation. Mr. Ommeed Shahrokh from

Stryker will have 10 minutes for his presentation. You may now begin your presentation, sir.

MR. SHAHROKH: Hello, I'd like to introduce myself. My name is Ommeed Shahrokh, I'm the Director of Regulatory Compliance and QMS Integration at Stryker. I've been with Stryker for a little over 11 years and I've worked in various departments from manufacturing to NC, CAPA, to postmarket surveillance and now I'm in the regulatory compliance group managing recalls for Stryker joint replacement division. I'd like to start off by thanking the FDA and the Patient Engagement Advisory Committee for giving us an opportunity to speak at this meeting; we're excited and we're looking forward to more collaboration in the future.

The Stryker mission aligns very well with the Patient Engagement Advisory Committee goals and that's together with our customers, we're driven to make health care better, and our values which we live every day are integrity, accountability, people, and performance.

Today's agenda, I'm going to go over a little bit of what a product field action is, I know there's going to be some other speakers who are going to get into a little more details around field actions, I'll just touch upon that. I'll discuss postmarket surveillance and what a postmarket surveillance program looks like at Stryker; discuss a little bit around PFA assessments, how we perform them, how we make decisions; PFA execution, once we decide to execute a recall, how at Stryker we go about doing that; and lastly, I'll discuss a little bit around effectivity monitoring. So once we execute a recall at Stryker, how do we monitor how effective that recall is and how do we contact our customers, end users.

Recalls, corrections or removals are governed by Part 806 of the Code of Federal Regulations, and a recall is a method of removing or correcting consumer products that are

in violation of laws administered by the FDA. Within the scope of recalls are corrections and those are repairs, modifications, adjustments, relabeling a product in the field. Recall is a voluntary action that takes place when manufacturers or distributors actively protect the public health from products that present risk of injury or are otherwise defective.

So I'm going to discuss a little bit what production and postmarket monitoring is. So when we develop medical devices through our new product development process, our design control process or risk management process, once the product is commercialized, we actively evaluate that product to make sure it's meeting its intended use and it's safe and effective. So we have multiple inputs that we monitor; these are nonconformances, complaints that come in from the field, adverse events, field actions. In the case of Stryker, we manufacture a robot, the Mako, so we have a service department, so we monitor work orders in the service department, any kind of change control, and threats, vulnerabilities, and threat sources in the cybersecurity realm. Those are all inputs or some of the inputs that we monitor. Data analytics is critical at Stryker, so we really rely on our systems to ensure our products and our product performance is within control.

And as I go through these slides, I want to share a hypothetical example of how an issue or how we manage an issue from start through the recall process. So in this case, there's a faucet and we start getting complaints from the field that after installing new faucets, we start seeing a leak. So we get multiple complaints, we notice that the rate at which we're getting complaints related to the faucet leak exceeds our control limits and we initiate a nonconformance. We send out a service engineer in this case, the service engineer identifies that a washer that's supposed to be installed as part of the manufacturing process is missing and therefore we have a nonconforming product in the field. So this is a faucet that is missing a washer, it's nonconforming, it's out in the field and

the complaints we're getting is a leak. And I'll walk you through this hypothetical scenario as I go through the slides.

So now we know we have a nonconforming product, we have an issue with product in the field, how do we assess it, how do we determine what to do with that product? And the mechanism we use is a product field action assessment and there's three essential components to a product field action assessment. There's a technical assessment which evaluates hazards to a patient and I'll discuss a little bit what that means next. We have a medical risk assessment and this is where a healthcare provider, in our case, the joint replacement division at Stryker, we use a clinician and orthopedic surgeon that does our medical risk assessments, to identify any harms that may be associated with the nonconformance or the issue. And lastly, we do a health hazard evaluation where we evaluate the severity of the harm, we evaluate the hazard, we evaluate the occurrence of the harm, and this all relates to patient safety and then we make a decision in terms of what kind of recall action we will do to address the nonconforming product in the field.

I'll discuss a little bit technical and medical assessments, that is our hazard and harm identification. So the technical assessment identifies potential hazards associated with a nonconforming device and a hazard is a potential source of harm. Hazardous situation is the last observable set of conditions prior to a harm and circumstances in which people, property, or the environment are exposed to one or more hazards.

So when we do these evaluations, what we do is we look at the nonconforming condition or the issue and we look at the sequence of events from that nonconformance all the way into the use of that nonconforming device to evaluate what are the potential harms that could occur to a patient if they were to use the nonconforming device.

So in our example, below here is a good example. We had a nonconforming faucet

which was missing washer, that could lead to a hazard of a leak which could then ultimately result, if I follow the sequence of events, to a hazardous situation of a puddle on the floor and ultimately, that standing water on the floor, somebody can walk by and slip in that water which would ultimately cause a harm, which will be our next slide, again, for some of the details of harm identification.

Once we have the hazards, a medical assessment is performed and this is done by a healthcare provider, like I mentioned earlier, that in joint replacement, the Stryker division that I work with, an orthopedic surgeon performs a medical assessment and the orthopedic surgeon evaluates all of the hazards and determines what are the harms that are associated with the hazards and these are harms to the patient, could be also harms to the user, but in most instances, we're evaluating harms to patients, and a harm is physical injury or damage to the health of people or damage to property or environment.

So if we follow this example from start to finish, we have again the nonconforming faucet missing a washer in the field, results in a leak. The hazard is a leak that forms, the hazardous situation is a puddle that could form on the ground and this could ultimately result in a harm where somebody can slip on the water and fracture their hip bone. So this is the start to finish, how we go through a sequence of events as part of a nonconforming device in the field to determine what are the harms to our patient. And this hypothetical example, as we go through the assessment, we see that this nonconformance could potentially result in harm to a patient in the field and this would trigger us to take an action. As the example, a hazard of slipping on a wet floor can result in a potential harm.

So now we're ready to execute a recall. What is a recall? Why do we take recalls? It's to reduce the health risk posed by the device or remedy the violation of an act caused by a device which may present a risk to health, and all our decisions are based on what is

the health risk to our patient as a result of the nonconformance.

There's two elements of the recall, there's a removal, and that's the physical removal of the device and we may reach out to customers in the field and ask them to return the device where we can correct them or we can destroy it or we can correct it. In this hypothetical example, what we can do is we would send out a service engineer to maybe go out in the field and install the washer. So in this particular example, if I go through the two examples of a removal and correction, we may ask our customers who have not installed the faucet, return it back to Stryker and then we would destroy it, and for customers who have already installed it, we would send out a field service engineer to repair or add the missing washer.

So how do we get this information to our customers? We get it via product field action letter, it's the certified letter that we send to our end users in the field. I want to touch upon a really important part of medical devices and medical device recalls and that's traceability. So there's elements like UDI, which is the unique device identifier that we use, which really helps us trace product from manufacturing through distribution to end user.

So this allows us to identify when we do have issues with product and specific lots of product, it allows us to trace that product from manufacturing all the way to the end user to ensure that we're getting the product field action letter to the right customers. In our cases, our customers are usually hospitals, the risk management or recall coordinator of hospitals or the end user, in this case which would be a surgeon.

The product field action letter provides a description, the scope of the products which is the catalog or lot numbers that are affected; as I discussed earlier, it would include any hazards and harms and any risk mitigations and additional actions that are required to be taken.

So again, if we use the hypothetical, we may include risk mitigation, maybe turn off the valves to the water or to the sink to ensure that it's not used until the correction is implemented, and any additional actions when our surgeon does their medical assessment, if they provide any other additional recommendations, maybe around patient follow-up or increased patient follow-up, we would include that, as well, in the recall letter.

Once we issue the recall letter, what we require is that there is an accountability and acknowledgement form that's completed by the customer and it has to be returned to Stryker. We do this to ensure that the customers receive the recall letter, they understand the actions that need to be taken, and to confirm the actions have been taken. So in the case of the sink, if we shipped out 100 nonconforming sinks, we would expect to receive 100 accountability acknowledgment forms and we track that. So as we approach a hundred, if we're missing any, we will go back out to customers either through letters, e-mail, phone calls, and follow-ups to ensure that we get as close to a hundred percent effectivity as we can with recalls.

So that's really high level, just want to give you guys a little bit of insight into how Stryker executes their product field actions, the importance of executing product field action, give you a little flavor through this hypothetical example of how we would take an issue from start to finish to execute a recall and hopefully, folks that are not that familiar with the recall process get some insights into how industry and how Stryker manages recalls. Thank you.

MR. CONWAY: Thank you very much, Mr. Shahrokh.

It's about 11:15 and right now we'll go ahead and take a 10-minute break. Committee members, please do not discuss the meeting topic during the break amongst yourselves or with any virtual member of the audience. The meeting will reconvene in this

room at 11:25, actually 11:26. At that time we'll continue with presentations, hearing from healthcare provider and the patient. So we'll reconvene at 11:26. Thank you.

(Off the record from 11:16 a.m.)

(On the record at 11:27 a.m.)

MR. CONWAY: Great. Welcome back, folks. It's now approximately 11:27 and we'll go ahead now and we'll hear from healthcare provider perspectives on medical device recalls from Elizabeth Eisenberg, and a patient representative on benefit-risk recalls from Kimberly Platt. You each have 10 minutes for your presentations.

Ms. Eisenberg, you may go ahead and begin your presentation.

MS. EISENBERG: Good morning on behalf of ScrippsHealth and diagnostic healthcare professionals across the country, I am honored to share our story with you this morning. Today, in our short time together, I would like to cover three points: first, how a clinically integrated supply chain supports a rapid, coordinated response to medical device recalls; second, I'd like to share two recent examples of medical device recalls and our response to those; and finally, I will close with highlighting the important work that's already been accomplished by healthcare providers, manufacturers, distributors, and other key stakeholders in collaboration with the FDA.

ScrippsHealth is an integrated delivery network with five hospitals on four campuses, over 30 clinics, located in southern California, that functions within a centralized supply chain structure. Contracting, purchasing, accounts payable, logistics, and value analysis report under one domain. The full procurement-to-pay process resides in the department and is supported by a supply chain technology team. Ordering systems are managed by this team to collect, store, track, manage, and interpret data coming from different departments across the organization. The master item file is our source of truth. The

supply chain nurse team, embedded in the department, creates that clinical connection between the manufacturer, the supplier, purchasing, the clinician to physician, and ultimately, the patient experience.

Recall notifications come into the organization from a variety of ways, in an array of formats, digital and hard copy. Some notifications have missing key data elements and most are not referencing the unique device identifier or UDI to assist in that recall process. In some instances, a phone call heads-up is the recall notification trigger. The recall process is manual, requires us to transcribe and interpret the information, which delays the process. We have policies, procedures, and standard work as to how we handle and coordinate device recalls.

This system-wide policy and complicated Visio diagram covers all the required recall steps. We make sure the device or product is completely removed from the supply chain. The reason I showed this busy Visio diagram is to outline the sheer complexity, the number of manual steps required that could have the potential for human error and ultimately impacting the patient experience.

How do we respond? Recall notifications come into our organization and we immediately pull the purchase history data. We have a full-time supply chain technology team member who is responsible for managing, coordinating, and triggering that recall process. On average, he will process 8 to 10 recall notifications in 1 day. He asks, "Do we buy it? How many and when? Where is it? On what shelf? At what hospital or clinic? Was it implanted in a patient?" Sometimes it's a very easy pull-and-replace with only certain lot numbers affected, while other times it's a very complicated project requiring clinical equivalent substitutions, staff training, clinical practice and policy changes.

In the next slide, I will cover specific device recall examples and our response to

those recalls. The Philips Respironics CPAP and BIPAP device recall back in June of this year triggered an interdisciplinary system-wide team to urgently come together. Because the impact of this recall affected both inpatient and the out-of-hospital experience, this became our priority project for that week. On the outpatient side we identified over 5300 patients with affected devices. We also identified eight of our sleep study devices were affected by this recall.

This grid outlines the complex manual work that our system-wide respiratory care practitioners performed. On the left side, you see the team counted every device, located and removed 44 total recall devices from patient care, 41 of the V30s and three of the Omni Labs, within days of receiving the notification.

On the right side, they determined devices that are currently in use, which patients were on it, were they affected and do we have an alternative. They identified alternative devices that can perform the same treatment modalities, although not ideal. The team determined how many devices would be needed for emergency capital funding request to support patient care, as well. The V60 was identified as a substitute device but it's not comfortable, it's louder, not ideal for a restful sleep. The mask and tubing are not what the patient is used to, and most patients refuse this as a clinically acceptable alternative.

The respiratory care practitioners possibly could have been telling these patients for the very first time about the recall device entering our facilities. We put together standard work and standard communications rules that were developed to help them manage the situation. From assessment, to intervention, to the documentation, each step was outlined to be consistent.

This is our standardized communication tool for clinical practice alerts, recalls, discontinuations, or back orders. We use SBAR (situation, background, assessment, and

recommendation) to communicate any significant change to the organization. This is sent out system wide through a standardized e-mail communication process both in acute care and in the outpatient setting.

The document on the right is the e-mail communication template used by our sleep study center to notify those patients about the recalled device.

On the provider side, in order to help the medical staff office and the physicians, standardized e-mail templates and office staff talking points were developed to coordinate our response to patients. We even mailed out letters to patients as a secondary measure, doubling our work efforts to ensure they received the communication.

In the next two slides, I will cover the Medtronic HeartWare HVAD Controller recall and response.

I'd like for you to meet Bob Simpson. Bob was a recipient of the Medtronic HeartWare HVAD system. The HVAD system is a left ventricular assist device that helps the heart pump and increases the amount of blood that flows through the body in patients with advanced heart failure. The HVAD system was authorized to be used as that bridge to cardiac transplantation in eligible patients. The Medtronic recall notification with a specific list of lot numbers notified us that Bob has a controller that's defective and his internal pump may delay or fail to restart as warned in the Medtronic letter. Bob's care team held several multidisciplinary committee meetings to discuss his case. Unfortunately, because of his advanced age, frailty, prior surgeries, he would not be eligible for a new device and if it fails to restart, he will likely have to go on palliative care or hospice. Bob understands the device issue and is in alignment with the care team; he was happy to share his story with you today.

Next, I'd like to share the specific recall steps taken for the HVAD recall. After that

heads-up phone call, my ventricular assist device manager quickly called the care team together and notified them about the recall. Twenty-four hours later, we received the official notification from the FDA, we identified seven patients with the device but luckily, only two had affected lot numbers. We shared one of them and that's Bob. Within 24 hours of that recall notification, all patients had been contacted letting them know whether they had the recall device or not.

Upon visiting Bob at his home, the care team placed a bright pink neon sticker on the outside of that controller, identifying it as a recall device. The sticker was put into place to assist the 24/7 emergency call line to troubleshoot the device when patients have an issue or a question. The care line team members were educated to ask the patient having that neon sticker on the controller in order to take different troubleshooting steps with the device.

In closing, I would be remiss if I did not mention the incredible work of AHRMM, the Learning UDI Community, industry leaders, AHVAP, all in collaboration with the FDA. The vision of having one consistent unique identifier allowing the device to be tracked from creation throughout the supply chain continuum and into the patient's medical record was the driver of the UDI regulation. The UDI was set to improve patient and device safety by enhancing patient safety recall systems and adverse event reporting. I wonder, myself, if we have all of these strategies in place, let's work together with our manufacturing and distributor partners in order to eliminate all of these manual steps prone to human error. Beyond the patient safety aspects, this process lacks consistent identifiers to make the recall management system less time consuming and less costly to health care.

Healthcare systems and providers should be able to receive timely notifications in a standardized digital format so that the data feeds and technology language can integrate

with our supply chain and clinical software systems. We need to eliminate the manual work, the delayed response times, and create a rapid process for identifying the device by calling the device by its unique name. The groundwork and a strong foundation has already been established and now it's time to formally implement this across the supply chain continuum.

Thank you very much, I appreciate having the opportunity to share our processes, our communication strategies, and Bob's story with the Patient Engagement Advisory Committee. I look forward to the live session and any questions from the Committee members.

MS. PLATT: Hello. Thank you for this opportunity to speak to all of you today. As you can see, I am a survivor of breast implant associated anaplastic large cell lymphoma.

A little bit about me. I was diagnosed in 2017 after being part of a research IRB that started in 2004. At that time, it was with McGhan textured breast implants. After my diagnosis, I found it to be very lonely and very much of an emotional roller coaster as I basically was dealing with having this cancer diagnosis from an implant that I chose to put inside of my body. At that time I was also a nurse manager of an ambulatory surgery center and had lots of interaction with plastic surgeons and vendors for the different types of breast implants, so I believe that not only from my professional aspect of having to deal with breast implants, becoming a patient and having to understand the process of dealing with manufacturers after a diagnosis that is so personal and also just having to understand how to work within the system as a patient versus a professional caregiver.

I did speak in front of the FDA in March of 2019 after my diagnosis as an advocate wanting to have textured breast implants recalled and removed from the market. After that experience, I found it to be very rewarding to understand really how the process works

within the FDA and to really advocate for women who I was hoping would not have the diagnosis that I had from textured breast implants.

In July of '19, as we all know, is when the recall occurred for the Allergan Biocell implants and at that time, the world really opened up for my advocacy and also the other women that, unfortunately, joined me with this diagnosis in ways that was beyond what we had ever expected.

As an advocate and someone who really wants to help others to try to find out what's going on with their personal health status and their emotional status when this recall came about, several things were very concerning. There were many women who had no idea what types of implants that they had or have in their bodies and that was due to implant cards being misplaced, maybe they never even received them; surgeons' offices being closed because of retirement or transferred to another city; and this left many with the option of taking a chance of living with their breast implants not knowing, and some very much had their implants removed just for the emotional safety and the wellbeing for their own health.

What I have found after this recall is that the manufacturers really have very little knowledge of who have their implants. The HIPAA laws that have been placed federally for patient protection plays a lot into this but yet, I think as a patient that has gone through this, seeing it from a different angle versus a professional who is involved with patient information protection on a daily basis, it really kind of transformed my outlook on what should be HIPAA related and maybe what should not be.

As stated here, a year after the Biocell recall, the FDA messaged to Allergan that they were not dedicating enough time to find their patients with their implants, and so that really led me to think about how recalls are performed in the United States and how supply

chain actually affects this and what that looks like.

You know, the FDA is here to help protect the U.S. American consumer. When it comes to our food source or our food supply, everything is bar coded and we know exactly where things are going. When it comes down to implants, whether it be breast, knee, hips, anything that we put inside of the human body, does not have the same strict guidelines as our food supply chain, which concerns me. I think we need to look at the overall supply chain for human health, should really be regulated in the same aspect, but from my experience, it is vastly different.

As someone that works in the electronic medical record daily, it is surprising that -- or I guess I'm hoping to say that in the future when more recalls like this occur, will the EMR actually still be a hinder or will it help? I can tell you from my personal experience, when the Allergan recall came about, in my previous role I had to grab implant books from years leading up to 2019 and go through those implant books looking for textured expanders and textured implants so my organization could actually inform these patients of their potential risk. At that time, I was still working -- not still, but I was working in the EMR, so instead of attempting to pull records from when the EMR was implemented to current time, it was still felt that going through the implant logs was the better way to do it. So I'm hoping that as time moves on and we become more savvy with the EMR, those types of situations will go away and be a lot easier for us to find information that we need.

I also took part in the informed consent process that the FDA sent out as a survey and for suggestions as to how to make the consumer for breast implants be more informed. You hear me say the word patient and not women because there have been transgender patients that have had my diagnosis, as well, and so this just does not affect women, this affects people on many different levels and it's something that we really need to be mindful

of. By creating a more robust informed consenting process, I am in full agreement that patients as consumers of these types of implants will have a better educational platform to make sure they are making the decision that they believe is the right decision for them.

I also want to communicate that I currently still do have breast implants, so I am not one that advocates for all implants to be removed from the market because I firmly believe that there is a place for breast implants. But as a patient advocate, I feel that there needs to be a robust patient education leading up to that decision.

And at this time I would welcome any questions or comments from the group. Thank you.

MR. CONWAY: So I'd like to go ahead and thank the FDA, Stryker, Ms. Elizabeth Eisenberg, and especially Ms. Kimberly Platt for their presentations and I would like to ask my Committee members here to indulge me on this for a second. We have a hard deadline where we need to encourage folks to get involved in the Virtual Breakout Session and that's very important for the substance that we'll be able to recover from those discussions.

We have time for one or two brief questions to the folks who recently presented information to us, FDA, Stryker, Ms. Eisenberg, and Ms. Platt. If you have a question, if you could go ahead and indicate that. I do have a fair amount of text I need to read for the Virtual Breakout Session. So we're trying to recover time, I need to get those sessions going by noontime, but is there a brief question that anyone has of them? If not, I'll roll into instructions for the breakout.

(Pause.)

MR. CONWAY: I'm not seeing any hands right here. Again, I'd like to thank those who have talked to us this morning. For the --

MS. CAPANNA: I'm sorry, Paul, I saw Rachel Brummert and Cynthia Chauhan had

their hand up.

MR. CONWAY: Oh, okay, my apologies. Thank you.

MS. BRUMMERT: Thank you for bringing that up. I would like to ask of the Stryker manufacturer, the diagrams were really cute but we're talking about medical devices here. So to use an example, I have a Stryker implant in my neck and I'm about to get a new replacement. How would Stryker notify me, as the patient, about a recall?

MR. SHAHROKH: Thank you, Rachel. Yeah, Stryker, we follow or we notify our end user, which would be the hospital or the surgeon, of the recall and then we, through them, request through actions if they reach out to any downstream patients that would have received the implant.

MS. BRUMMERT: Would you consider including the patients in that communication, though, because no -- you know, we're not receiving it from doctors, we're not receiving it from the manufacturers. What would you do to include patients?

MR. SHAHROKH: So if we have that traceability through patients, Rachel, we would reach out directly to patients depending on the circumstances. Our traceability or at least our ERP traceability goes through our end user which is, again, the hospital or a surgeon.

MS. BRUMMERT: Thank you, sir.

MR. SHAHROKH: Thanks for the question.

MR. CONWAY: And the second question? Go ahead, Cynthia. Cynthia, you're still muted. Thank you.

MS. CHAUHAN: Cynthia Chauhan. Ms. Platt, I'm wondering if you could share with us a little bit more about what I heard as your concerns about how HIPAA may or may not interfere with this process.

MS. PLATT: Well, I believe, as the Stryker rep just stated, is that the hospital would

be notified for the dissemination of the information of a recall. My understanding is that hospitals cannot provide information to the manufacturers of who is receiving their implants. You know, from my understanding and from my experience, there is really even no way to even, as a patient, to advocate for myself to provide information to the manufacturer. It's kind of like if you buy a new oven and you have a registration card and you submit that information, we don't have that same capability of doing that. So it's really a catch-22, I feel, is that because of the HIPAA Act for patient privacy, really limits how much information can be going to the manufacturers so that we have real-time notification of these recalls.

MS. CHAUHAN: Thank you, that's very helpful.

MR. CONWAY: Great. Is there one last question before we roll into instructions for Virtual Breakout? Go right ahead, Ruth. You're still muted.

DR. R. PARKER: Thank you. So this is more from, I guess, a regulatory standpoint, I just want to get clarity on product liability for devices and where that lies. I hear reference to the customer, which sounds to me like the -- usually a health system or a healthcare entity. So I'm trying to understand, I guess I'm comparing it to medications where the large entity -- I just wondered if somebody at the Agency can clarify that for me as it relates to safety.

MR. CONWAY: Kathryn, would you like to -- or Erin?

MS. KEITH: Yeah. This is Erin Keith. The regulation requires us in the way that it is implemented is for manufacturers to contact their customers, so the customer is the one that has that relationship that then becomes involved in helping with the recall process and confirming that the products have undergone the activities that are specific to the situation, whether that's the correction or the removal of the product. And that is varied, depending

upon the product. It can be a hospital or the caregiver themselves or it could be to retail outlets where the patient is able to obtain the device themselves independent of the medical relationship with a healthcare provider.

MR. CONWAY: Great. Thank you very much. I'm going to go ahead and move to encouraging folks that have confirmed, as participants of the Virtual Breakout Session, to log out of the webcast and log in to the Zoom link they were provided so the Virtual Breakout Session can begin at noon. During the Virtual Breakout Session I invite those participants of the Virtual Breakout Session to participate in discussions that are focused on the scenario questions that were previously provided to them, as well as included in the background materials posted on the FDA's website for this meeting. FDA moderators will provide breakout participants with additional instructions for the breakout session once they are logged into their Virtual Breakout rooms.

As a reminder, this part of the meeting will not be webcast and the Committee members will not be present. The Committee members, as well as those that are viewing via webcast and those who participate in the Virtual Breakout Session as well as those who are not confirmed participants for the Virtual Breakout Session will rejoin the meeting when it reconvenes after the 12:30 lunch concludes, which is 1:00 p.m. Committee members should return to the Zoom platform and those that are viewing the webcast will need to rejoin the webcast at 12:55 p.m. to continue viewing the rest of this meeting. The meeting will officially reconvene at 1:00 p.m.

Committee members, please do not discuss the meeting topic during the break amongst yourselves or with any member of the virtual audience. Again, the meeting will resume to the general public at exactly 1:00 p.m. Virtual Breakout participants, please be aware that it will take a few minutes to get everyone situated, so if you can go ahead and

head over on to that link that's been provided, that would be terrific. Please begin logging in to the Zoom platform. AV, you can go ahead and proceed with closing the webcast. Thank you.

(Whereupon, at 11:59 a.m. the Virtual Breakout Session commenced and a lunch recess was taken.)

AFTERNOON SESSION

(1:01 p.m.)

MR. CONWAY: Great. It's now 1:00 p.m. and the Committee has returned and I'd like to resume this Committee meeting. We will now begin our Virtual Breakout Summations. The summations will reflect the major themes that were discussed in the breakout rooms in response to scenario questions. The summations will not be transcripts of the discussion, but instead highlights from the discussion.

Moderators, please note that if there are additional points that were not covered by prior moderators, subsequent moderators can feel free to add comments when called upon to report out.

I'd now like to go ahead and ask the moderator from Breakout Room 1 to summarize your table discussion.

DR. CHEN: Hello, my name is Allen Chen representing Breakout Room 1. Our question focused on "How would you feel learning about the news of the recall?" And the overall theme from Breakout Room 1 was a feeling of concern and wanting to know more.

Another theme that I heard was puzzlement, for example, "Hmm, did I get this device or maybe I didn't get this device." "Did my doctor give me any documents upon my discharge that might help me understand if I have this device?"

In terms of the feeling of questioning, some of the types of questions that were elicited in our group were “What are the issues?”, “Am I affected?”, especially, “How do I know if I'm affected if my surgeon isn't here anymore?” So overall, we heard concern and wanting to know more.

MR. CONWAY: Great. Thank you very much, Mr. Chen. Appreciate your summary.

I'd now like to go ahead and ask the moderator for Breakout Room 2 to summarize your table discussion.

MS. ENGLEMAN: Hi, everyone, this is Donna Engleman from the FDA. The question that we will be sharing today is "What information do you most want to know?" So the feedback from the participants were they were very much interested in details of the risk of the product, what the lot numbers were, and how can they find out how they may be impacted by this medical device recall and what are the necessary steps that they need to do to ensure their safety given this is the first time they're hearing about this. Also, they wanted to know whether their device was affected and what lead the company was providing to identify these certain lot numbers and what the word recall means.

Another theme was why the device was being recalled, what were the risk factors and were there other similar devices like this one that they might need to know about, as well.

MR. CONWAY: Great. Thank you, very much, Ms. Engleman, appreciate it.

I'd now like to go ahead and ask the moderator for Breakout Room 3 to summarize your table discussions.

MR. WALKER: Good afternoon. So Breakout Room Number 3, the question there was "What other questions do you have about this recall and where would you go for more information?" So the additional questions that were captured were:

- Does the implanting physician know of this recall?
- Does the implanting physician know the lot number and the serial number of my implanted device?
- Do I have the recall device implanted within me? If so, what are my options going forward?

- What are my risks? What are the risks in this, with these options?

Additional sources for information would be Google, of course, Googling a device name in the recall to find additional information; FDA's websites and all of their databases; and also, the manufacturer's website to navigate or to investigate if they have a specific resource area of this one recall.

A big comment that everyone really agreed with in the breakout room was because it's so confusing to customers, providers, patients, and caregivers when there are so many different available outlets around the recall with information, it would be great if there was one global, one specific place where they can go to find truthful information about the recall.

MR. CONWAY: Great. Thank you very much, Mr. Walker, for your summation.

I'd now like to go ahead and ask the moderator for Breakout Room Number 4 to summarize your table discussion.

MS. FORD: Hi, this is Kemba Ford and I'm going to report out on our discussion within our group. We were posed with the question of two:

- Option A: Would we keep the device while monitoring closely for the problems?
- Option B: Would we remove the device and replace it with an alternative knowing about this recall?

Within our group, both decisions, A and B, we decided we needed more information before making a decision. We wanted to know more about the safer alternative, we wanted to know the likelihood of sudden death. We wanted to know if the doctor was making his recommendations specifically for our case. We also wanted to what are the unknowns. What do we know about the recall? Is it Class I, Class II? What are the adverse

events? And then also, what is the doctor's experience with the alternative device in a procedure?

And we also noticed that the scenario talked about there were no adverse events or no warning signs. What are the warning signs of the device? Maybe we don't know what to be aware of. So within our group, we needed more information before deciding on Option A or Option B.

MR. CONWAY: Okay. Thank you very much, Ms. Ford, for your summation. Appreciate it.

I'd now like to go ahead and ask the moderator for Breakout Room Number 5 to summarize your table discussion.

MS. KONDURI: Good afternoon, this is Indira Konduri from the FDA. Our group discussed Question 5, which essentially asked if the patient was not having any negative effects or signs of problems from the recall device at the time they heard about this news, what would make them want to remove the device and replace it with an alternative device?

General question and the discussion that went about was very similar to the themes we've heard, there was consensus that there was a need to know more about the risk of the device and the benefits of having a second surgery. General consensus was they would want to avoid surgery if the risk was deemed to be low; or if the risk was deemed to be high, then they would opt for the trouble of going through and the associated complications of a second surgery.

Additionally, it was also noted that this is a very complicated space and it's very difficult for consumers to make this decision, so they advocated for FDA to develop communications that are specific to consumers and have that available to the healthcare

providers and also have it available so consumers can be more educated when they have the conversations with their healthcare providers, because this is such a complicated space.

They also talked about the speed with which the information should be provided because patients get very anxious when they hear that there is a recall that may impact them, so get the information out quickly, try to package the information so it is more focused on consumers. And there was also a concern that a lot of healthcare providers may consider a recall to be just, they are so busy that they may just advocate for a replacement. So that's why consumer education and what FDA can do to help consumers understand and have a more educated discussion with the healthcare providers was advocated for.

And also was noted was trying to make this information available in a culture where not all of us are watching the nightly news every day, how can you make this information available and also available to a wide variety of audience and make sure that it's multi-culturally targeted, as well, and in different languages, if necessary. Thank you.

MR. CONWAY: Great. Thank you very much, Ms. Konduri.

I'd now like to go ahead and ask the moderator for Breakout Room Number 6 to summarize your table discussion and I know you're going to be wearing two hats in summarizing Breakout Room 7, also, but if you could go ahead and start with Breakout Room Table Number 6.

MS. BITTLEMAN: Sure thing. This is Katelyn Bittleman, the FDA.

So first Question 6, the scenario was based around not talking to your healthcare provider about the recall and the Question Number 6 is "How would you find out if this recall affects you? What approach would you take and where would you go for more information?"

So our breakout room talked a lot about trust and trusted sources and the

importance of having those trusted sources. So they would go to another healthcare provider to get their opinion if they couldn't trust their original one, as well as do as much online research as possible including going to patient chat rooms. They would also go straight to the manufacturer to find out more information about which specific lots and which specific devices are affected.

MR. CONWAY: Great. Thank you, Ms. Bittleman. And then can you go ahead and summarize also Table 7?

MS. BITTLEMAN: Can do. Again, this is Katelyn Bittleman.

So Question Number 7, this is "After going through this recall experience, what would you like to see FDA and industry change to make it easier to (1) get the information you need about recalls and safety issues for devices you use; (2) quickly determine if the recall or safety notification affects your specific device; and (3) make decisions about the best course of action for you in response of your recall?"

Again, the discussion mostly focused around trust and credible sources for information. There was a theme about how FDA may not always be a trustworthy source of information and they would like more access and transparency to the information. So having more access to credible registries, implementing the UDI system better, having recalls communicated more like car recalls where there is a direct connection between the manufacturer and the patient or in that case, the car owner, and see it directly on their phone. They would also like to be linked directly to devices and be given a card for every implant received so that they know exactly what is implanted in them.

MR. CONWAY: Okay, great. Thank you very much for the summary.

And since we have some time here, I'd like to ask the FDA moderators, the professional staff, are there any other insights that you were able to glean in your sessions

that might mirror or reflect some of the other questions here that were asked that you may not have been able to weigh in on? We would appreciate it. And the Virtual Breakout Session participants brought a lot of value, obviously, to this meeting and they had unique insights. Is there anything that might have been missed or that you'd like to reinforce based on things that you've heard from the other moderators?

DR. CHEN: Hello, this is Allen Chen representing Breakout Room 1. Thank you for the opportunity to add further insights from our group. I'd like to add some insights on some of the core questions.

The first one, Number 2, in addition to what was stated by Breakout Room 2, one other insight that the group voiced was that they would be interested in knowing how much time that they have, so upon hearing about the recall, how much time do they have before they have to make a decision or act.

For Question Number 3, in addition to searching on Google, participants from the breakout room talked about some of the existing datasets on FDA's website, about 15 of them, where they might go, but they also expressed that they hope that that might be consolidated. One of the questions that they might want to seek an answer to as they're searching for information would be how many people have been hurt or died.

For Question Number 4, some additional insights that were additional to those that were voiced from Breakout Room 4 were that it seemed that participants in our group thought that in Option A, where the physician recommends that the device be kept implanted but the patient continues to closely monitor for any potential signs, the participants were more likely to listen to their doctor in that case, and then in Option B, the option of actually replacing the device with an alternative device, they might be more hesitant and would want to get a second opinion.

Additionally, one participant noted that they thought that a third option should be considered, also, and they would be interested in if they should just completely remove the device.

Those are some additional insights from Breakout Room 1. Thank you.

MR. CONWAY: Sure thing, Mr. Chen. Appreciate it.

For the other moderators, any other things that Mr. Chen might have triggered in his recollections and summations that may not have been raised in your prior summations that would be helpful to the Committee as we move into the afternoon? I think not only the remarks from this morning and the presentations from this morning, but also the highlights of the Virtual Breakout Sessions are very important to Committee members to reflect upon as we're answering different questions and posing different questions.

MS. FORD: Hi, yes, this is Kemba Ford representing Breakout Group Number 4. I just want to share additional feedback that we discussed, specifically, "What information do you want to know?" Within our group, we wanted to know what the manufacturer and FDA may not know, like you are going to develop a communication and say be aware of X-Y-Z, but also tell us what you may not know, we may not know the likelihood of this occurring, we may not know the likelihood of this other adverse event occurring, and that will also help make an informed decision.

And then also, what information do you want to know is "Is this device a lifetime device? Will it have to be replaced eventually, anyway?" Having that information will also help make a more informed decision about what to do with that device.

MR. CONWAY: Great. Thank you very much, Ms. Ford.

Any other insights that folks have? I know that one of the goals that we have for today is specifics in terms of granularity of platforms, tactics, sequencing on

communications. Any other insights that were developed in the Virtual Breakout Sessions that anyone would like to share?

MS. ENGLEMAN: Hi, this is Donna Engleman from the FDA. I'd like to share some additional perspective.

In regards to Question Number 4, if your doctor had recommended in the options where either that you keep the device while monitoring closely or Option B, removing your device and replacing with an alternative, our participants were very interested in knowing how detectable the problem might be if it was recommended that they would monitor this device and keep it implanted, and also regardless of whether it was recommended that it is implanted or remains implanted or replaced, the participants were very interested in what are the costs and is there any coverage for replacing the device should that be the recommendation, and would this only be the case if this is a life-sustaining device.

MR. CONWAY: Okay. Thank you very much, Ms. Engleman.

Now what I'd like to do is go ahead and make note that we'll move to an open committee discussion so that fellow Advisory Committee members can go ahead and pose questions to the FDA moderators. So to be clear, are there other members of the Committee that would like to pose questions to the FDA professional staff who moderated the Virtual Breakout Sessions? And if you could raise your hand so that I can see that and then when I call on you, go ahead and state your name for the record for the court reporter.

Go right ahead, Ms. Brummert.

MS. BRUMMERT: Thank you. Rachel Brummert, I'm the Consumer Representative. I wanted to ask the moderators whether it came up that patients would like there to be accountability in terms of the manufacturer just saying one letter go out to say a recall notice goes out but there's no accountability. Was there any discussion around that?

MR. CONWAY: Moderators, please. Mr. Walker.

MR. WALKER: Okay. James Walker, moderator, Breakout Room 3. So one of the comments that was brought up and I was unable to mention it because we had to shift to this section, but having the recall information like the notification letter be pushed to electronic health records and so as soon as that recall is available was being aware that information would go directly to a healthcare provider and they would instantaneously be able to at least inform their patients of the issues earlier than versus in the scenario where they heard it like on TV or a news headline. So that was a great point that was brought up in Breakout Room 3.

MS. BRUMMERT: Thank you.

MR. CONWAY: Great. Thanks, Mr. Walker.

Other questions from Committee members to moderators?

Go right ahead, Ms. Edwards.

MS. EDWARDS: Necie Edwards. What I wanted to know, was there any questions come up at all concerning how patients would like to be notified? And also, were there any questions at all about the ECRI database that healthcare facilities use to update information on recalls?

MR. CONWAY: Let's go ahead and go to Ms. Bittleman.

MS. BITTLEMAN: Yes. So in our breakout room, we did talk about how they would like to be notified. There were some similarities brought up about other industry recalls such as car manufacturers, they would like to be directly notified either through e-mail or through their phone or have it -- instead of being passively told that they are affected by a recall, have them be actively contacted.

MR. CONWAY: Great. Thank you.

Other questions from the Committee members? Go ahead, Mr. Banerjee.

DR. BANERJEE: I was just curious if there was any discussion along the -- a more detailed discussion around the timeline question which is what is the timeline during which the patient needs to take an action? So for example, would it be interesting for the patient to know that their risk of, let's say, a severe illness is X percent in X time, so is that among the vital information useful and was there any discussion along those lines?

DR. CHEN: This is Allen Chen, thank you for that question. Breakout Room 1 was the room that stated this suggestion and there was no additional discussion.

MS. ENGLEMAN: Hi, this is Donna Engleman from Breakout Room Number 2. In relationship to the timeline question, in Breakout Room Number 2 there was interest in knowing what the life expectancy was of the device that may potentially be recalled as that may have some bearing on any decisions a patient may make.

MR. CONWAY: Okay, thank you very much.

What I'd like to do is go ahead and roll over to questions now from some of the Committee members. I'll come back to you, Ms. Bittleman.

Dr. Parker.

DR. M. PARKER: Yes, I think there may be some -- I need some clarity. One of those questions that we've had from other discussions is I'm concerned that a lot of people are getting devices implanted and they don't know what the lot numbers are, they don't know what the identification of their particular device is, and I didn't hear anywhere mentioned that anybody actually got that. So in Breakout Room 2 they said well, we'd like to know what the ID and the lot numbers were and I think it came back someplace else.

So it seems like the consumer is not given enough information at the very beginning, so let's just say we're getting a hip replacement or a joint replacement. When you're

discussing this with the orthopedic surgeon, it's not clear that they're ever having a discussion about the device manufacturers, what the risks are of failure of this particular device. I mean, I think I'm accurate in assuming that that device, that information is not given, that may be what the different discussions are relating to, this isn't information that's necessarily widely disseminated, right?

(Cross-talk.)

MR. CONWAY: Go ahead.

MS. KONDURI: Thank you. This is --

MR. CONWAY: All right, Ms. Konduri.

MS. KONDURI: Yeah, this is Indira Konduri and I was in Breakout Room 5. We did talk about this and we had very educated participants, so they talked about they were aware of the implant card and one of the participants said that they would take that implant card, make sure there's an electronic copy of it, and save that information. However, the participant's mother didn't know and when the participant's mother was asked, the answer was "Oh, it's there somewhere," in the file and having knowledge of having an implant card with the information that's crucial to them in these situations and you know, so I don't think -- that's an education issue is what we gleaned from our conversation. Informed and educated consumers would know, but not everybody and that is the reason they wanted more focused communication to consumers on these sorts of issues, and also making sure that that information is available to them and the healthcare provider is able to talk to the consumer about the importance of such information.

MR. CONWAY: Thank you very much. I have several questions, but I wanted to go back to Ms. Bittleman and see if you wanted to add something.

MS. BITTLEMAN: So no, Indira hit on the topic that we discussed, as well, about the

implant card.

MR. CONWAY: Okay, great. Thank you very much.

Ms. Roy.

DR. ROY: Hi, this is Dr. Rita Roy. So a couple of things that have come through from the different breakout rooms was patients not knowing what implant they have and a couple that Mr. Walker mentioned, patients want truthful information about the recall, that's in Room Number 3. Ms. Bittleman, you talked about trusted sources in Room 6. And in Room 7, again, trust and credibility on sources for information, maybe FDA's not always the trusted source.

And I think that oftentimes patients are going to see their doctor and their doctor says I'm going to do this procedure on you and you're going to get a replacement and you're going to do great, and patients don't know that they can ask for information about their implant or that they even have a choice and that kind of touches on supply chain. So like maybe this hospital only carries X-Y-Z devices, so that you don't even really have a choice. You don't know what your choices are. And so there's -- we live in a shared decision-making model in health care. Patients are going to the Internet for information. There's confusion, there's ranges of experiences.

And so I guess my question is -- and I think this was touched upon in Room 7, Ms. Bittleman, you know, I think -- is there an opportunity for patient advocacy groups to be the sort of advocate alongside the FDA in maintaining registries on a voluntary basis, people can decide if they want to be in some kind of database to get notifications on their devices and is that a role for patient advocates to play in this arena?

MS. BITTLEMAN: So this is Katelyn Bittleman.

MS. CAPANNA: Paul, if I may.

MR. CONWAY: Yes, sure thing.

MS. CAPANNA: Excuse me, I'm sorry.

MR. CONWAY: This is Ms. Capanna from FDA. Go right ahead.

MS. CAPANNA: Thank you, Rita, that's a wonderful question. I would just suggest that we take those types of questions into the discussion session for the panel later on because you're asking questions that go beyond the discussion questions that the breakout discussed, so I think that would be a perfect time to bring this back into the conversation. Thank you.

DR. ROY: If I could just say -- thank you, I just -- in Breakout Room 7 they did talk about patient advocacy groups, I just wanted to hear a little more about that, thank you.

MR. CONWAY: Great. Thank you.

MS. BITTLEMAN: Yeah. And so I'll touch on that. So yes, we did talk about registries, not specifically about patient advocacy groups, but there were brought up about patient chat rooms and other registries and things like that. And so yes, there wasn't a direct connection that was brought up to patient advocacy groups, but those types of discussions were had in our room.

MR. CONWAY: Great, thank you

Before we go to Mr. James and Dr. Reed, Ms. Engleman, you had something that you wanted to raise?

MS. ENGLEMAN: Oh, yes, thank you. This was in regards to the last question and in reference to patients wanting more information on lot information and device identifiers. In our group there was discussion along, while as healthcare providers and informed industry members, if you will, they were aware of checking the GUDID database but there was concern for patients who may not have that awareness that additional lot and device

identifiers could be made available through the UDI program.

MR. CONWAY: Great. Thank you very much.

Mr. Jones. Sorry, Mr. James.

DR. JAMES: Thank you so much. Two quick questions. I'll ask one and if time permits, a second one. Actually, the first one is to Ms. Engleman. You spoke about the fact that the word -- there was questions around what the word recall means. Would you be able to add some comment to that?

MS. ENGLEMAN: Hi, yes, this is Donna Engleman. And the statement was when they are receiving notification that their device had been recalled, they were requesting more information as to what exactly that had meant. There were further comments along, in our breakout room, in Breakout Room Number 2, that they would like additional information about not just what the reason for the recall was but what the root cause may be, as well. So they were interested in more information, what exactly does it mean that my device has been recalled.

MR. CONWAY: Great. Thank you very much.

Before I get to Dr. Reed, just for the transcriber, that was Advisory Committee Member Jijo James that was asking the prior question and it was responded to by Donna Engleman from the FDA.

Now what I'd like to do is go ahead and roll over to you, Dr. Reed. Thanks for your patience.

DR. REED: Thank you. Shelby Reed. My question relates to whether any of the participants brought up concerns about privacy, there's often tension around that. I've heard that, from everyone reporting, that patients want to know directly from the manufacturer whether their device has been recalled. My question relates to whether

there are concerns with regard to privacy, manufacturers knowing that information, or whether these patients would still like to have notification directly from their healthcare providers.

MR. CONWAY: Thank you. Is there a moderator that would like to go ahead and weigh in on that?

(No response.)

MR. CONWAY: We may be able to come back to that, Dr. Reed. Okay, thank you very much.

Go ahead, Ms. Edwards.

MS. EDWARDS: Yes, Necie Edwards. My question is did anything come up in any of the groups about once you receive notification of a recall and if it comes down to having it surgically removed, did anybody express any concerns or mention anything about the cost of this, who is going to bear the burden of the cost to remove this, because what about people who may not have any insurance that can afford to have the device removed?

MR. CONWAY: Did that come up in any of the discussions? Would a moderator -- go right ahead, Ms. Engleman.

MS. ENGLEMAN: Hi, this is Donna Engleman from Breakout Session Number 2. And the conversation did come up in our breakout room, the participants were very interested in knowing what the economics were associated with the request to have a device removed and particularly interested in whether or not the manufacturer would be covering these costs or would insurance cover them, so the question did come up as to wanting to understand more about the costs associated.

MR. CONWAY: Great. Thank you very much.

And I'll remind everybody, before you speak if you can, again, say your full name, I'd

appreciate it.

The next question here we have from our Committee member, Mr. James.

DR. JAMES: Thank you. Jijo James. I think Mr. Walker brought this up, but it was a common theme that I heard across around the use of electronic medical records in the recall process. Did any of the breakout rooms discuss barriers that may exist to why this information may or may not be there in EMRs?

MR. CONWAY: Is there a moderator that picked up any insights along that line?

(No response.)

MR. CONWAY: And if not, Mr. James, we may be able to come back to this later today in discussions, okay.

Our next question is from Mr. Banerjee.

DR. BANERJEE: Hi, Samprit Banerjee. My question is, I believe, for Breakout Group 4. I think it was mentioned that if people wanted to know what FDA does not know, so I wanted to get a sense of what is meant by that. Was there any discussion on, let's say, multiple types of outcomes outlining harm or around uncertainty of the risk estimates that can be provided with a recall?

MR. CONWAY: Is there a moderator? Okay, go right ahead, Ms. Ford.

MS. FORD: Hi, this is Kemba Ford from Breakout Group Number 4 and we did discuss that. Specifically about the uncertainty, we really wanted to know the likelihood of risk occurring, whether it's with the surgery or if you kept the device and we were looking for that communication to have that information. And if the person communicating with FDA or industry was not aware of the likelihood, it would be helpful to have that in the communication, as well, because that will lead to a better discussion with the healthcare provider about what decisions to make.

MS. BITTLEMAN: This is Katelyn Bittleman. Oh, go ahead.

MS. FORD: I can pass it to you, Katelyn.

MS. BITTLEMAN: Just to piggyback on Kemba, this is Katelyn Bittleman, our group also had to talk about learning about what the least amount of harm would be, as well, so not knowing what all the bad risks or the high risks are, but what the range of risks would be.

MR. CONWAY: Okay, thank you very much.

Any other questions for the moderators?

(No response.)

MR. CONWAY: I'll go ahead and throw one out. I was curious whether or not in the breakout discussions, the virtual discussions, there was any mention of a list of sources of manufacturing that were considered potential troublesome actors or bad actors and I'm talking about nations of origin for where devices are manufactured, did anything come up like that, that anyone had any type of a concern as a patient?

(No response.)

MR. CONWAY: Okay. Again, any other questions for moderators based on the breakout discussions?

Go right ahead, Ms. Edwards.

MS. EDWARDS: Thank you. Necie Edwards. One of the questions that I was curious about is when you think about the devices and recalls, were there any questions concerning the devices that had to be repaired? How do you know if they were adequately repaired before they are replaced back into the market? Anyone have any concerns about that?

MR. CONWAY: Any insights from any of the moderators on that?

(No response.)

MR. CONWAY: Okay. Seeing none, what we're going to do now is we're going to go ahead and take a 10-minute break. Right now it's 1:36, so we'll have folks come back at 1:46 and we'll start public comment a little bit early here. So thank you very much. Again, back at 1:46. Thank you.

(Off the record at 1:36 p.m.)

(On the record at 1:46 p.m.)

MR. CONWAY: I'd like to thank each of the FDA professional staff for your role as moderators for our Virtual Breakout Sessions, and thank you for your time and for your service today to the Advisory Committee. I'd like to thank all of those who participated in Virtual Breakout Sessions and we had done that in advance through the meeting process. This concludes the Virtual Breakout portion of our meeting and what we will now be doing is transitioning over to our Open Public Hearing.

During this portion of the meeting, public attendees are given the opportunity to address the Committee and present data, information, or views relevant to the meeting agenda. Ms. Williams will read the Open Public Hearing Disclosure Process Statement.

Go right ahead, Ms. Williams.

MS. WILLIAMS: Both the Food and Drug Administration (FDA) and the public believe in a transparent process for information gathering and decision making. To ensure such transparency at the Open Public Hearing session of the Advisory Committee 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 written or oral statement, to advise the Committee of any financial relationship that you may have with a 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 your 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 the issue of financial relationships at the beginning of your statement, it will not preclude you from speaking. Thank you.

MR. CONWAY: Thank you very much, Ms. Williams.

And now we'll go ahead and proceed with this session of the meeting. The FDA has received 13 formal requests to address this Committee. Speakers who submitted their requests to speak by the deadline indicated in the meeting's *Federal Register* notice will be given 5 minutes to speak. We will begin with a presentation from Mr. Peter Pitts, President of the Center for Medicine in the Public Interest and a visiting professor at the University of Paris School of Medicine and a former FDA associate commissioner.

Go right ahead, Mr. Pitts.

MR. PITTS: Good afternoon. My name is Peter Pitts and I'm the president of the Center for Medicine in the Public Interest and a former FDA associate commissioner.

The traditional role of the patient voice in drug development has been to share the human component of disease. To date, this has largely meant the sharing of personal, emotional anecdotes, "save my child or my mother or my spouse or me." These highly charged stories certainly help to make the drug development process more three dimensional, but does playing the victim card result in the most meaningful engagement? Anecdotes have impact, but is it impact of the right kind, of the most powerful nature? No. The plural of anecdote is not data. Regulatory actions are and must always be data based. Patient passion is important, but it must be combined with a more dispassionate scientific understanding of regulatory paradigms. The 21st century patient voice can and must evolve

into a tool used to impact regulatory decision making for both the heart and the head. That is the true pathway to meaningful engagement, the Tao of the patient voice.

Senior voices from inside the FDA speak out regularly about the importance of more evolved patient voice in regulatory decision making. The same is true in the upper echelons of the pharmaceutical industry. Now when they say it, they mean it. But can the same be said for the rank-and-file drug reviewer or the rank-and-file pharmaceutical executive? Just as important as not allowing the emotions of an anecdote to overwhelm the realities of data, is not to assume that commitments from the top equates to an enterprise-wide embrace of advancing the role of the patient voice in regulatory decision making.

Based on my numerous conversations with law reviewers inside regulatory agencies on both sides of the Atlantic and around the world, there remains significant depth as to the wisdom of more actively engaged patient advocacy. The same is also true within the legal and regulatory cloisters of big pharma.

How can we begin to address this invisible and insidious roadblock to progress? As Oscar Wilde quipped, "The truth is rarely pure and never simple." Shame on us all if we allow a recognized obstacle to go unaddressed, even if it is politically incorrect and inconvenient to do so. If you cannot measure it, you cannot manage it.

Just as the FDA assiduously collects reports and learns from its various Prescription Drug User Fee Act measurements, perhaps the Agency can develop a metric to identify where more effort is required to inculcate the karma of patient engagement in both the review and postmarketing surveillance of medicines.

One idea is to develop a WOQUE score (Wide-Open Quality Engagement) that can be compared center to center, review division to review division, in order to devise best practices and drive broader acceptance. Driving professional staff WOQUE-ness can

become a new PDUFA requirement. The time to have this conversation is now.

Similarly, inside pharmaceutical companies, how can scientists and their legal and regulatory review teams be similarly WOQUE-ed? We must design a learning health system that enables research to influence practice and practice to influence research. A timely example I once studied carefully for the lessons it teaches us is how a more educated and focused patient voice has changed and advanced development of various disease-specific guidance documents.

For the FDA, the advancement of regulatory science, such as the incorporation of patient-generated real-world data, depends on both the willingness and ability to implement new regulatory approaches based on infrastructure, capabilities, and trust between stakeholders.

Developing a more integrated role for the patient voice to help advance patient involvement in the development and safe use of medicines requires more than dynamic statements from the healthcare ecosystem's senior leadership. We must strive to develop the rules and measurements for success. One size will not fit all patients, regulatory systems, or pharmaceutical companies. As with any ecosystem, the component parts of drug development and review are not necessarily equal to each other, but they are all requirements for success. What the patient voice must fight for is equal respect and recognition of mutual value. It is not a question of equal, but of integral.

Thank you very much.

MR. KUCERA: Hi, everyone, my name is Rich Kucera and I'm the CEO and one of the co-founders of Symmetric Health Solutions. I'm speaking today as both a patient, family member, and tech CEO in health care. Prior to starting Symmetric, I spent several years as a consultant in Accenture's healthcare supply chain and operations practice working within

hospitals. During that transformative time, I started to appreciate the complexities and dependencies that exist in health care.

Sharing the stories of hospital process breakdowns with friends and family is usually first unbelievable and then frightening, especially around implanted device recalls. The majority of people believe they will be promptly notified by their healthcare provider if a device in their body needs to be removed. This is not always the case.

Last year my brother-in-law, who I'm quite close with and is familiar with device recall challenges from the business, had a medical device emergency with his father. He began passing out and was rushed in to the hospital multiple times without any explanation as to what could be going wrong. He immediately got a hold of his father's original implant card, which luckily he had saved, and began searching in our database. Lo and behold, the shunt implanted in his brain at a prominent hospital in Baltimore, Maryland, the same one he was being taken in to several times, had been recalled in 2017. Luckily, the story ends well after an emergency surgery, but it makes you wonder how many countless others do not.

So where are the failure points? First, unless a hospital is scanning UDIs or item barcodes, as I like to say to those who are not in the industry, there is often many details about the items missing. In fact, during my time in hospitals as a consultant, I saw just the word "implant" documented many times on patient records. Luckily today, many hospitals have started scanning UDIs at point of use in the patient records.

Second, if a recall occurs, it's often communicated via a letter in the mail to the hospital and in similar, unstructured text to the FDA. As a hospital, you now have to manually read and decipher this document for FDA's website, identify the items in question within the text, then search across your internal systems of item records, which generally

ranges between 30,000 to 700,000 items. Then you must go through the thousands of patient records to identify anyone impacted. As you can imagine, this is quite a tedious and error-prone process. One of the biggest reasons for creating the GUDID or G-U-D-I-D database was to automate the patient safety risk by allowing everyone to search, match, and communicate programmatically about medical devices.

Today there's well over 3 million items with a UDI or barcode, and at least over 400 hospitals have used barcodes aligned to their internal systems of records for each item and are scanning them into patient records. What doesn't exist today is structured recall formats containing the UDI or barcodes.

In fact, we did an audit over the years of the implantable devices recalled that didn't contain any UDI. What you're seeing is that as of last year, just over 20% of recalls contained a UDI. This is not only alarming, but quite sad given the investment the U.S. manufacturers, hospitals, and many other countries around the world are making into UDI adoption. As I said in the beginning, hospital operations is quite complex and dependent on other parts of health care.

So then, to rectify this patient safety concern in our society and prevent the story of my brother-in-law's father, the FDA needs to invest in a structured and programmatic device recall process that contains fields for UDIs or barcodes the world is using to properly and automatically identify medical devices with today. This will enable hospitals to automatically alert impacted patients of a potential life-threatening concern in a timely manner.

I appreciate your time, consideration, and the opportunity to present today. Thank you.

MS. REED: My name is Terrie Reed and I'm director of patient relationships at

Symmetric Health Solutions. I'm a patient with an Acumed plate and 13 screws in my left clavicle. This hardware was implanted in me in March 2012. I'm also an expert in FDA and global unique device identification regulations, and in the adoption of UDI and electronic health information. For more than 8 years I've advocated with thousands of others for policy standards and collaborative efforts to improve patient care by advancing the scanning and use of UDIs in the data in FDA's AccessGUDID.

Today I speak as a patient who believes that FDA should clarify their own regulations, leverage the regulations of sister agencies, and support the work of committed UDI adopters by engaging manufacturers, care providers, and vendors seeking to improve the recall notification process.

I acknowledge I'm not a typical patient. Most patients have never used the FDA recall website and don't stay up to date with recall notifications like I do. But I believe I share the desire of all patients with implants, to optimize the use of data and technology so that recall information is sent to us in a way we can use it, rather than us having to seek it out. I know that this is possible because UDI regulations and EHR certification requirements are driving UDI adoption in hospitals. I personally know of over 400 hospitals, large and small, that are adopting UDI, most of them to improve supply chain operations, documentation of implants, and the effectiveness of recall management.

Today, because of the Office of National Coordinator for Health IT regulatory requirements, the majority of EHRs can capture UDIs as part of implant procedures. Manufacturers are the source of UDI data, so they could easily include that same UDI in a recall notification about that device. The FDA could support these efforts by requiring manufacturers to include the UDI in recall data, just as ONC required certified EHR vendors to include UDI as part of implant documentation.

But while these uses for recall data can happen, they aren't happening. There is no requirement for a manufacturer to submit the UDI as part of a recall, there are no requirements on manufacturers to submit recall data to FDA in a structured format, and no requirements to make recall data available in a form that allows for electronic use of this information.

Hundreds of thousands of patients have received implants since the time of my implant procedure. Tens of thousands are receiving implants on a daily basis. Today it is inexcusable that I or any other patient should have to be proactively tracking recalls associated with our implants, or have any doubt that the healthcare system has an efficient recall process. We should not have to monitor FDA websites for a particular device recall.

When my car has recalled parts, I don't find this out by monitoring the National Highway Traffic Safety Administration website. I get notified via my mailbox or through text that have linked my car registration to my van. My hope is that implant and device safety are as important as car safety.

For me and other patients to receive a direct recall notification, the device recall system must change, starting with ensuring that health records include accurate device identification information based upon UDIs, then that UDI be used by manufacturers and FDA, along with other structured recall information, and communicated in a form that supports it reaching patients in a timely and efficient manner. To me, that can only be realistically achieved if FDA requires manufacturers to report recalls to FDA using electronically structured data, not e-mails or PDFs as is the primary form of reporting recalls today. And if FDA provides access to recall information, it should be in a form that can be used to make appropriate action.

If these changes were made, patients could be more effectively notified about recalls

affecting their implanted devices, and materials management staff at hospitals would receive more timely recall information and be able to more effectively pull that recalled product out of inventory and avoid patient harm. I have no doubt that my 3-year-old -- has recalled parts. I will be directly notified if a recall happens. I want the same concern for any patient that receives an implant and I think it's possible for FDA to lead the way in making that happen.

MS. GMITRO: Hello, everyone, my name is Maria Gmitro and I live in Charleston, South Carolina. I am a former educator, harmed patient, and now a patient advocate soon to be board certified. I am president and co-founder of Breast Implant Safety Alliance, it is a nonprofit, and also the director of community outreach and patient advocacy for TrackMy Solutions, which is a healthcare IT company that -- in medical device tracking and recall notifications. This company only exists because of the very issues we are discussing today. I am also part of several collaboratives and boards and I'm very thankful for the opportunity to speak with you today and provide recommendations based on my personal and professional experience.

We are all aware of the problems, I've addressed them in my written comments. The Allergan Biocell recall exposed major issues that need to be addressed.

I've asked patients what they want. They want trust, they want to trust the FDA and to trust their doctors. But they also want to know has their device been recalled, with an ability to search a system. They want to know exactly what's in their bodies, including their UDI. They want to know which devices have the most adverse event reports. They want digital alerting in real time. They want simple symptom reporting, ability for caregivers to monitor their devices, and a quick check for MRI safety usage.

Here are my recommendations. Bring this into the digital age. Rather than just snail

mail, use text messages and e-mail. Use social media to spread recall information like the CDC does on COVID-19 or recently, I noticed that the FDA was prompting the new nutrition labels. Need to update MedWatch, possibly bring back MedWatcher. Use more patient speak or language that the average patient will understand, such as symptoms, using the word symptoms rather than adverse events. Many patients don't understand what that is. Some additional recommendations. Mandate UDI adoption and make the patients aware of their UDI. Stop the sale of recalled medical devices. Scan medical devices with UDI/barcode. Be sure the medical device is not already recalled before it's put into a patient. And I think we need to consult the auto industry because they seem to easily connect with consumers on recall.

Most important, we need to increase reviewing of adverse event reports to identify possible recalls sooner. When recalls happen, review similar devices that are already on the market. Consider the patient harm when a medical device is withdrawn rather than recalled. Implications can be devastating or life changing. We need better informed consent and communication and we need to bridge the gap between the patient, physician, and manufacturer.

How can healthcare professionals and patients make informed decisions without more accurate data? Some of my final thoughts. I am very thankful that the FDA has stopped the practice of alternative summary reporting, but we need more accurate data. You need to increase funding for postmarket surveillance. The FDA needs to review the adverse event reports faster, and we need strict consequences for noncompliance.

And finally, engage your patients. We are the ultimate stakeholders. This quote is from harmed patient, Terri McGregor, she had the recently recalled Allergan Biocell textured breast implants and suffered from the cancer the implants caused, BIA-ALCL.

Please continue to engage with us.

Thank you again for the opportunity to speak and provide recommendations. I'm looking forward to seeing the FDA take action. Feel free to contact me with any questions. Thank you.

MS. KINARD-TOMES: Hi, my name is Madris Kinard and I'm here today to talk about recall communication and recommendations. I work for a company called Device Events and I'm the CEO of that company. I previously worked for the FDA as the UDI program manager and as an adverse events subject matter expert. I also worked on the Firestone tire recall in the year 2000, so I do have some experience with recalls. If anybody remembers that one, it was actually fairly large, about a hundred and forty-eight people died before the tires were recalled.

Recalls are almost always voluntary and on the manufacturer's timeline. This effectively devalues the FDA's reputation for protecting patients. When a device is recalled, if the device was based on a predicate, it also doesn't fall under scrutiny for safety problems. So a device can be based on another device and cleared for use even if the device that it's based on was recalled already.

The FDA needs to mandate recalls and do it in a more timely fashion. Safety signals typically take 2 months to 2 years to be acted upon. Often, recalls occur in concert with the clearance of a newer model, so that begs the question of whether that recall could've been done earlier and they were simply not wanting to give up some market share and left their device on the market until their newer device was available.

The public's trust is violated when the FDA doesn't enforce the rules and fine companies who abuse the public's trust. The public in this instance includes physicians and care providers who are putting their trust in the FDA.

Recalls are not timely and many times, the FDA allows a commercial withdrawal instead of a recall and that's a very different beast and I'm going to explain why this matters.

When there's a recall, hospitals are notified and physicians are notified. Sometimes patients are notified, but most often not. And there is some patient recourse available if a patient is harmed by a Class II device. With a commercial withdrawal, hospitals only learn of the withdrawal if they are seeking to reorder a device and often will use up the rest of the stock. So when the FDA allows a commercial withdrawal instead of mandating a recall, there are a lot of reasons why hospitals are hurt by this, patients are hurt, and even physicians and physicians' reputations are hurt by this.

Physicians often think a newer version means that the device is improved. Physicians who have already paid for the devices continue to implant them. And there's no patient notification and limited funding is available if they need to explant the device.

The access UDI database is public facing and is used by hospitals, they use this to update their item masters about information on the devices and this record includes commercial distribution status. As you can see, this is an Allergan Biocell implant, Natrelle. This was recalled almost 2 years ago and as of yesterday, I pulled this file and it's still listed as in commercial distribution. I'd like to recommend that the FDA also take charge of making sure this database is updated since hospitals are using it and relying on the information.

So what needs to happen now? CDRH needs to increase postmarket surveillance staffing to keep pace with the number of devices on the market. Since two-thirds of recalls begin as an adverse event report, they need to have enough staff to read those reports. The technology helps but does not replace the need for analysts.

If CDRH wants to prioritize innovation over safety and effectiveness while approving or clearing new devices, then they need to be just as willing to strengthen enforcement actions when a signal is found, indicating a device might be more risky than initially thought. CDRH needs to utilize mandatory recalls more readily than they currently do. And CDRH needs funding to improve signal identification and technology and not rely on NEST, which has numerous third-party dependencies because it uses EHRs and device registries. CDRH needs to utilize moratoriums when possible, if postmarket studies are more than a year late or if the device is under investigation to be recalled. Recall notices need to be understandable to the patients and actionable. If I have this device, what do I do now?

Thank you for allowing me to speak today, and my contact information is available if you have any questions.

MS. CONNORS: My name is BettyAnn Connors, I'm from Pittsburgh, Pennsylvania. First off, I would like to thank the FDA and Patient Engagement Advisory Committee members for allowing me to speak today. I'm speaking as a patient and presenting facts and seeking answers, also making note and informing the FDA that education, compliance, and penalties should be in place in regards to reporting adverse events.

My experience with Sculptra, which is a Class III medical device that I was never informed of and probably one of the very first patients it was injected into outside of the clinical trials. Note that the clinical trials were 100 men with HIV/AIDS. We are now 10 years into Sculptra and yet it is still under a PMA. I would like to understand how long a device is under a PMA and questioning when the device will fully be approved. I am throwing this out there as the COVID-19 and PMA and the final FDA approval took only months.

Why I am here today is because from day one, I informed the doctor that something

was seriously wrong and that I felt like the product was migrating. I believe I was injected in my left temporal vein, as I remember telling her, when she was injecting me, it was burning specifically in that area. She insisted it could not possibly be migrating and repetitive calls to her office to inform her. I have hundreds of lab reports, BIVADs, MRIs, Dopplers, that are also a different story, right here if anybody wants to see any.

So a different story, and the doctors are surprised when the techs come back reciting exactly what I was saying. Now they shy away from any further testing. I also have doctors who have totally removed test results from my medical records as it has been brought to the attention of HHS regarding the standard of care.

Since the injection, I have severe osteoporosis down my arms, which is ironic, I have stated from day one, the injection, that it was affected in my arm because I kept feeling it. There's no osteoporosis that runs in our family. I have MGUS, the doctor has not even shown that in his medical records, but all my blood labs come back, there's a protein issue there. High microphages consistently. Nodules everywhere, my face, my arms -- I've got this huge scar now -- occurring in my knees, my feet, nodules. Thyroid antibodies high. Chest X-ray has been abnormal. Consistent low IgG, IgA, IgM levels. Kappa/lambda light chain ratios are high. ANA direct positive. High scleroderma antibodies, not just by the ELISA test, as my doctor stated; I had several, I had four or five. I had a cardio infarct from five different EKG machines. Severe fatigue. Facial deformity is mentioned. Doppler stated bilateral depressed arms. This is confirmation of Raynaud's. My eyes, I was told I have cataracts. Thyroid growth after 10 years of being in menopause.

There is more I can say or add to it. Because of limited time, I just want to ensure that I'm getting across to the Committee and the FDA that doctors are not reporting adverse events. One doctor did attempt to report to Galderma, but it was never reported

to the FDA. Galderma, for some reason, didn't report it.

Also to make note, it was further like explanation as when a voluntary submission is made to the FDA utilizing the MAUDE database, the vendor, manufacturer, does not respond. The reality is that physicians should be reporting, but it seems when extreme adverse events occur, they are not taking ownership. This can be validated. There seems to be a blockage of some sort, whether by pharma, the manufacturer, the FDA, etc., somebody.

So at this time, because of my limited time, I just wanted to thank the FDA and again, this Committee for allowing me to speak. And I would be available for any questions or any further documents, if anybody needs. Thank you.

MS. RICCARDI: My name is Gretchen Riccardi and I am presenting my observations and my experience related to Boston Scientific's S-ICD Class I recalls and advisories.

In December 2020, Boston Scientific issued three product advisories for the S-ICD defibrillator system. In February of 2021, the FDA issued two Class I recalls for the S-ICD components. In both cases, the FDA recommended that physicians enroll and monitor patients through Boston Scientific's Latitude remote monitoring system and to quote the FDA, "Ask patients to do weekly remote checks," otherwise known as alert checks.

The problem with the FDA's Class I recall instructions is that Boston Scientific's remote monitoring paradigm, while covered by HIPAA security law, operates outside of HIPAA privacy law. Patients don't have the right of access to anything you see on your screen. Boston Scientific operates as a business associate to cover entities utilizing them. A Latitude remote monitoring system is a very efficient system for physicians, but it tramples on patients' civil rights. We are the ones walking around with implanted cardiac devices covered under Class I recalls and we rely on our implanted devices to save our lives, but we

don't get direct access to the data produced by our S-ICDs.

Physicians log in to Boston Scientific's Latitude physician portal to check on implanted patient devices and review quarterly interrogation of cardiac event reports, but there aren't specific alert reports for physicians to provide back to patients, so patients don't get feedback. Patients have no idea if our devices are functioning or not. This is an extremely unsafe situation for patients. In fact, it took my physician 6 days to notify me that my S-ICD was malfunctioning.

The FDA recommends that patients do weekly remote checks; however, there are no specific alert reports generated, so OCR can't help patients get the results. I push a button on my FDA-approved home communicator. My home communicator wirelessly checks my S-ICD for alerts configured remotely in the physician portal and I can't get the feedback generated from this alert test. I can't even get feedback on how my physician configured my alerts in the physician portal to be remotely checked. Believe me, I've tried. I've been through the entire HIPAA complaint process and OCR reconsideration request and in both cases, OCR can't help me get my alert results or even information as to how I'm being remotely monitored.

My remote monitoring experience over the past 4 years isn't news at FDA/CDRH. I presented 2 years ago at the FDA PEAC meeting on cybersecurity. I have worked with three separate FDA/CDRH ombudsmen, as well as CMS and the ONC-IT (ph.), my U.S. senator, two of my U.S. representatives and countless others at Boston Scientific. While the U.S. Supreme Court hasn't ruled on the constitutionality of medical device remote monitoring operating outside of HIPAA privacy law, I believe the FDA's S-ICD Class I recall instructions infringes on my right to privacy as well as my right to protection from illegal search and seizure. I physically own my S-ICD and it is implanted inside of me. I know the FDA wants

access to real-world data and the FDA requires that device manufacturers conduct postmarket surveillance, however, you can't do it at the expense of my civil liberties.

What can the FDA do to help patients with medical devices under recalls and advisories? You regulate the medical device manufacturers. Boston Scientific has to clear all Latitude NXT software upgrades with the FDA. In fact, Boston Scientific was just scheduled to release the Latitude NXT 7.1 software on September 27th and had to get this latest Latitude release cleared by the FDA. Please help us because the current remote monitoring paradigm isn't safe for patients with devices under Class I recalls. Please require Boston Scientific to give patients direct access to our device data. We shouldn't have to rely so completely on clinicians who work from 9:00 to 5:00 Monday through Friday. I am happy to discuss with the FDA areas in which the Latitude NXT platform can be improved to make it safer for patient use.

Now, slide 8 and slide 9, they both detail my experience with a malfunctioning S-ICD and on this last slide is a listing of the available S-ICD remote monitoring alerts and whether or not they can be configured.

Thank you in advance for improving the safety of patients living with S-ICDs currently under the FDA Class I recalls by requiring Boston Scientific to provide patients with direct access to our remote monitoring data.

DR. GRECO: Good afternoon. My name is Dr. Gregory Greco from New Jersey. I'm the board vice president for health policy and advocacy for the American Society of Plastic Surgeons. As part of my leadership role at ASPS, I oversee initiatives related to advocacy, patient safety, and best practices and healthcare delivery. I have nothing to disclose.

The American Society of Plastic Surgeons (ASPS) is the largest plastic surgery specialty organization in the world and represents more than 93% of all board certified

plastic surgeons in the U.S.

ASPS and our research arm, the Plastic Surgery Foundation or PSF, have a longstanding relationship with the FDA and industry regarding medical device data collection and education. When there's a medical device safety communication or device recall, medical specialty societies such as the ASPS are well positioned to be strategic partners to support rapid, unbiased, and patient-centered communication. As I reflect upon ASPS's recent experience with the voluntary recall of a type of breast implant, I'd like to discuss how medical specialty societies are key components of the multichannel communication strategy the panel is discussing today.

First, ASPS, like many other medical specialty societies, has a robust clinical data registry program collecting longitudinal data on plastic surgery procedures, devices, and outcomes. For example, ASPS has two registries specific to breast implants. The first is our National Breast Implant Registry or NBIR, which launched in 2018 and tracks all breast implant procedures performed in the United States. The second is our PROFILE Registry, which is a rare disease registry collecting detailed case information on over 300 U.S. cases of anaplastic large cell lymphoma in women with breast implants. NBIR has already had more than 1100 plastic surgeons provide data on more than 40,000 breast implant procedures in the short time the registry has been open. For our NBIR and PROFILE registries, we work collaboratively with the FDA and have structures in place so we can appropriately communicate registry surveillance data and reports.

Our annual procedural statistics estimate 300 to 400,000 breast implant procedures are performed each year. The sheer volume of patients with breast implants in the United States requires a robust tracking mechanism across all manufacturers and devices. We regularly review data and can identify safety signals earlier with this data infrastructure.

We communicate regularly with the FDA regarding both NBIR and PROFILE and are able to address queries that they have or queries identified by other members of our registry steering committees.

Beyond serving as a key partner to the FDA through our registry data collection efforts, medical specialty societies like ASPS are also uniquely positioned to help industry and manufacturers in the event of a medical device recall. As mentioned, the National Breast Implant Registry, developed in collaboration with the FDA and the breast implant manufacturers, was designed to leverage the existing breast implant device tracking infrastructure to serve as the registry's backbone. Now, manufacturers are able to access their device tracking data from the NBIR to assist in provider outreach, transmission of industry recall information, and key contacts to physician members.

On top of providing device tracking data, medical specialty societies can also partner with industry to ensure that there's clear and direct information to reduce uncertainty around physician practice management concerns related to device recalls. For example, reimbursement and coding questions for explanted devices, these are often the areas where doctors need additional information to support their patients effectively.

Patient engagement. Medical specialty societies can also provide strategic communication support directly to patients and serve as an important bridge from the patient community to physicians in the event of a medical device recall. When device recall information is initially shared, there can be a tremendous amount of uncertainty for patients and their families. Having a trusted source for unbiased and comprehensive information is key. ASPS and other medical specialty societies can and have served as a trusted third party. We can design and disseminate patient education guides to reduce the complexity around the kinds of decision making and cost benefit evaluations that patients

are going to need to share with their physicians.

Additionally, groups like ASPS can collaborate through established and ad hoc patient partnerships to share initial and ongoing communications. We can obtain patient perspectives for physician members and industry partners on an immediate and ongoing basis.

ASPS and the PSF regularly work with patients and patient advocacy groups to ensure that their voices are heard and that our public-facing and informed consent language and educational materials about devices and procedures are informative, clear, and easily understood.

It almost goes without saying, but if there is a medical device recall or safety communication, medical specialty societies like ASPS can rapidly activate national and state member communication networks to share information directly with thousands of physicians and their office staffs. We can deploy member-wide e-mails, social media posts, member discussion board communications, and relevant educational and news content to create a surround sound effect, as well as update physician-facing safety materials and the informed consent collateral in real time to support physician-patient decision making.

When a recent voluntary recall happened regarding a specific type of breast implant, we were able to communicate almost instantaneously with thousands of ASPS member physicians to ensure that they and their patients were made aware of this most important safety communication. We updated website materials for both patients and physicians to ensure that the information shared was harmonized and complete. Our staff answered calls and e-mails directly from physician members to provide feedback and informational support as quickly as possible. And now, because of the National Breast Implant Registry, physicians can easily track their patients, which would allow them to quickly query their

own data and identify which of their patients would need to be contacted if there was a potential issue.

Finally, medical specialty societies have relationships with the media, which ensures that we can serve as authoritative subject matter experts and unbiased third parties to those who provide content and influence the public. ASPS realizes that many patients may hear of a device recall through online social media and news outlets. We believe medical specialty society physician spokespeople should be positioned as key players to provide scientific and patient-centered perspectives.

In conclusion, I want to thank you for this opportunity to speak today. We applaud the Agency for convening this meeting and we look forward to working with the Agency on behalf of our surgeons and to ensure optimal patient care and education. Thank you again.

DR. MAURI: Thank you for the opportunity to participate in this Patient Engagement Advisory Committee meeting, and thank you to the FDA. It's really valuable for us to be able to listen to the discussion and to share these remarks with you. I'm Dr. Laura Mauri, I'm the chief clinical and regulatory officer at Medtronic, and we are a global medical technology company and we make products treating patients with a range of illnesses, from heart disease to diabetes to neurologic conditions like stroke and Parkinson's, to robots that assist in surgeries of many different kinds, and other products, as well. And like FDA, we are committed to putting patients first in everything that we do and this meeting is a really valuable resource for us to be able to hear from the panel on these deliberations about how we can better incorporate patient input into communication. It's vitally important to us that when we manufacture products and these products are used by patients and by providers, that we can also provide the most up-to-date and reliable information back to patients in a way that's understandable and helpful. So this input into how we do so is

something that we take very seriously.

I want to just say that as a physician and researcher, I know that the medical and scientific community really intends to put patients first in everything that they do. At the same time, the patient voice hasn't been fully recognized in that type of work, historically, and sometimes it's taken for granted that we understand what those needs are. This meeting today is a really important step in recognizing that we have more listening to do to be able to develop systematic approaches going forward.

So at Medtronic, we are in the midst of investing and developing a more comprehensive systematic approach to receiving patient input along the range of activities that we have, whether it's in clinical trials or whether it's in patients who have already been treated with our devices. And this discussion is an important first step. We recognize that patients are important determinants about their own experience and their outcomes, and the more that one can be engaged in one's own care, the better control over one's own outcomes and experiences. And so this is a key underpinning of why this matters. The issues around this topic can be complicated. Many of our medical device products are implanted and patients have a long-term relationship with these life-changing therapies and also with their families around their illness, as well as their doctors and nurses who may be involved in their care. And so there's a whole network that we have to think about, the complex environment where that information is provided, and we want to be able to do that as effectively as possible. We want to be able to do everything that we can to support the optimal care of patients and the empowerment of patients in their own decision making.

So it's really with that perspective that we want to frame our thoughts about how to improve patient input into our medical communications as we seek to do that more and

more frequently, getting patient representatives and patient advocacy organizations involved in the postmarket setting.

So I want to thank you very much for allowing me to participate today and I look forward to the discussion of the Committee, as well as supporting future collaborations with stakeholders, patients, and the FDA. Thank you.

MS. JAGGAR: Thank you for the opportunity to share our views. I'm Karuna Jaggar and I'm a patient advocate on the Breast Implant Working Group. Our group represents harmed and unharmed patients, surgeons and public health researchers, working to improve informed consent for patients and raise the standards for breast implant safety. Our members include two former presidents of the American Society of Plastic Surgeons; the president of the National Center for Health Research; the CEO of Device Events, which analyzes adverse events; and current and former board members and staff from Breast Cancer Action, Our Bodies Ourselves, This is in Love Foundation (ph.), and Breast Implant Safety Alliance. I've never received funding from any medical device company. Many patients tell us they are not getting the information they need when a device is recalled. I'll briefly share our perspective on how best to improve that situation.

Currently, FDA may require device companies to notify doctors who use the product when there is a high-risk recall. But even if the doctors want to notify their patients, they may lack the staff or updated contact information to do so, and what about patients whose doctors have retired or died? Unfortunately, all too often, patients are not informed by their physicians about problems with an implanted device in their body. Instead, patients may learn about a recall through mainstream news sources or social media. I note here that when Allergan's Biocell textured implants were recalled, the company asked patient groups to help spread the word without offering any resources to do so.

The recall information that patients receive is usually reassuring. Rarely, if ever, is it recommended to replace or remove a recalled implanted device that's not causing symptoms. Instead, patients are told to be aware of the risks and potential complications, leaving many people concerned that they are ticking time bombs. Patients may feel betrayed by FDA and the device company, which previously assured them the device was safe, and may worry they are not being given complete and unbiased information.

To ensure that anyone with a recalled medical implant gets transparent, complete, balanced, and accessible information about what this means for them and what their options are, we recommend the following. FDA should play a leading role in announcing medical device recalls and safety announcements. The Agency should engage in at least the same level of outreach and public engagement regarding recalls as when new devices are approved. The FDA should develop standards for Class I recall announcements that include all of a person's medical options and the risks and potential benefits of each option.

This underscores the need to adequately warn patients about risks before they get implanted devices with unbiased, understandable materials well in advance of surgery. Everyone facing a potentially life-altering recall deserves access to the most comprehensive, up-to-date information in order to make their own decision about what's right for them.

Thank you for your time and attention.

MR. CONWAY: Thank you. Now I'd like to go ahead and introduce Dr. Diana Zuckerman, President of the National Center for Health Research. You may go ahead and begin your presentation.

DR. ZUCKERMAN: Thank you very much. I'm going to try to share my screen and hope for the best. Okay, one more thing to do here, I think. Oh, okay. Okay, thank you so much for the opportunity to speak today. I'm Dr. Diana Zuckerman, President of the

National Center for Health Research, and we're a public health think tank in Washington, D.C.

You've heard a lot of the things that I was planning to talk about, so I'll just be brief here. You know, one of the things that we worry about, of course, is that when industry is informing people about recalls that focus on informing the FDA and the direct customers, such as doctors and medical centers, and as you've heard repeatedly, patients aren't usually directly informed.

So which are the patients that should be informed as soon as possible? As you've heard, obviously patients with recalled implants need to be informed as soon as possible and one of the questions that has been asked is, "Is that true for all risk levels of recalls?" and I would suggest that it is all levels, although obviously, especially the highest risk and the moderate risk recalls. And in addition to that, patients should be notified who might be using the recalled device such as a contact lens, something like that which might be used regularly but isn't implanted.

So when we think about what patients need to know, obviously they need to know if they are using a recalled device, they need to know if the recalled device is implanted in your body. And you've heard about the problems with the UDI and I just want to mention that when the law and the regulations were first put together, these identification numbers were supposed to be on the implant itself, in addition to being in the medical records and unfortunately, as you've heard, they often aren't, most of the time aren't in the medical records but even worse, they are not being put on the implant itself because at some point FDA said that would no longer be necessary even though that was the original agreement.

Next is "What's the risk level?" That's one of the things patients need to know, what is the risk level for the recall and what is that based on. Certainly, it's different if there's a

flaw in the device versus a flaw in the instructions, those are different kinds of issues.

For implanted devices, as you've heard, the issues that need to be shared is what are the known risks of removal versus doing nothing and what are the unknown risks and that's -- those are the issues that are not so easy to explain because a lot of times there isn't really good data to know what is known and there are a lot of unknowns.

And for devices that aren't implants, what are their options? Patients need to know would they be refunded if they want it to be replaced, are there fixes that can be done that don't require them doing much of anything other than getting something fixed and how much can they rely on those fixes.

Transparency is so important and one of the things that you've heard a little bit about, and I just want to emphasize, is that generally when there's a recall, their default option is to reassure patients. We don't want patients to panic, but you can overdo that reassurance and it results often in patients feeling like they're uninformed or that they're confused because if this is a high-risk recall, why are they being told they don't need to have the implant taken out of their body? These are the kinds of questions that patients have that aren't being answered adequately. And so those efforts to reduce patients' fears can be interpreted as a cover-up. And a big question is who should be providing the information to patients about these risks of removal versus doing nothing? Why does the FDA usually post industry press releases about recalls instead of their own press releases? Will the company ever be considered an unbiased source of information? Will CDRH be considered an unbiased source of information? Who will be considered the unbiased source of information? And that's been a real problem for recalls.

And then just last, I want to talk about user-friendly information, which I think most people will agree that's never been FDA's strong suit. FDA explanations tend to be rather

technical and hard to understand. They're not at the sixth grade reading level even though that is the average reading level in the United States. Sad, but true. And FDA databases, which is where a lot of recall information is available, are really not patient friendly. Actually, they're not friendly to pretty much any users. It's very hard to use those databases if you don't have experience doing it.

The other thing that we heard about this morning was FDA's desire to really do a lot more with message testing. I guess I was shocked that FDA hasn't been doing that for decades, but better late than never, so yes, please do message testing.

And I just want to give one example from a PowerPoint that FDA had this morning where it said customer pushes the information downstream and implements correction or removal. I'm left and I look at this kind of language all the time, who's the customer? Who is downstream? How are the corrections or removal implemented and by whom?

So oh, then I just wanted to say patients' access to information has been limited. If the company needs patient groups to help notify patients through social media and so on, they should be supporting those efforts with money and other resources for the patient groups to help with, or the consumer groups. CDRH --

MR. CONWAY: Dr. Zuckerman, you have to wrap up.

DR. ZUCKERMAN: Okay, I will. Thank you. CDRH should require companies or FDA staff to objectively evaluate the success of those warnings and CDRH should notify media of recalls as actively as they notify media of approvals.

So last but not least, I just want to say you heard from a lot of harmed patients and I think you've gotten a really good understanding of how much they can help you as you think about these recall issues. Too often the harmed patients aren't the ones that are being talked to and aren't the ones being included and we hope you'll do that.

Thank you very much.

MR. CONWAY: Thank you very much.

Our next speaker is Ms. Carol Small, a patient. Go right ahead.

MR. VEIZIS: Carol, can you please unmute?

MS. SMALL: I got it, I found it.

MR. CONWAY: Thank you.

MS. SMALL: I'm sorry. I'm new to Zoom. I've read all of these other medical device messages and my message, similar, is about a manmade cancer that is caused by a UDI -- I mean a breast implant, BIA-ALCL. As a BIA-ALCL Stage 4 survivor, I'm continually surprised at the inadequate patient information given by doctors dealing with patients who may be considering breast implants.

The FDA has noted the dangers of the breast implants, as Diana Zuckerman said, since 1970, since the 1970s, and a woman named Sybil Goldrich has personally presented every year to the FDA since 1984 about the dangers of breast implants. *JAMA* has written articles about BIA-ALCL. The two journals for plastic surgery have published articles on BIA-ALCL.

Outside of calling it a rare disease -- by the way, it's not rare, it's simply undiagnosed -- there is no reason why every physician in especially our country, and the world, does not know about BIA-ALCL. *Plastic and Reconstructive Surgery — Global* journal published in September 2021 that BIA-ALCL is not well known and that other brands of textured implants were also found to cause BIA-ALCL. *Gland Surgery* journal of January 2021 published a large article about advising patients of BIA-ALCL. These are but two examples of what is in the literature for medical practitioners. Yet, why are all of the women coming to us in social media on our Facebook groups with terrible symptoms telling us that they only found us, no

doctor ever advised them of the dangers of their implants? I just heard here that 300,000 to 400,000 breast implants are given every year. So why are these women not notified of the risks of breast implants?

One of our advocates in Arizona was able to get the state legislature to pass a law that women be advised. Need we lobby in every state for this? How can we, as advocates for women, and you, Patient Engagement Advisory Committee, going to save the other thousands of women who have symptoms or who are considering implants? How are we together going to advise women of these risks of breast implants before choosing implants? How will patients who choose implants know that they need to exchange those implants at least every 7 to 10 years with repeated surgeries due to the toxicity of the degrading shell? FDA has already said that.

A Facebook group that's called Fierce Flat Forward (ph.) offered to volunteer to do voluntary presentations at a national conference for breast surgeons on what patients want and what they need to know. I often think how helpful it might be for them to see -- "them," the physicians -- to see what we, the patients, are thinking.

Prevention magazine, September 16, 2021, Beth Howard, she said, "Why Breast Cancer Survivors Who Don't Want Reconstruction Face Pushback — Or Worse," even doctors don't always support women who want to say no to breast reconstruction. I have links to the article, also.

So anything you can do to help us, you know, we've been doing this for years. Madris Tomes said this and so did Diana Zuckerman, that the FDA and the journals aren't doing enough. Somehow, other than social media, we need to tell women that they need to explore the risks before they get an implant, notwithstanding the fact that they need to know the symptoms after the implant.

Thanks for listening to me.

MR. CONWAY: Thank you very much.

Now we'll move to our last speaker of the day, Mr. James Cook, ALCL in Women with Breast Implants Facebook Group. Go right ahead.

MS. COOK: Thank you. It's actually Jamee, my name is Jamee Cook. I'm speaking on behalf of ALCL in Women with Breast Implants.

MR. CONWAY: My apologies.

MS. COOK: That's okay, www.biaalcl.com and Breast Implant Victim Advocacy. I'm here to specifically address Allergan breast implants and expanders that were recalled in 2019. We have women in our group today who are just now being informed that they have recalled devices and in 2021 there's simply no excuse for an uninformed patient. These breast implants were recalled due to an associated risk of lymphoma. Many patients implanted did so in response to breast cancer and reconstruction. They put themselves at risk for a secondary manmade cancer.

Implant registries could have helped with patient follow-up, contact, and data collection. However, the National Breast Implant Registry took way too long to implement and we have missed many patients and many adverse events. We have breast implants that are placed in the patients and, due to lack of tracking, do not even have a denominator to determine the true risk of this cancer. A recall was made, the manufacturer and FDA made public announcements. Some doctors informed their patients, some didn't. Some doors were closed, records destroyed, etc. The effort to inform the public of an airbag recall is much more significant than the effort to inform a patient that they were implanted with a device that has been recalled. Many patients do not even know the device they have. Some patients have contacted manufacturers only to be told that they are not registered in

their system. We're 2 years after the recall and a warning letter to the implant companies, yet we do not have easy access to full info about the failed regulation or the devices. We have to start with transparency to the public about the recalls, the warning letters, and releasing the information about how these companies respond without hiding this information behind a wait list of extremely slow FOIA requests.

The current data on BIA-ALCL is not thorough enough, unfortunately, to say that removal of these recalled devices will reduce the risk of cancer. Medical coverage for removal is not sufficient. These patients are left in limbo with very little solid data to base their decision on and very few resources should they choose to remove them. Transparency about implant-related cancer is not available. Trusted websites are not maintaining current statistics, so consumers cannot make informed decisions about their recalled devices without adequate data to derive their decision from.

We recommend improved postmarket surveillance, including electronic surveillance options; an increased effort to put recall information out to the public, including more social media and advertising efforts; that the FDA engage more with patient advocate groups who are on the front line of interaction with these patients who are coming across recall information by happenstance; that the FDA step up their staffing efforts to accommodate public requests for documents that are related to device safety and recalls; that the FDA hold companies accountable for failure to follow approval guidelines and failure to properly track and inform their consumers. And lastly, we recommend that device registries be mandated and stronger so that patients can be tracked and contacted when a concern arises. While we may not be able to fix the errors that have already occurred, we can work together to be proactive and make sure this does not happen again. A strong registry may have recognized this cancer years earlier.

Thank you for your consideration.

MR. VEIZIS: Sorry, Paul, you are muted. You need to unmute.

MR. CONWAY: Thank you, my apologies. Thank you very much, Ms. Cook, for your presentation.

I'd like to go ahead and thank all of today's Open Public Hearing speakers. We very much appreciate both your willingness and your courage to share your perspectives with us today. I now pronounce this Open Public Hearing to be officially closed and we will proceed with today's agenda.

We will now have an open committee discussion and clarifying questions from the Committee. As a reminder, although this portion is open to public observers, public attendees may not participate except at the specific request of the Committee Chair. Additionally, we request that all persons who are asked to speak identify themselves clearly each time. This helps the transcriptionist identify the speakers.

Before we begin, let me make one note. Prior to our last session, we did have the ability to speak with the FDA moderators that conducted the discourse on the Virtual Breakout Sessions, so right now we will have time to pose questions to those who testified in the public hearing. We had asked that folks be available and we will see as we go along who has been able to stay for that.

The second reminder I would have to the Committee is that the hearing today is not a device-specific Advisory Committee meeting and so if you can, when you're posing questions to those who presented in the Open Public Hearing, try to relate the fact to some of the general themes and purposes of the meeting today.

Why don't we go ahead and if you don't have your microphone -- when you do speak, go ahead and take your microphone off of mute and right off the bat, we'll go ahead

and go to Cynthia Chauhan. Go ahead, Cynthia. You can go ahead and unmute.

MS. CHAUHAN: I'm trying to. There we go.

MR. CONWAY: Go ahead.

MS. CHAUHAN: This is Cynthia Chauhan, thank you so much. I want to thank all the speakers for their information and their passion. My question is to Dr. Pitts, is he still available?

MR. CONWAY: He may not be, Cynthia.

MS. CHAUHAN: Oh, okay.

MR. CONWAY: Is there somebody else that you'd like to pose a question to, Cynthia?

MS. CHAUHAN: Mine was specifically to something that he said, so that's it for right now, thank you.

MR. CONWAY: Sure thing, thank you.

Any other Committee members?

Go right ahead, Dr. Parker.

DR. M. PARKER: I guess I'm a little concerned, the last two presenters had a lot of concern about information regarding breast implants, of cancer that's associated with them. I find their discussion is in a little bit of discordance, if you will, with Dr. Greco from the American Society of Plastic Surgeons, who indicated that they track implants and adverse events and I'm kind of confused about whether that's actually happening or not because they indicated that they were working not only with the manufacturer, but with news organizations to talk about recalls and other things. But if I go by what the last two presenters said, this kind of information has not been widely available. Specifically for those of you who may have missed some of it, the latter two speakers were talking about

the incidence of something called anaplastic large cell lymphoma that develops in women who have breast implants and there's an associated risk with people who've had breast implants after not just so much for cosmetic use for breast enlargement but for reconstruction after cancer surgery. So I was just trying to understand what was happening there because it seems like, according to Dr. Greco and plastic surgeons who are taking responsibility for establishing registries and making sure that procedures and adverse events from these various procedures were being tracked, and if I went by what the last two speakers said, this kind of thing, this is a very important kind of complication of breast implants, wasn't being tracked, am I wrong?

MR. CONWAY: Dr. Greco, would you like to go ahead and respond and then give your full name?

DR. GRECO: Sure. I apologize, I was put in the waiting room for the first portion of that but yes, my response is -- first off, thank you. My name is Gregory Greco, I represent the American Society of Plastic Surgeons, and I really do appreciate everybody sharing their stories. So the NBIR, one of the things we do realize is that with the recall it has been difficult to track, and we only want to do the best for our patients, so the NBIR was developed in order to do just that. Now we have the opportunity every time -- as a plastic surgeon, I do a case, I take out my phone, I use the UDI code and I can track, I can register the implant, and the nice thing about this, it's one step.

We no longer have to use paper tracking, we've kind of taken all the legwork out of the difficulty with the tracking of these implants. So I can now push a button, I know how many patients of mine, what implants they have. Again, no longer textured obviously, so -- because we found that this was a problem getting the information. So again, this has streamlined it and now we have the NBIR PRO, the patient-reported outcomes, in the

works, as well. So we have the ability for patients to self-report, as well, because this information is essential, just like all of you have said, to be available to our patients. So again, this is something that we have been working on and we've been trying to get as much member engagement with this as possible. You know, we want all of our members to use the NBIR, but we also want the patients to have the opportunity to also self-track because of exactly what this entire hearing is about today.

MR. CONWAY: Great. Thank you very much.

I'm going to go ahead and ask Ms. Zuckerman to respond, as well, and then we're going to go back to Cynthia because we have Dr. Pitts back on.

But go ahead. Go ahead, Diana. You're muted.

DR. ZUCKERMAN: Thank you so much. So a couple things. One is that that kind of information was not available on the registry at first and we're glad that it's going -- that it's being added, but it wasn't before. But also, a lot of women who get breast implants aren't using surgeons that are members of the ASPS and so therefore any doctor or dentist can call themselves a plastic surgeon and put in breast implants and so they're just not going to be included. So there will still be, you know, hundreds of thousands, potentially, of women who aren't going to be in the registry. And I'm sure Maria --

MS. CAPANNA: Paul, if I -- I'm sorry, Paul. If I --

MR. CONWAY: Go right ahead, Ms. Capanna.

MS. CAPANNA: -- can jump in on a matter of protocol. Thank you. Just on the matter of protocol per the Advisory Committee process, this is a time for the Committee members to pose direct questions to any of the speakers, but back-and-forth amongst the speakers is not the format here today.

MR. CONWAY: Great. Thank you very much, Ms. Capanna.

What I'd like to do now is go back to Cynthia Chauhan and if you could go ahead and pose your question again, we have Dr. Pitts back on.

MS. CHAUHAN: Thank you. This is Cynthia Chauhan.

Dr. Pitts, I heard you comment, I believe, that anecdotes are not data and I have some concerns about that statement because I do believe that anecdotes lead to data. So that also felt a bit dismissive of patient input and so I'd like for you to respond.

MR. PITTS: Thank you. Firstly, I'm not a doctor, but thank you for the promotion.

MS. CHAUHAN: Oh, my pleasure.

MR. PITTS: I don't mean to be dismissive at all, I have tremendous respect for patients. My point is that the patient voice is incredibly underrepresented and that an anecdote here and anecdote there can be very easily dismissed by regulators and by physicians. The only way to really enhance the value of the patient voice is to make the patient voice more technically accurate and speaking more in regulatory terminology.

I think one thing that the new communications director at CDRH made at the beginning of this meeting this morning was that there needs to be more education and I'm all for education, believe me. But what was not discussed by anybody, just briefly a little bit in the last 20 minutes or so, was how do we enhance the patient's knowledge that they can actually report themselves to their doctor and to the FDA issues that they're having, it doesn't exist, and this is -- again, this is not a breast cancer meeting, a breast implant meeting or strictly speaking, a device meeting and there are inter-center learnings here that can be made. CBER and CDER, the drug and biologic centers, have done tremendous work in educating both healthcare professionals and patients as to their responsibility to report adverse events and I think CDRH could learn a lot from those so that the anecdotes, while they're important and they need to be gathered, can be turned into usable data to prevent

problems from happening to other people.

MS. CHAUHAN: Thank you, I appreciate that. A small step FDA has made is -- I take a lot of prescription medication and on every bottle there is a number for me to call the FDA with adverse events. It's a very small step.

MR. PITTS: It's a small step but it's an important step because if you're not empowered to speak to the authority, you are disempowered across the board.

MS. CHAUHAN: Thank you.

MR. CONWAY: Thank you very much, Mr. Pitts. And thank you, Cynthia.

Thank you for your patience, Ms. Brummert, I'll go to you.

MS. BRUMMERT: I wanted to ask a question of Laura Mauri from Medtronic.

DR. MAURI: Yes. Hello, Laura Mauri here.

MS. BRUMMERT: Hi.

MR. CONWAY: Go right ahead.

MS. BRUMMERT: My name is Rachel Brummert. I wanted to -- I appreciate you being here and listening to some of the advice that some of us have to engage our patients and to get information. Are you here for information or do you have information already that patients should know but are not getting?

DR. MAURI: First, I appreciate you asking the question and I'm here representing Medtronic. I am responsible for the clinical research, medical and regulatory functions there and we believe that it's important to have this discussion and that the space of really getting the most input from patients to how they want to be communicating with is a field that's developing. And so I would say one of the primary reasons that I'm here is to listen to this conversation and think about, across our programs, how do we do just that.

We do that currently with many of our products. It's different according to what

type of product we have. In many instances we have products that are -- where we have a close relationship with patients where we're able to communicate directly and we take advantage of that. In other cases we have products that are implanted by a specialty physician where the primary way of us communicating important information is through that specialist who can help that patient interpret how to use that information. So I guess the short answer to your question is that yes, we do have information that we do share with patients and other stakeholders in their care, but I'm also here to listen to the conversation and think together with this group about how industry can contribute as we develop this field further.

MS. BRUMMERT: And would you happen to have an example of where that was successful in notifying patients?

DR. MAURI: Yeah. I think we have a range of products, but if we look in our diabetes products, we have communicated directly with patients. In that case, that's a product where patients manage their condition on a daily basis and so it's a very important one where we value the ability to be able to communicate directly.

MS. BRUMMERT: Thank you, ma'am.

MR. CONWAY: Great. Thank you very much.

So in queue, we'll go to Amye Leong and then we'll go to Parker and Roy.

Go right ahead, Amye.

MS. LEONG: Thank you. And actually, this is a question for also our ninth speaker, Laurie -- Laura from Medtronic. Laura, I appreciate your very brief but somewhat comprehensive view of how you engage patients in your communications, but because patient engagement is something, I'm sure, the panelists as well as I are truly very, very --

(Audio feedback.)

MS. LEONG: -- within medical devices. Can you give us some examples of how Medtronic is systematizing communications with patients in particular, not just diabetes but just in general --

(Audio feedback.)

MS. LEONG: -- rather than a disease-specific or device-specific methodology?

DR. MAURI: I think I'll be honest that I think we're at the beginning of that journey to make it something more systematic.

MS. LEONG: Okay.

DR. MAURI: I think I tried to make that point in my remarks that were -- you know, that I recorded earlier. But I think what that means is we're looking at what's appropriate for different points in time and for different products and trying to look at this from a centralized perspective to give each of our product areas the tools necessary to do that, so defining what we think the best practices are and making that possible and the range of ways that we do that might range from -- you know, one of the things that we've done quite a few times in the past is even if we don't have the ability to communicate directly with patients, providing that 1-800 number for patients to be able to use, putting information on our websites and then exploring what other mechanisms are going to be effective, recognizing that there is a diversity of ways that people will access information effectively. So it's an area that we think needs to be developed further and more across the board and come up with the best practices together with this community.

MS. LEONG: One final follow-up question, do you have any priorities in -- because it's a very large area and you have so many different disciplines as well as devices, priority areas that you've targeted to begin to look at?

DR. MAURI: Well, I think what we're working on is developing that framework --

MS. LEONG: Framework.

DR. MAURI: -- and I think some of the considerations are how will a patient use the information that we might provide, how do we think about either risk or influence that the patient has on their own outcomes and being able to prioritize how we make those attempts. You know, I think one of the things that's been discussed quite a bit is even having the ability to contact patients directly is potentially a barrier because we don't always have that direct ability. But I think we have to begin with the principles of where we want to be able to do that and then think about how do we do that.

MS. LEONG: Thank you.

MR. CONWAY: Great. Thank you very much.

Before we go to Dr. Parker, just a reminder to the Committee that this is a meeting in general matters related to medical devices, not a specific medical device. So what the FDA is trying to glean is the insights that we can develop through this meeting on some of the larger issues and the granular tactical details of communications for a recall.

Dr. Parker, go right ahead.

DR. R. PARKER: Thank you. So my question, it strikes me that postmarketing surveillance has not always been an area -- it's a challenge, it's a challenge across devices and it's a challenge across products. I wanted to specifically ask the public speakers who've had agency experience in their background from the other side and then where they currently sit. As we think about the current ecosystem and the possibilities, did you link data connectivity that were not the option that they were, say, a decade ago or more and the importance, sort of underscoring the importance of data-driven input and especially as it relates to safety signals?

So thinking through that, I wondered, I had heard about the data connectivity and

we know the challenges with electronic health records and we don't have a universal EHR for everybody in our country that connects everybody and interoperability are huge challenges on the ground. But I wondered about the data input from payers and whether or not there have been explorations and thoughts about either the UDIs or other key components of content being likewise connected to data sources linked to payers, given how robust that system is broadly. I didn't hear it discussed and I just wondered if there was thinking along those lines, as well. Thank you.

MR. PITTS: Can I jump in here?

MR. CONWAY: Sure thing.

MR. PITTS: I mean, I've been at the FDA and still do a lot of work on FDA issues and I think one of the problems, whether it's a drug or a device center, is that the philosophy of staff is to be wary of signal-to-noise issues and they view, for example, patient complaints or comments through social media, for example, as noise. It can't be captured in a way that fits into a neat, acceptable piece of data. It's the difference between data and evidence. And it's certainly data, but how do you validate it? Nobody knows. But certainly, where there's smoke, there's fire. And I think that's been accepted, for example, in the drug and biologic centers as an important new piece of data and there are artificial intelligence tools that can be put against that.

And I can't tell you that I know for sure, but I would be extremely surprised if payers, especially private payers, didn't have that type of technology because it's their money at risk there and it's a sound financial investment. I think, from a regulatory perspective, whether it's image array in the UK or European Medicines Agency or the FDA, we're still pretty much stuck in kind of a paper mentality of fill out the form, if you're missing one field it doesn't count and that's got to change.

MR. CONWAY: Thank you very much. And could you go ahead -- that's Mr. Peter Pitts.

MR. PITTS: Oh, excuse me. Thank you.

MR. CONWAY: No problem. And again, two more reminders real quick for folks, state your name clearly. And then the second thing for the Committee members, really, I think what's beneficial here is if we can -- as we're listening, what we want to be listening for is not simply one company's approach, but what could be done for the entire industry. Those are some of the insights that we're trying to gain here.

So with that, I'll go to -- go right ahead, Ms. Capanna.

MS. CAPANNA: Thank you, Mr. Conway. I just wanted to make sure to make a clarification for the Committee as well as for those who are listening along to the webcast, that that prior question was directed to folks who formerly were at the FDA and so therefore those comments are not official FDA positions and therefore are not reflections of our current practice, per se.

MR. CONWAY: Great. Thank you very much.

I'll go to Dr. Roy. Thank you.

DR. ROY: Hi, thank you. I'm going to pick up on an earlier theme that I brought up during the breakout sessions and presented to this group and I'm going to try to tie together some themes.

So we live in a shared decision-making model in health care, so patients are increasingly expected to take part in their medical decision making. But it seems, ironically, looking at the supply chain for devices, the end buyer is not the patient, as is the case in pharmaceuticals, so there's not a lot of direct consumer advertising in devices, and the doctor and the hospital is the purchaser. So the patient is often presented with not

knowing what their choices are or that there even is a choice or maybe there aren't choices when they go to see a doctor for a hip or knee or spine implant.

So the question is -- and I appreciate Peter Pitts's commentary and candor in talking about sort of the difference between complaining and data but that complaints lead to data and how do you capture that and I wanted to hear from Dr. Greco and maybe others who -- I think Diana Zuckerman sort of pointed out that, in her presentation, that perhaps there should be funding to consumer groups to help with obtaining patient-reported outcomes so that complaints get translated into data and that gets aggregated and looked at. And our patient groups, the trusted source -- so that's sort of the theme that I was trying to bring in here -- maybe people don't trust the FDA, they don't trust manufacturers, where is the trust factor? And perhaps it's advocacy groups that are the trusted and that are dialed in to patient communities and that are the advocates for patients, and that might be a critical role for patient advocacy groups to play along with the FDA in obtaining patient-reported outcomes and in doing amplification of messaging on recalls and the important information there. And I just sort of wanted to hear from Dr. Greco how that's going, you did mention your program, the NBIR, and you're going to have the PRO aspect that's coming out and not specifically about that, but the doctor is ultimately the one in charge of putting the device in, right? So there's got to be a place in this whole arena where a transaction is happening where data can be collected and communication can be amplified and enhanced. And I think the challenge here is that we're looking at where are those points of entry and who manages and controls that communication message. So I just wanted to get some feedback on that.

DR. GRECO: Thank you. Gregory Greco, American Society of Plastic Surgeons. Ms. Roy, thank you for that question. You know, again, it's obviously a multifactorial

question, but we are -- I suppose the patient is the end user -- but we are, I suppose, the consumer, the initial consumer of the product. So just like you mentioned, I think shared decision making ultimately is something that is our responsibility, the patient's responsibility, and the patient advocacy groups.

To be quite honest with you, I will never sit down with a patient and I can say that you've done your job, every patient who comes in, we have a very well-informed discussion about ALCL, we talk about BII, you know, these are all discussions. Patients are informed now, everybody's doing their job, and I think that we do engage with the groups and we want to know what information our patients are getting, we want to be able to let everybody make an informed decision, then we talk about device tracking and I think that unfortunately, like was mentioned, we can't control every single person who's putting in a device.

You know, we are a registry-heavy organization, we truly believe that data is the answer that's going to help us move this forward. So the NBIR and in particular with the release of the NBIR PRO hopefully in the near future -- with the patient-reported outcomes -- we already have what's called BREAST-Q which is where patients who've had any type of breast surgery, whether it's breast reconstruction, cosmetic breast surgery, can report their overall experience, whether it has to do with their medical condition, their sexual or psychological wellbeing, you know, we track these outcomes. Like I said, I think that we are looking to have data in order to move this forward. So I think, ultimately, the responsibility does fall on the three people involved: the manufacturer, the physician, and the patient.

You know, patients receive information at the time of their surgery and I can only speak to my patients and most colleagues that I know, we give our patients the information regarding their UDI code, they get all the manufacturing information and I would say 40 to

50% of patients who come in with implants have their original device card, which is extremely helpful because it's very difficult to go find notes like so many of the patient stories have mentioned today, it is very difficult if you have a device and it's really -- it's everybody's shared responsibility.

And again, I think that it's an imperfect system, we're all working really hard to do our part, and I think that the communication, the interoperability of a medical record is something that's mind-blowing, the fact that -- but then HIPAA compliance comes into place, you know, there are so many places where this gets hung up. So I think that social media, the fact that the iPhone was 12 years ago, I think, something like that and social media, there are too many platforms now for patients not to have access to this information and I think it's very -- we're trying to be technologically advanced and do our part with our patients so everybody is as informed as they can be right now. And the NBIR has been a real true success for us, we have over 40,000 cases tracked already, so that's -- and we hope to keep this going with a momentum that every breast implant that gets put in is tracked through this and the patients having public access to this so if their dentist is putting in their breast implant, they can go register it as long as we get the message out there.

MR. CONWAY: Great. Thank you very much, Mr. Greco.

We're going to go ahead and move to the last question here and that would be for Committee member Mr. Banerjee.

DR. BANERJEE: Samprit Banerjee from Weill Cornell Medicine. I have a very simple question for Diana Zuckerman. You mentioned in your presentation that FDA, in their communication, sometimes overdoes reassurance. While reassuring the patient is important, overdoing it might be harmful because efforts to reduce patient fear may be

perceived as a cover-up. I was just wondering if you could explain a little bit more on that, maybe give an example of what -- a situation where this might be perceived as a cover-up and how can that be mitigated.

DR. ZUCKERMAN: Thank you for asking that question. I guess the simplest example, possibly two simple examples that come to mind, one would be when it was found that the Biocell textured breast implants could cause cancer and then patients were told, "But don't worry, you don't have to take them out as long as you don't have any symptoms," and then there were women who had been diagnosed with this kind of lymphoma caused by their breast implants who said, "Well, I didn't have symptoms and if I had followed that advice, you know, I would've potentially died." So that's one example. Essure would be another device where the device was taken off -- in that case, actually taken off the market. There were a lot of media exposés regarding women who'd been harmed but again, women were being told, "Don't worry, you don't have to have it taken out unless you're having symptoms," and there was this feeling like well, if it's not on the market anymore or in the other case where it was a recalled breast implant, that doesn't make sense to me. If it's been recalled and it's not being sold anymore, why are you telling me not to take it out? And I'm not claiming that they should have had it taken out, I'm just saying it's very confusing to patients, it seems like a mixed message and it's hard for a lot of patients to take it seriously and to feel like they're being given all the information they need to make that decision, which can be a difficult decision.

DR. BANERJEE: Thank you. And just to clarify, these messages were from the FDA, correct?

DR. ZUCKERMAN: Yes, from the FDA and from the implant -- in those cases, implant companies, but it was a consistent message on the FDA website as well as from the

companies.

DR. BANERJEE: Thank you.

MR. CONWAY: Great. Thank you very much, Ms. Zuckerman. And thank you, Mr. Banerjee.

At this point we'll go ahead and take a 10-minute break. Committee members, please do not discuss the meeting topic during the break. We'll see you back here at 3:35. Thank you.

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

(On the record at 3:36 p.m.)

MR. CONWAY: It's now 3:36 p.m. and I'd like to resume this Committee meeting. At this time, let us focus on discussion questions from the FDA. Committee members, copies of the questions were included in the materials you previously were provided. I would ask that each Committee member identify themselves clearly to facilitate the transcription. I would also like to remind members of the Committee that this meeting in particular is classified as a particular matter of general applicability because the issue to be discussed by the Committee is a particular matter that is focused on the interests of a discrete and identifiable class of products but does not involve specific parties or products.

I would like to remind public observers at this meeting that while this meeting is open for public observation, public attendees may not participate except at the specific request of the Committee Chair.

At this time I would like to ask FDA to please read the questions. Commander Olele, would you please go ahead and proceed?

CDR OLELE: Good afternoon, this is Commander Chinyelum Olele with FDA and I'll be reading the committee discussion questions.

Once a medical device is available in the U.S. marketplace and in widespread use, unforeseen problems can sometimes lead to a recall. When a device is defective or potentially harmful, recalling that product — removing it from the market or correcting the problem — is the most effective means for protecting the public. Under certain circumstances, such as when a medical device issue represents an urgent situation which poses a potentially serious risk of harm, the FDA may issue a public notice related to a recall, to raise awareness and to communicate methods of preventing unsafe use of the device. Question 1:

a. What information do you think is most important to clearly convey to patients and caregivers about medical device recalls? Consider the following:
    i. details about the issue with the recalled device and which devices are affected;
    ii. possible actions you could consider taking to mitigate risks, including the use of alternative devices;
    iii. risks and benefits associated with continued use of recalled devices versus switching to alternatives, if available;
    iv. level of urgency to take action;
    v. describing what the FDA does not yet know, and the level of uncertainty about the information provided; or
    vi. any other information (please specify).
b. How can the FDA and industry clearly convey the most important information patients want to know about recalls?
c. Is it important to consider different information needs for patients who currently use a device versus patients considering use of one?

MR. CONWAY: Great. Thank you very much, Commander.

Now we'll go ahead and move to discussion. So go right ahead, Dr. Parker, we'll start with you.

DR. M. PARKER: Monica Parker. Dr. Monica Parker. I think one of the most important inputs of information to convey based on all the discussion that we've heard is, first of all, what is the safety and efficacy of the intended device being planned for implantation, whether that's a breast implant, a hip implant, or any other implantable device? I think that patients should be given the safety and data. Well, in research we say data and safety monitoring reports, but they should be given an updated report about what the safety is of whatever that device is and give them alternatives for their use.

This should ideally be conveyed by the provider implanting the device. But in the event that they're not comfortable with it, there should be an easily accessible interface where people can get that. I don't know that I believe in Google because there's a lot of misinformation on Google, but maybe that's through an advocacy board's or registry's information site or hospital, I'm not exactly sure where the best place should be, given the discussion, but I think most importantly the safety data and recent complaints or concerns about any device that's going to be implanted should be conveyed and given to the patient not only in a verbal discussion but maybe in writing and giving them a resource where they can look these things up themselves such that they can determine whether or not they can make an informed decision about whether or not they want whatever the device is implanted. I think that's one of the most important things that needs to be conveyed and certainly, that information needs to be updated on a regular basis. If I took anything away from that, it's like people don't know what the safety data is or the adverse events are regarding whatever it is that's been implanted.

MR. CONWAY: Great. Thank you very much, Doctor.

We'll go to Cynthia Chauhan.

MS. CHAUHAN: In thinking about recalls, I looked at the six choices and I just thought which are most important and I ordered them accordingly. I think the level of urgency is really important. Oh, let me back up. I think patients should be notified directly, I don't think they should have to wait for it to come through other channels. So the first is the level of urgency and that's a way of getting our very strong attention. Second, the risk and benefit. No. Second, the details about the issue. It's urgent, what is it? And third -- I'm sorry, I can't read my own writing, just a second. And third, the risk and benefits. So first, the level. Second, the details. Third, the risk and benefits. And it should all go directly to the patient with urgency.

MR. CONWAY: Great. Thank you, Cynthia.

Why don't we go ahead to Dunlap, Bennet?

MR. DUNLAP: I lowered my hand because I think Cynthia said exactly what I was going to say.

MR. CONWAY: Okay. Thank you very much, Bennet.

Mr. James.

DR. JAMES: Hi, Jijo James. Thanks again. And I agree with what Dr. Parker and Dr. Chauhan said and -- Ms. Chauhan said, and just to add to that, I think one of the other things that I heard this morning, starting from the FDA communications presentation around the need for social science and social studies to understand how to communicate and also, from one of the breakout report-outs around not really understanding what a recall is. Suppose a question about that, do we really have a good understanding of what patients comprehend when they hear the word recall? Is that word in itself a catchall that

may be leading to confusion?

From an industry perspective, when we look at recalls, it ranges anywhere from a "Dear Doctor" letter in terms of actions all the way to taking a product off the market. So do we have an opportunity out here to research better to understand what are terms that are more easily comprehended by those we're messaging to? It's probably something for us to consider during these deliberations.

MR. CONWAY: Thank you very much.

We'll go to Necie Edwards right now and then we'll come to you, Amye.

MS. EDWARDS: Necie Edwards. One of the things, while I agree with everything that has been said thus far about the recalls, but I would also like to know the number of patients that have been affected by this recall. I would also like to know when did you first find out. And what I'm also concerned about is let's say you're a patient that received one of these devices and your provider is now deceased, where does that leave you? Where do you go for help? Because I'm dealing with that situation myself right now. And in addition to that, what are my options and how to proceed. Thank you.

MR. CONWAY: Thank you very much.

Go right ahead, Amye Leong.

MS. LEONG: I'm going to second the latter of motions that have been going on or suggestions and agree with all of the things that have been said, including the concept of recall. At least in California, we know recall, it's from the industry of autos that we know that and it doesn't mean you buy a new car, it means you have to take it in for some sort of discussion with your mechanic and whatnot, so there is clear examples in the land of consumerism for that to exist.

Further clarification and easier understanding might be really suggested, but I want

to take a big step, probably in a more macro way, and I ask myself who has the responsibility to really touch those lives of patients, as Necie has said, where the surgeon is no longer in this country or on this earth or in a different profession at this point in time, what does that person do? And I start thinking about it in terms of now, going forward, and then looking back historically.

As some of you know, I've got 22 joint replacements and I can tell you for every single one of those 22 I don't know the name of the manufacturer, I know the dates of install and other important dates, but even I, as a patient advocate at the national and international level, have not been given that information even though I asked and it was never followed up.

So the level of communication disconnect is most severe, at least from what I've seen in the advocacy, patients in bones and joints see it as at the installer level, I think. I use that term that is most appropriate, might be the surgeon level. In our pharma area it would be different, some sort of other doctor who prescribes a drug, but the installer side, we are the ones who --

(Audio feedback.)

MS. LEONG: -- we're walking around in it, with it, and if FDA does not touch our life in any way, whether it be through an ad on TV, an ad on the radio, through the interconnectors of many, many circles of advocacy, physician, associations, hospital systems, then we'll never get touched but we have to be included as the end user, the ultimate end user. I call the user the device owner, that seems to be -- have been taken off the discussion. What we've heard today from many people is that it's the end user and that's the surgeon or the hospital system and I really take issue with that because we've all worked very, very hard to get health advocacy to the point today where we, anyone, can

feel empowered to seek resources.

And so I take everything of what's been said so far, but actually lay it back on our feet, which is FDA's feet, to say we have a moral-suasion and the regulatory gentle persuasion, not demands, but persuasion, to say that every manufacturer that makes something ought to be responsible for crafting materials, perhaps guided in general points by the FDA and its communications, new director of the communications groups, to have a framework of communication that these manufacturers can then work with the physician associations and patient advocacy groups, but I think that it's time for FDA to step up with the type of gentle -- I don't want to say enforcement, the gentle nudge of education surrounding recalls.

MR. CONWAY: Great. Thank you very much, Amye.

We'll go in this order. Mr. Banerjee will go and then we'll go to Ms. Brummert and Dr. Reed.

Go right ahead, Banerjee.

DR. BANERJEE: Thank you. This is Samprit Banerjee. I agree so far with what has been said, I just want to mention two set of points that came across to me throughout the day. One point is on the level of urgency or the timeline question as to when a patient needs to take action and I believe this timeline question is hard to answer without robust data. And we had a lot of discussion around why we need to have registries and collect data and I understand that data collection is based on a device type, device type is also a loaded question, but it has to be one device at a time.

But beyond data collection I just want to highlight a couple of things. You know, understanding time is important because it gives actionable items to the patient, but evaluating time is also scientifically difficult because it depends on the type of outcome.

What outcome are you really looking for?

So for example, I'm shamelessly citing a study that I have done because I think that's a good example. So we looked at the landscape of postmarket surveillance on a few devices, for example, let's say total hip replacements or total knee replacements, just to get reasonable confidence on when the device fails it depends really on the outcomes. If you think about revision surgery as an outcome, you would need like a really large sample size because it's a rare outcome, but if you think about functioning or quality of life as an outcome, then the sample size needed is smaller. So there is a question of how much data you'll need.

And that leads to the second point I want to make is on the uncertainty. So FDA is going to communicate estimates of risk and benefit in their communication, but these risk estimates also come with a lot of uncertainty. There is a classification system for the risk, we have Class I devices, Class II, and Class III devices, but I think a good -- a suggestion from me would be to have a classification system for uncertainty.

So uncertainty can be on the quality of -- uncertainty can be many faceted, right, so uncertainty could be on the quality of evidence, on the size of the data on which this is based on, so having a system of classifying uncertainty off the risk estimate that you're providing, I think, is going to be important. And from the breakout sessions, it seems that there is -- you know, patients really want to have this kind of detailed information. So these are the two points I want to submit. Thank you.

MR. CONWAY: Okay, great. Thank you very much.

Ms. Brummert.

MS. BRUMMERT: Okay, I wanted to sort of piggyback on what Amye was talking about, you know, patients are not getting the information. I think that patients need to get

information straight from the FDA, I think the FDA should -- press releases it should be getting to the public so that patients hear it. You know, patients can't rely on the manufacturers to give them that information, so I think the FDA actually needs to step up and become that trusted source because I've got to be honest here, nobody trusts the FDA anymore.

So I think the FDA needs to step up and get the information across in a timely manner, in a way that everyone can understand, and include patient advocates in these decisions on how to communicate because these are the patients who know what happened with these medical devices and they don't want other people to go through what they went through. So I would also advise to work very closely with the patient advocacy groups. It seems, you know, a lot of groups tell me that oh, we're trying to work with the FDA, the FDA just sort of dismisses them and I think it would be a very big mistake.

MR. CONWAY: Okay, thank you.

We'll go now to Dr. Reed and then we'll go to Dr. Parker and then we'll come back to Cynthia and then I'll probably move to go ahead and summarize this, but we'll see how we're doing at that point.

Dr. Reed, go right ahead.

DR. REED: Thank you.

MR. CONWAY: Thanks for your patience.

DR. REED: Shelby Reed. I wanted to address the initial question which was what are the most important elements that people want to know about. First of all, it strikes me, and this has been discussed many times, people need to know about information on their specific device that they have so that they can deal with that. Beyond that, I know a lot of pieces of information that really, it's difficult to prioritize their importance because they're

interdependent and they do end up painting an awful picture, so I think that's going to have to be sort of specific to each type of recall or specific event.

The other issue I wanted to highlight is the one that Dr. Banerjee mentioned and that is to the extent that we want to identify safety problems early with devices, that often means that we're going to have less certainty about what those risks actually are. So I really like the idea that you put forth about having some sort of classification system about the level of uncertainty because that goes hand in hand with timing when that information starts to come together as a signal. So thank you.

MR. CONWAY: Great. Thank you very much.

We'll go to Dr. Parker.

DR. R. PARKER: So this follows pretty directly from what some others had said, I think, but frames it slightly differently. I think recalls, it needs to be clear to the eyes of everyone that recalls are an issue of safety. That word has to be up front because safety heightens the awareness of everyone and we know that products come to market because their safety and efficacy is reviewed by the Agency before they come to market and there's a high bar for safety, so a recall is an issue of safety and that needs to be completely clear in all use of the language around recalls.

Regarding what people need to know, I think I'm echoing some of what we've heard. Number one, how do I know if this relates to me, that is absolutely, I think, as Dr. Reed said, the elephant in the room, the use of UDIs, creating data-driven approaches to knowing that it's mine, so I'm pushing myself a little bit on that to say we know when the National Academy reports to look at issues related to drug safety, that among the most important things is for patients, the users, to have an accurate and up-to-date list of their medications. My thinking would be that devices need to be included on all medication lists, they have a

life once they are a part of the patient, and perhaps beginning to think about how we look at devices as a part of that list long-term could improve the more global approach to safety here. So if everyone were to think of the devices that are implanted as a permanent member of that list, that could be an important step because it will engage not just the patient or their caregiver as the holder of that, but also the payers and those that are seeing them on a more chronic basis. So I think that's something to really think about, how to make this systematically viewed and treated as something that goes on a medication list which has a priority, so it could be medication and device list if it comes systematically incorporated in how we approach all clinical care and from all the various stakeholders that are involved.

So number one, there's a recall, it's an issue of safety, how does that relate to me? Well, I look at my list or I access my list and I find out if it relates to me, so I think that's number one, "Does it relate to me?" Number two is the level of the urgency and the third one, I think, is the action, "What do I need to do?" And I think a lot of the other content that is incredibly of interest will be of variable interest and that is that's the appended stuff that you find through hyperlinks, it's systematically presented sort of like drug facts and other things, it becomes standard and there's a way to approach it in a systematic way that can orient patients and care providers to all be able to see it, find it, and use it in the hopes of improving safety. So those are some of my thoughts on that.

MR. CONWAY: Great. Thank you very much.

To the other Dr. Parker, go right ahead. You're muted, Dr. Parker.

DR. M. PARKER: I don't have anything additional to add, my questions were answered.

MR. CONWAY: Okay. Thank you very much.

Now, Dr. Roy.

DR. ROY: This is maybe a question for Ms. Capanna. We received some information from patients prior to the meeting and I didn't know if that was to be discussed in the earlier part of the meeting or not, but there was just a comment in one of these patient submissions to the Committee that I thought was interesting and I wanted to share a thing of this, from a protocol standpoint, if this is an okay time to talk about that.

(Cross-talk.)

MS. WILLIAMS: Hi, this is Letise, the DFO. This is Letise, the DFO. Yes, you can use any of the written comments that you received from the public in your discussion to help you with your answering of questions or recommendations.

DR. ROY: Thank you, Letise --

MS. WILLIAMS: You're welcome.

DR. ROY: -- for that clarification.

MR. CONWAY: Great. And then if we could come back around to Cynthia, I think you had --

DR. ROY: Oh, I'm sorry, I was going to just point out --

MR. CONWAY: My apologies, okay. I didn't know if you were going to go ahead now.

DR. ROY: Sorry, I went on mute there accidently. So we had a submission from a patient named Mary Baude, I don't know if I'm saying that --

MR. CONWAY: I think you're on mute.

(Cross-talk.)

DR. ROY: I'm sorry, I don't know why that happened. We had a submission from a patient named Mary Baude and there's quite a bit of information in her elbow prosthesis

story, but one of the things that she very acutely points out is the fact that we have the technology to create databases and registries, I mean, that technology exists and I just -- I love what Dr. Ruth Parker said about thinking about our medication and devices as just a surrogate, I love that, I just want to second that. But in addition to that, I think we should be thinking about this concept of a registry, of getting yourself registered in and being able to be notified because that's -- there's nothing earth shattering about that, that technology exists, it just needs to be done and this patient, Mary Baude, referenced AAOS, having their link. The Kaiser Family Foundation has a link, even Wikipedia had a link.

So I just wanted to share that with the Committee, kind of echo again what the plastic surgery group is doing and that -- you know, these things are out there and the UDI registry, that just wasn't working and if FDA is going to play a role in this and become a trusted partner, as Rachel Brummert points out, there needs to be an investment made in that and it's just simply a matter of software programming and program management and then deployment and dissemination. So that takes a level of resource that someone needs to think, decide -- not me to decide, but decide whether or not that is where an investment needs to be made.

MR. CONWAY: Great. Thank you very much.

And Ms. Capanna.

MS. CAPANNA: I just have a clarifying question to Dr. Roy on that point. Are you recommending that those external registries could potentially play a role in helping to directly notify patients that are affected or did I mischaracterize your recommendation?

DR. ROY: Yes, I am making that point but I am also saying that it is fragmented, so there are these registries that are fragmented and maybe that's okay. You know, I just bring that to the Committee because if you have an orthopedic implant, then maybe you're

in the orthopedic association's registry and they own and manage that, and the education and the communication on that, and if you've got a breast implant, maybe you're in the plastic surgery registry. And some smart person today said that the truth is complicated or something like that, so it's complicated, right? So I think wouldn't it be great if there was just one massively huge thing that covered all implants? That's not really practical. So if you break it down by systems, maybe that is more practical and more manageable and more doable. And where is the FDA's role in partnering there as an authority?

MR. CONWAY: Thank you.

And Cynthia, we'll go ahead and go to you and then I think, given the fact that we have five questions and less than an hour, I think we'll move it along.

But go ahead, Cynthia.

MS. CHAUHAN: This is Cynthia Chauhan, I'll try to be brief. First I want to go back to what Amye was saying because she made a really important point. Some of us have a lot of devices in our bodies and we don't know any of the information that is pertinent to this discussion. But secondly, I happen to be so lucky, I have devices for heart, eye, and limbs. My limbs devices I know nothing about. My heart devices and my ocular devices, I have a lot of very direct information that was given to me and that I was told I must always keep this available at all times. So I wonder if the FDA can look at how the different device groups manage and decide what to tell us and what's important for us to know because that appears to be out there.

My other thought was -- oh, Dr. Ruth Parker, when you talked about adding devices to our medication list, I'm fine with that, I think that's a good idea, except I do not think payers should have access to that because payers, for better or worse, look for ways not to provide services and I do not want them to be able to look at how many devices Amye and I

have in our bodies and say, based on that, they're not eligible for X, Y, or Z service. Thank you.

MR. CONWAY: Great. Thank you, Cynthia.

And my apologies, before I wrap, Jijo James, go right ahead.

DR. JAMES: Thank you so much. So great discussion out here and great discussion on registries and we can discuss this further later, but the challenge with registries is the fragmentation and not necessarily having the ability to require them to notify patients, it depends on the basis on which these are set up. We would like nothing better than to have that.

I think an option that we've spoken about a lot is UDI. It's one thing to get that implemented and have manufacturers follow through on it, the challenge there again is if I don't have that stored in an electronic database somewhere, it limits my ability to be able to trace and act on it.

So the question becomes, and this is not within FDA's purview, but the question becomes what can we do to push electronic records vendors, EMR vendors, to have that as a field so that it becomes part of our normal practice, the same way you put medications in that way. And under new regulation, you, as a patient, have access, a right to access your own data and you can download some of that in a PHR. Doing something like that kind of builds that ecosystem, drives shared responsibility and accountability, and that is something that might help us to communicate much better and much more effectively.

MR. CONWAY: Great. Thank you very much.

At this point, Ms. Capanna and Ms. Keith, with regard to Question Number 1, in a general sense, the Committee generally believes several things. One, nomenclature matters, and so words like recall and safety and what that actually means has tremendous

significance.

The other thing I think the Committee generally believes is that the sense of urgency has to be at the top.

The Committee also believes that there are several different opportunities, there are opportunities both in industry and there are opportunities for the FDA, it's been articulated as either the FDA stepping up or the FDA becoming a better partner in terms of systems and partnerships with stakeholder organizations.

There have been a number of other concerns that have been raised, as well, including practical issues in terms of what happens if a doctor goes out of the country, what happens if a doctor or a provider passes away, and many other related concerns about that.

There have been analogies made in terms of what could be modeled or what could be replicated perhaps from the consumer industries, car industry is one of them that was mentioned.

The idea of what type of data and what type of information has to be communicated out to patient communities, the safety of devices, alternatives, types of interfaces that would make it easy for patients and patient consumers and caregivers to get timely information, the idea of including devices just like you do in medications in terms of prioritization and access and how it's understood.

And I think Cynthia articulated something that's been heard throughout the day, also, and in some of the documents that have been provided, that those who manage chronic conditions and multiple devices need data in terms of how those probably interact and how they rack up with each other.

And then very specific things have been mentioned in regard to data and outcomes, and I think a very important point that was raised is in terms of sample size and especially

on issues of quality of life, that that perhaps would not have to be as large of a sample size but nonetheless, to patients that is extremely important information. I think in general, across the board, everyone sees a tremendous number of opportunities, there have been a lot of specifics that have been identified and captured.

Ms. Capanna and Ms. Keith, is this adequate in response to Question 1?

MS. CAPANNA: I do have one clarification for -- I don't know if we can have the slide back up. For part (c), we were looking for any feedback from the Committee on whether you all think that it's important to think about information needs differently for patients currently using a device subject to recall versus patients considering or prospectively looking at potential device use.

MR. CONWAY: If I can make one comment on that, there was at least one comment made in terms of for those who have a device, the safety of a device plus alternatives and that was specifically brought up in terms of information that could be made available, so for those who not only have one in them but people that might be considering a particular device, they would see something that was of concern that they would know how to access or be aware of what alternatives might be. Is that responsive?

MS. CAPANNA: Yes.

MR. CONWAY: Okay. With that, Commander, can you read the second question?

CDR OLELE: This is Commander Chinyellum Olele with FDA.

Question Number 2: Communicating recall information to patients with implanted devices (such as a defibrillator or deep brain stimulator) is particularly complex. The choice patients often face is whether to remove and replace the device or continue using the faulty recalled device. Each patient, in consultation with their physician, must weigh the risk of surgery or other procedure to remove and replace the device compared to the risk of

continuing to use the recalled device. These can be difficult decisions as neither option is without risk.

a. What recommendations do you have for the FDA and industry in communicating recall information to patients facing these kinds of decisions?

b. What other types of devices do you think may warrant special communication approaches? Consider for example, devices that are worn, devices used at home without supervision of a healthcare professional, or other devices that patients "depend on."

MR. CONWAY: Great. Thank you very much, Commander.

So we'll go right to Cynthia Chauhan for the first question and then we'll go to Dr. Parker.

MS. CHAUHAN: For the first question, I believe that there should be direct communication with patients because if you rely on the physician, it may be that the physician, for whatever reasons, may choose not to honor the recall and I think the patient has to be an integral part of that decision. So somehow there needs to be direct communication with the patient based on the things we talked about in Question 1.

MR. CONWAY: Great. Thank you very much.

Dr. Parker.

DR. M. PARKER: In addition to the safety and risks involved in removing or replacing a recalled device, it's important to consider who's actually going to cover the cost of removing and replacing that device. You know, we've talked about it but we haven't really given real clear answers about it. You know, when I have a car recall, the idea is -- and I really like the idea of treating implanted medical devices pretty much the way you treat the things on your car, the manufacturer of the car gives you that information right away and

tells you how that's going to be resolved. I think that when it comes to implanted medical devices, it's not clear that the manufacturer is going to cover the cost of replacing and removing and putting whatever the device is in place, so I think that the FDA does bear some responsibility for making that clear.

MR. CONWAY: Great. Thank you very much.

Mr. Banerjee.

(Off microphone response.)

MR. CONWAY: I'm sorry, Mr. Banerjee, you're muted.

DR. BANERJEE: Oh, so sorry. So I completely agree with Ms. Chauhan that FDA needs to communicate directly to the patient and not just simply rely on their provider or the surgeon. But I have some thoughts as to how such complex communication in these complex situations can be given.

So I heard from the FDA that they are considering personas, personas might be a very good strategy to getting information, but I wonder if that persona should also be a data-driven persona. So you know, again, we've talked about the use of data submitted is critical in getting information about a device, but I can think of many statistical ways -- sorry, I'm putting my statistician hat on -- and statistical ways to create data-driven personas that will cover the continuum of patients or the distribution of patients would be representative with a certain amount of error. And if you take these personas and provide solutions or communications specific to these personas, I think it might be an effective way of communicating to patients.

MR. CONWAY: Great. Thank you very much.

Necie Edwards.

MS. EDWARDS: Necie Edwards. One suggestion that I have is very similar to the

vaccine deployment, so that if you experience an adverse reaction, VAERS, so when I had an adverse reaction, VAERS is tracking me. And so it started making me think about with the recalls, if we had a system somehow or a national database to make it easier for reporting so that patients can also be followed up with, and I think this needs to be very stringent, I think it needs to be readily available and the biggest concern is it should be something that patients have access to, to know where to go to get the information, how to report the information, how to report their concerns. I've had a lot of concerns about some of my devices. I know firsthand that some of my doctors are not the ones I need to speak with, they don't have that information. So if we had some type of reporting system in place that we can send information to patients, you know, alerts of some type, that would be helpful. And then the other thing that I want to say real quickly is can we have some type of a reporting guide? So I was thinking in terms of the government printing office, they have all manner of reports. Not reports, but materials you can get for diabetes and different disease states. It would be great if we had some type of guide for recalls. Maybe we do, but I have not seen that in there at all. And also, it depends upon where you are on that patient journey.

And the last thing I want to say is when it comes down to communicating with patients, we need to also take into consideration the mail system. The post office recently made some new changes with Louis DeJoy, so the mail is now being slowed. So if this information is being mailed, it may not get to the patients timely, so that is definitely a concern. Thank you.

MR. CONWAY: Great. Thank you.

At this point I'll go ahead and start asking folks -- okay, go ahead. Jijo James.

DR. JAMES: Jijo James. Thanks again. And this is definitely a challenging question

because ultimately you do want to get to the patient and the individual who is impacted and communicate the information to them. But what causes me pause is the examples that I've been given, these are not simple communications, these become challenging. So how do you do that in a manner that's simple, understandable, actionable?

So perhaps an opportunity exists for us to use that same combined shared responsibility model and explore ways to get the patient voice in that benefit-risk assessment so that that can potentially help us communicate this information to those who are impacted. Again, when you look at the question, we talk about "how can industry and FDA." Why not industry, FDA, and some kind of patient body together figure out that messaging and figure out better ways to communicate? I think there is that patient voice that's missing in that communication that we should consider.

MR. CONWAY: Great. Thank you very much.

Cynthia, I'll come to you and then I'll ask folks to be free in your opinions, but we've got four more questions to go and less than 45 minutes there. So go right ahead, Cynthia.

MS. CHAUHAN: Cynthia Chauhan. Very briefly. I think the FDA should consider using television, which is in almost all homes in America, to alert patients that they're getting mail or whatever about a recall, because the previous speaker's point about the mail system is very important, but if I know to look for it, that helps, too. We've just got to reach the public very quickly, very precisely, without causing panic. Thank you.

MR. CONWAY: Great. Thank you.

Ms. Brummert, do you have a point that you'd like to make?

MS. BRUMMERT: For once I do not have any questions or comments.

MR. CONWAY: Okay, thank you very much.

Any other opinions or views on this? Go right ahead, Dr. Roy.

DR. ROY: Oh, I just wanted to respond to Cynthia. I love that message, but there are a lot of homes in America that don't watch TV. So yeah, but social media, you know, other media.

MS. CHAUHAN: Yeah, combine them all. Oh, that was Cynthia Chauhan.

MR. CONWAY: Thank you very much.

At this point I'll probably go ahead and summarize unless other folks have opinions. We're trying to get as many opinions as we can. So Ms. Capanna, do you want me to go ahead and summarize?

(Off microphone response.)

MR. CONWAY: Great. In regard to Question Number 2, the Committee generally believes that there should be more communications and I think the consensus that you're seeing from the Committee is what type of communication, on what platforms, and use all platforms to try to penetrate it.

I think one of the most important points has been made, and it's been echoed across the day, that this is an extremely complex terrain with many different stakeholders that are involved before you get to the patient or the patient/consumer and in light of that, communications have to be simple, they have to be understandable, and they have to be actionable.

There are questions that have also been raised and concerns by the Committee in regard to who covers the cost. What is the role of FDA in this process?

I think there also have been good points raised about the use of other means for communications, in terms of the data and statistical basis so that things could be portrayed to patients in an understandable way. I think that probably ties in with some of the information we heard in the first question of being able to tier what the risk is so people

understand what risk is.

In terms of how to communicate with patients, we've heard multiple things in terms of printed reports, access to information in terms of how it comes through the mail and also the lack of access to things as commonly understood as TV. But I think the Committee probably agrees that it's multiple means of communication in the most simple way possible given the complexity of the terrain.

Ms. Capanna and Ms. Keith, is this adequate?

MS. CAPANNA: If I could just probe for some clarification on part (b) and I recognize we're running short on time, but also there's a lot of interconnection between these questions, so I'm hearing responses to some of those questions already. So the part (b) here, here we're really looking at advise the recommendations to help us with looking at different approaches for different device categories and so we've talked a lot about and we've heard a lot of discussion around implants and we're wondering whether there are other device types that you all would recommend that need a special approach. We have some suggestions here to consider, devices that are worn, devices used at home without supervision, the healthcare professional, or other devices that patients depend on. I'm wondering if the Committee has any recommendations to that.

MR. CONWAY: I'll go ahead and put one out. I usually reserve personal opinion to the very end, but I think in an era of more mobile devices and more -- and the home becoming a center of care with telemedicine and telemedicine-backed devices, there should be some way that manufacturers, as they come through the process, if they're actually looking for patient insight data in the product development life cycle, these ought to be some of the questions that they ask, that in the event of a recall in the age of more technology centered devices and enabled devices in a home setting, what are the means

that are already going to be built in at the front end, as they come in to the FDA for approval, that anticipate a recall on how a patient could easily find out that information and be able to process that information, and also especially caregivers in the home who obviously may not be medical professionals but they have as large a stake in making certain that that person remains healthy and strong. Is that responsive?

MS. CHAUHAN: Could I just add?

MR. CONWAY: Go right ahead, Cynthia.

MS. CHAUHAN: Cynthia Chauhan. I just think it's important for us to remember that stock --

(Audio feedback.)

MS. CHAUHAN: -- devices have external equipment that is used and so that external equipment is also very important.

MR. CONWAY: Great. Thank you.

Dr. Parker.

DR. R. PARKER: So I was thinking when I read that question about the potential for, if you will, smart devices which the manufacturer can signal in concert with the Agency when there is an urgent need. So technologically that's possible, but to really push that and explore that with someone, I'm sure that's already being explored out there by some of the manufacturers, but I'd really take a close look at that because I think leveraging technology as an assistance to support the communication is truly a part of the future and probably already a part of reality in some places, some countries more than ours. And so I would --

(Audio feedback.)

DR. R. PARKER: -- just throw out, as an example --

MR. CONWAY: Great. Thank you, Dr. Parker.

And I think, Ms. Capanna, you have another comment quickly here from Dr. Roy.

DR. ROY: No, I'm sorry, I don't.

MR. CONWAY: Okay, great. Is that responsive, Ms. Capanna or Ms. Keith?

MS. KEITH: Yes, thank you very much.

MR. CONWAY: Great. Thank you very much.

Commander, could you go ahead and read the third question?

CDR OLELE: Sure. This is Commander Olele with FDA.

Question Number 3: When making decisions about potential device recalls, FDA's policy outlines a benefit-risk approach. This includes patient perspectives about continued use of recalled devices, the suitability of available alternatives, and challenges patients may face should widespread shortages of alternatives occur after a recall.

a. What additional methods do you think the FDA and industry should consider to incorporate patient perspectives on these factors into benefit-risk decision making around recalls?

b. What additional information do you think healthcare providers should have available to aid their individualized discussion of benefits and risks with patients?

MR. CONWAY: Great. Thank you very much.

Go ahead and move to discussion here, and Mr. Dunlap.

MR. DUNLAP: So it's Bennet Dunlap. With respect to Abbott and Costello, you know, who's on first, what's been recycled and I don't know about third parties keeping a database. If you're using language like customer and end user to mean hospital and a medical practice, you're playing Abbott and Costello with language gags and not putting patients first.

And I think that little levity aside, FDA can't be the one keeping these databases as they're a third party, they can certainly be the umpire and they can do that -- you know, there was a comment this morning about the pharm supply chain and the FDA should be able to have the same or better traceability of a medical device shortcoming through those supply channels as they do through tainted -- through pharm supply chains.

The FDA can make it clear that what patient communication should be by putting them up front and putting it in with a device approval because that's when the manufacturer's twisting their cap in their hands and trying to get an approval, and I would encourage the FDA to clarify the guidance to approve a device as safe and effective so that it includes communication protocols that will be used to inform device users, individual users, that there's a problem. Specifically, that guidance should clearly define patients as critical stakeholders beyond hospitals and doctors' offices as customers and users.

The premarket approval should consider the communications protocols, so if the Bennet Dunlap Company is getting a device approved, I have to say these are the protocols I'm going to use. Those protocols are going to be different depending on the risk of the device. And I think if we look back at some of our other conversations, it needs to take into consideration artificial intelligence and is that going to be a means of communicating directly with patients. The FDA needs to approve that communication process, be the umpire that enforces it, but they can't be part of that communication chain because they quite frankly don't know.

The protocols should anticipate the possibility of different classes of recall or it needs to communicate with patients. Further, they should anticipate that -- we've talked about hospitals may go out of business, doctor practices go out of business, the relationship is between the device manufacturer and the patient and that's where the database has to

be maintained and the FDA should be the umpire making sure that it happens. And with that, I will turn off the old radio.

MR. CONWAY: Great. Thanks, Mr. Dunlap.

Dr. Reed.

DR. REED: Hi, I'm Shelby Reed. I just wanted to answer the question of what FDA and industry can do to help, you know, kind of consider how to --

(Audio feedback.)

DR. REED: -- and to point out that some of the data-driven approaches that we can use are available, that there are types of work that my group does, does help to use patients' voices to generate evidence on benefit-risk tradeoffs. And so that's one thing that we have to keep in mind and I think it could be useful in the situation with a recall. You know, recalls evoke a lot of emotion in people and there's a lot of concerns about safety and rightly so. But what might be useful is then to go back and do some research where we can sort of remove the emotion and allow people to evaluate the benefit of the device maybe that they have, the potential benefits of a replacement device, as well as the potential risks associated with the recall issue, as well as the risks of removing and replacing the device. So it is certainly multifactorial, but I think that might help bring to bear what patients think about when they think about the totality of all of the benefits and risks that are associated with a recall and potentially getting a new device.

MR. CONWAY: Great. Thank you very much.

Amye, go right ahead.

MS. LEONG: I agree with previous speakers in this area. I found Question Number 3 quite interesting because to me it was more of a statement. Yes, I do believe that FDA should be working with industry and directing in an umpire-like way, as Bennet had said, to

help develop that benefit-risk approach and profiles. And I work primarily in the musculoskeletal, so where there's physical pain, there's depression, there's anxiety because you can't move, you can't pick up your baby, your child, you can't work, you can't do the dishes, you can't be who you are in a career because of those kinds of things. To have that patient in some of the circles I'm working in is developing benefit-risk profiles, the actual development including patients in that development of a framework.

That framework is then used in a shared decision-making environment like we've talked so wonderfully about. It's not just one person's decision, whether that person be the surgeon, the hospital, or just the patient, it's a combination of all of that expertise and experience, but certainly to promote that engagement, the patient voice in the development of benefit-risk profiles, to then be incorporated. And I think that the FDA has the muscle and I call it the moral-suasion to say to industry "your job is also, as you're moving toward or have to move toward recalls, is to develop a framework for shared decision making for the various health professionals and patients to go through to make those decisions together, never a one-off, never a one-only kind of approach," and I think that kind of voice has to come from the FDA.

MR. CONWAY: Great. Thank you very much, Amye.

Necie Edwards.

MS. EDWARDS: Necie Edwards. Where I would like to go to real quick is going back to the supply chain, because I think that's where it starts with the patient, up front. Let's say that your healthcare facility purchases a new batch of medical devices from a distributor, but they're not going through the manufacturer. So then the hospital is not always provided with those specific lot numbers and because the distributors didn't record those lot numbers that they sold, they resend all this information and the notices to all the

hospitals.

The patient's fate is suffering because now they're dependent upon the manual deciphering of what often was filed was a lot number consisting of numbers and letters. So I think that the FDA needs to take more control of this process because there are so many pieces in the making here that are moving, too many hands involved, and still it needs to be regulated more. Thank you.

MR. CONWAY: Great. Thank you very much.

Mr. Banerjee.

DR. BANERJEE: This is Samprit Banerjee. I think, you know, I was going to make the point that to me it seems like the first question, somewhat related to the first question is how do we weigh benefit and risk and how do patient perspectives weigh in on benefit and risk? And to understand patient perspectives, we do need data and we do need patient-reported outcomes. So they can't pull that idea when the first question is quality of life versus revision surgery might have very different decisions whether to recall a device or not. So I think we need more data on patient-reported outcomes.

MR. CONWAY: Great. Thank you very much.

And we'll go to Dr. Parker and then we'll probably move to summary unless people have other questions or comments. Dr. Parker.

DR. R. PARKER: So I would just underscore that when I think of the Agency and the Agency's purview in this, I can't get away from that of safety, because I don't know who else is going to take that on from a public health perspective if not the FDA. So I really, in my mind, prioritize the Agency being able to help with clarity on safety. And recalls, as I said earlier, are related to safety, they're related to product safety.

And we all know that risk tolerance varies greatly on an individual level and that's

what makes the incorporation of patient perception, patient input, patient preferences, it's much harder to codify than the issue of do we have a safety concern, safety signal, yes/no. And that is what I think needs to be prioritized as the key point of the communication that the Agency is overseeing, recognizing that risk tolerance on an individual level really does vary, but being clear that there is a safety concern is something that can be made clear.

So I totally support and recognize and feel understanding how patient understanding is incorporated really does matter, but I think within that we always need to keep in mind that we also know that risk tolerance varies significantly. Is there a safety signal, yes/no, how is that being communicated as part of the recall, to me, seems to be the top priority from the lens of the Agency.

MR. CONWAY: Great. Thank you.

Dr. Roy.

DR. ROY: This is Rita Roy speaking. Dr. Parker, I guess one of the things that I'm still a little bit confused about, and I don't know if others feel the same, maybe someone can clarify for me, but as we think about safety and recall, recall is kind of voluntary, right? So to me there's something there about the whole recall and how that -- you know, how that happens and I want to underscore my sort of hurrah for -- where did he go -- Peter (sic) Dunlap. I just agreed with his comments wholeheartedly that that's -- I don't think that the FDA can run and manage registries of patients and I don't think that's a role of a government agency to do that and I think, at the end of the day, there's a manufacturer makes a widget, a patient gets it in them and there are different levels of risk, but it's a company thing and a person has it in them and that's where, you know, that's a responsibility of the manufacturer to get the messaging to the patient because it's the patient that has it.

Bennet Dunlap, I just wanted to sort of underscore your comment in my sort of vote for your comments there because I think you're absolutely right and that the onus really is on the manufacturer to get the messaging on safety to the patient. Even if a patient, I mean, isn't ultimately the buyer but ultimately is the buyer. So it's a complicated thing, but I think that's -- you just boil it down to its simplest form. I mean, I have an implant in my knee, I don't even know -- I don't know anything about it, I kind of -- I think I know which company made it and that's about it and that's kind of sad, so it shouldn't be that way.

MR. CONWAY: Great. Thank you very much.

Mr. James.

DR. JAMES: I don't have too much to add. I think we would all like to communicate directly with the patient and we've had a discussion through the day as to some of the barriers and challenges that exist, so it's more of a systemic approach that needs to be taken to be able to do that and I wish it were that simple.

MR. CONWAY: Great. Thank you.

And Ms. Brummert.

MS. BRUMMERT: Dr. Roy was talking earlier about how adverse reactions are going to be reported. I want to submit that maybe FDA should make it mandatory for adverse reactions to be reported because then we're working with accurate numbers, just like risk-benefit, if we're not working with accurate numbers because things are underreported. So I just wanted to kind of throw that out.

MR. CONWAY: Okay, great. Thank you very much.

Cynthia.

MS. CHAUHAN: Cynthia Chauhan. I agree with what I think I heard the last speaker say and I want to react to Dr. Roy's comment about it should be a manufacturer, the

patient. I don't disagree with that, but I think that's very idealistic. I think the FDA has a very strong role in enforcing adequate and competent communication about devices, especially when those devices are on recall. So I just want to underscore the FDA's role in this.

MR. CONWAY: Great. Thank you very much.

And barring anything else, I'll go ahead and move to summarize what the Committee generally feels or believes. I think, to the FDA team, you've heard multiple expressions of endearment to you as umpires with a lot of muscle, a fundamental role that you play in the process that cannot be substituted by industry or by other third parties.

I think Bennet hit on a very important issue of outlining things at the front end in terms of the process for what recall communications and protocol would be before something is approved.

We've heard, again, reinforcing language on the need for clarity, the need for understanding clearly on safety, how safety signals and communications are done, risk tolerance and again, a reinforcing point on data.

As far as specifics, the use of artificial intelligence has come up in this, the responsibility on the provider side for being able to communicate risk, and also the issue of going further upstream in the process in taking a look at supply chain issues in regard to how -- where providers are, and not excusing providers from their role with -- manufacturers and providers in their role with communicating clearly to patients, and that far and away, the FDA sits in the center of this, again, the terms umpire, muscle, and regulatory authority have been used.

Ms. Capanna and Ms. Keith, is this adequate?

MS. CAPANNA: Yes, it is. Thank you.

MR. CONWAY: Great. Thank you very much.

So I'll remind the Committee, we have a very few short minutes and many of these answers are redundant, but if you can, listen very clearly to the answer and we'll try to get as many of these opinions in so we can finish.

And Commander, if you could go to the next question.

CDR OLELE: Commander Olele with FDA.

Question 4: The FDA oversees hundreds of medical device recalls every year, many of which are considered unlikely to cause adverse health consequences, or where the probability of serious adverse health consequences is very small. The FDA generally focuses efforts to raise awareness among patients and the public about a recall when use of the recalled medical device or product may cause serious health problems or death. Considering current practices, and balancing goals of being informative to patients while minimizing confusion:

a. What information do you think patients want to see in communications about lower-risk recalls? What factors should the FDA consider as "triggers" to identify which lower-risk recalls to prioritize for patient-focused communication?

b. Under what circumstances, if any, do you think the FDA should consider issuing a patient-focused communication to raise awareness about a recall before the FDA's assessment of the recall is completed?

MR. CONWAY: Great. Thank you very much, Commander.

On this one, we'll try to use as light a touch as possible, so who would like to go ahead and start on this? It looks like Cynthia is smiling, so I'm sure you have something, Cynthia, that you can do quickly.

MS. CHAUHAN: Actually, I don't.

(Laughter.)

MS. CHAUHAN: But thank you for noticing.

MR. CONWAY: I don't miss too much, thank you.

MS. CHAUHAN: No, you don't.

MR. CONWAY: Would anyone else like to go ahead and venture out first on this?

Go ahead, Bennet.

MR. DUNLAP: So I'll be brief. Under (b), what circumstances before they're fully aware, if it's life critical, you know, if it's a Class III device and it's potentially having serious problems and you got to get out of there, get it out before you know all the facts and one of the facts you do get out is we don't know all the facts, but be aware.

MR. CONWAY: Great. Thank you.

Jijo. Mr. James.

DR. JAMES: Jijo James. I'll keep it short, as well. I think, to the first one, it goes back to nomenclature and if we can better understand what nomenclature to use so we don't use the same term, I think that will help.

Number 2, in addition to what Mr. Dunlap said, if life critical, actionable, I should be able to do something with that information. Just saying there's an issue, even if it's life threatening and you don't give me a solution on what actions to take, it's not going to help.

MR. CONWAY: Great. Thank you very much.

Mr. Banderjee.

DR. BANERJEE: I'll be short. For 4a, I think that it's important to communicate the likelihood of risk, so for example, what is the likelihood of risk in 6 months or 1 year, and give a timeline to it. And an earlier point that I made, also, it's important to quantify the

uncertainty or classify the uncertainty around this estimate, so how certain are you about this estimate of risk.

MR. CONWAY: Great. Thank you very much.

Dr. Roy.

DR. ROY: I think, on point (a) we've talked about the role of patient advocacy groups and patients going to the Internet, into chat rooms and so forth, and I think getting patient communication out, I think again, just trying to underscore the value that I think trusted patient advocacy groups play alongside getting communication out to patient groups where patients can then have discussions amongst themselves and amongst advocates in decision making.

MR. CONWAY: Thank you very much.

Amye.

MS. LEONG: Very brief. The area that I see is that the full circle of deciding, by a patient and their family with the physician or surgeon, to go toward an implant does not embellish or contain the end part of it. You're agreeing to get this device, you're going to probably be seen for 6 months to a year, the FDA has a process of a recall system like the car system or however -- what kind of language we wish to use, but just the overall picture that a person is presented if they've never had an implant before, kind of the full circle of this. So not only about prioritizing and doing it early in terms of patient-focused communication, but whenever anybody is presented by a surgeon that you need X-Y-Z implant, the end conversation is when I'm done with you, you're done and you can go live a great life, it's really about care of your safety with respect to this implant. And we've said that time and time again. So going full circle with the concept and the discussion of implant should also include the system of recall awareness and action by the FDA and

manufacturers.

MR. CONWAY: Great. Thank you.

Without seeing anyone else raising their hand, I'll go ahead and move to summarize.

The Committee generally has concerns in regards to this particular question. I think in terms of tiering out, again, nomenclature has mattered consistently across this, but I think what it comes down to is the Committee generally believes that you have to be clear in understanding and communicating the likelihood of risk, the certainty of risk, and have those as the triggers and also how it's going to impact life, in particular. What the people need to know, what the patients need to know and what they need to know to act on it are probably the primary factors in taking a look at both (a) and (b) on this.

Can you tell me, Ms. Capanna and Ms. Keith, is that responsive?

(Off microphone response.)

MR. CONWAY: Sorry, Ms. Capanna, you're muted.

MS. KEITH: Yes. Yes --

(Cross-talk.)

MS. CAPANNA: Actually, Mr. Conway, I was just making your job even more difficult, I did have a clarifying question on the prior question, for Question 3, subpart (b), which had to do with information from a benefit-risk perspective for healthcare providers. I know there was some discussion, some members mentioned patient-provider shared decision making. I wondered if there was any other views on that or if that was a shared view from the membership.

MR. CONWAY: I'll go ahead and throw that back to membership. I don't know if, Dr. Parker, you have a comment on that or Dr. Reed, you might have a comment on that?

DR. M. PARKER: This is Monica Parker, Dr. Monica Parker. I think the issue of risk

and benefit is a shared thing. Certainly, the provider planning to do the implantation should be aware of the risks and the benefits and be able to appropriately advise about alternatives, but if they're surgeons, not necessarily so because their objective is to do a procedure. But I think that from -- I think that doctors should be able to convey the information of the risk involved in any procedure. I think that's what you were asking, right?

MR. CONWAY: Ms. Capanna? There had been a comment made, actually, in terms of the role of FDA in shared decision-making frameworks and whether or not the FDA might be able to do something like that and there were a lot of nodding heads at that point in time when we were discussing that. Is that responsive to you, Ms. Capanna?

MS. CAPANNA: Yes, although I noticed that Mr. Dunlap and Dr. Reed had their hands raised, so I didn't know if they had other views to add to the question.

MR. CONWAY: Dr. Reed and then Bennet.

DR. REED: Specifically addressing what additional information could be provided to healthcare providers, I think there is additional information that might be a little too much to give to patients and that is what are patient characteristics and comorbidities that seem to increase the risk of consequences from devices or implants. We do seem to be talking a lot about implants and not considering other types of devices, as well, but I think that is important for physicians to engage in shared decision making --

UNIDENTIFIED SPEAKER: But they do.

DR. REED: -- for individual characteristics.

MR. CONWAY: Okay, Mr. Dunlap.

MR. DUNLAP: I bumped it, my mistake.

MR. CONWAY: Okay. And Cynthia, go right ahead.

MS. CHAUHAN: The woman who just -- Cynthia Chauhan. I clearly support what the woman who just spoke said or what I heard her saying, which is when you're talking about a device with a patient, look at the patient's risks that are associated with that device that are highly individual.

MR. CONWAY: Thank you.

And Dr. Parker, did you have a last comment?

DR. M. PARKER: Well, I guess I'm of the opinion that most of the time when it comes to devices, regardless of what those devices are, the risks are generally discussed with the patient. Whether it's a joint implant or even a monitoring device, that's been my experience. You know, they're generally not referred for, let's just say, a defibrillator unless it's indicated and certainly before -- Dr. Roy could probably talk about this, but before you get an orthopedic weight-bearing procedure, the doctor generally gives you your risks for doing that and what you need to do before they implant those things. They don't do that out of -- just to be doing it.

MR. CONWAY: Okay, thank you.

Ms. Capanna, has that answered your question back on 3b?

MS. CAPANNA: Yes, thank you very much.

MR. CONWAY: Great. Thank you very much. And thank you, everybody.

Go right ahead, Commander, if you could do the next question for us.

CDR OLELE: Commander Olele with the FDA.

Question 5: The FDA communicates most recall information by posting information in searchable lists and databases on its website. In certain situations, the FDA uses press releases and public letters to industry, healthcare providers, or patients to raise awareness about a particular safety issue. Please provide any additional recommendations you have

about the FDA's communication approach for medical device recalls. Please consider:

a. how you believe patients want to receive information about medical device recalls;
b. existing channels through which information is conveyed (such as e-mail, web posting, and social media), as well as new ones;
c. additional approaches for reaching "must-reach" audiences, including partnering with other organizations or groups;
d. additional approaches for reaching harder-to-reach populations, including those in rural or other areas with limited access to healthcare providers, healthcare facilities, the Internet or other wireless technologies; or
e. availability and findability of information (including by search engines and mobile device viewing).

MR. CONWAY: Great. Thank you very much, Commander.

So why don't we go ahead and roll through this, as well. We'll go ahead and start with Necie Edwards and then we'll move to Dr. Monica Parker.

MS. EDWARDS: Necie Edwards. In regards to Question (a), I believe patients would like to receive information regarding medical device recalls in a variety of ways and some of the ways of sharing that would be through the PACS, many people have the PACS newsletter in their area. Nextdoor neighbor is where I tune in a lot to get information in my community or surrounding area. Also your village hall. So our village hall here in town, they have a lot of meetings for the community.

Also, most importantly, your local health departments because your local health departments really have a lot of information about what's going on in the community anyway and I feel that they need to be involved with this process. Also your local state

representative, because many of them have newsletters for their constituents that you send out. The other thing, too, and I don't know if I mentioned this, tribal councils, so hard-to-reach communities, rural communities, reach out to those tribal council members. Also, there's ethnic newspapers, there are community groups, there are local stakeholders, so I feel that these are a variety of ways in which we can reach many of these individuals. Thank you.

MR. CONWAY: Great. Thank you very much. And I'll remind folks that a lot of the details that would come underneath (a) and (b) I think we've touched on. (c), (d), and (e) I think might be of particular interest to the Agency because we haven't heard a lot about those.

So Dr. Parker.

DR. M. PARKER: One of the things that came up in the discussions earlier today when people were presenting was the advocacy groups partnering with media, specifically television shows, things like that. Be mindful of things like Good Morning America's health minute with the doctor, people do get a lot of information from the television. There are communities in this country that do not have wide broadband access to say go get it on Goggle or something like that, it's ineffective. People do listen to their radio, people do listen to television. In urban markets, African Americans use the radio as a good source of information.

So as Ms. Edwards pointed out, using local media outlets for distributing the information is important, but I thought that Dr. Greco made a really good point that medical societies and advocacy groups, in partnership with larger media organizations, are better at getting that message out. Look at what's happened during the pandemic, the CDC is using the television largely to get this information out about what's appropriate and what's not

appropriate. Dr. Fauci is on television, he's on radio, and different organizations have their own channels, but I think use of the most widely available accessible media points in addition to the use of the experts, if you will, talking about this on television is tremendously impactful.

MR. CONWAY: Great. Thank you, Dr. Parker.

Other insights on this? Ms. Brummert, have I missed you?

MS. BRUMMERT: Everybody has said everything else I was going to bring up, so I have nothing at this time.

MR. CONWAY: Okay, thank you very much.

Amye Leong. You're muted, Amye.

MS. LEONG: Yeah, I apologize for not mentioning my name all the other times, but when you say Amye, it looks like I'm the only Amye, so that is Amye Leong.

In terms of groups that might be difficult to reach, I think about my attorneys at the NIH and part of the discussion was just like what we're having here, how do we reach hard-to-reach populations, and the kinds of suggestions with tribal councils, the area aging agencies, those kind, regional health, public health kinds of things. As someone had said, we have learned from the pandemic that there are local health, public health -- I want to be very specific -- public health agencies as part of the county and state that are used to now communicate about particular subjects. Obviously, for the last 2 years it's been about vaccines. But going forward, as a public health moment, it could be about recalls, it could be about another kind of vaccine, it could be about those kinds of things coming out of the FDA.

I think what's interesting is we all have a role in this, so there are thousands of patient advocacy groups and probably equally as many health professional groups and it

would take probably decades for the FDA to fully go through many of those who represent those organizations to get a good sampling of underserved populations that they are known to reach. I think that could be done with a very small community of connected people who are health professionals who know the area, who are leadership in the communications agencies for communication areas, for their surgeons, their endocrinologists, the rheumatologists, the diabetologists, the patient advocacy groups, in a very short period of time you would have probably the top 100 health professional organizations and societies as well as the patient advocacy groups, and I think of it as the pebble in the pond that creates that ripple effect for us with the FDA in terms of recall. That's the kind of mechanism I see in place. I see that FDA has that responsibility to encourage and connect people, but not to do for organizations.

And in some cases where it's not represented, just as the NIH did when they felt that the NIH was not as represented or organizations were not as well represented in reaching out to underserved populations, they then targeted those groups to do, at the national level, for the communications to those groups. So I think that kind of model does exist and it could be very helpful in this case.

MR. CONWAY: Great. Thank you very much, Amye.

Is there anyone else who would like to make a comment on this before we move to summarize this and move to the last question?

(No response.)

MR. CONWAY: Great. Ms. Capanna and Ms. Keith, with regard to Question Number 5, I believe the Committee generally believes in focusing and trying to drill down hard on parts (c), (d), and (e) of the question, that in regard to the role of partnerships and collaborations with advocacy organizations, they provide a unique set of relationships for

reach into the media and then also into other stakeholder organizations, for example, many of the patient groups have existing relationships with health professional organizations that they work with.

One suggestion that I might personally make on that is that the federal government right now, through the Office of Personnel Management, has the index of combined federal campaign organizations broken out by different types of sectors, health care is one of them, and that might be a list that could be looked at and pushed out information to any organization that's in the combined federal campaign nationwide.

For hard-to-reach populations, I think the Committee generally believes that there are many different avenues that could be gone down at the local level on this. You heard several different tactical suggestions in regard to tribal communications, specialty newsletters and publications that hit ethnic populations, local areas on the agency on aging, local health agencies, as well.

In regard to availability of information, I think we've all touched on this throughout the day, in terms of various search engines and the reliability or non-reliability of those. The other thing that I might put out is that there are multiple platforms that are out there. So people think in terms of information and search engines on Google by word, there may also be opportunities on things like Pinterest and Instagram of a recall visual that could be used and seen, that draws people in to FDA or other sites, whether it's industry or government.

I think in terms of other concerns that the Committee has, I think it's been clear throughout the day that this is a very complex type of terrain that you operate on and the charge that the Agency has and the need for creativity and it's quite high and that creativity doesn't have to rest with the FDA alone, you have a tremendous number of advocacy

organizations and professional organizations that want to work with the FDA to help get the message out.

Ms. Capanna and Ms. Keith, is this adequate?

MS. KEITH: Yes, Chairman, it is. Thank you for your comments.

MR. CONWAY: Great. Thank you very much.

Commander, would you like to go ahead and read the last question for us?

CDR OLELE: This is Commander Chinyelum Olele with FDA.

Question Number 6: This question focuses on medical device recall terminology. The FDA assigns recalls a classification (I, II, or III) to indicate the relative degree of risk associated with use of or exposure to a recalled product. Class I recalls mean there is a reasonable probability that use of the recalled product will cause serious adverse health consequences or death. A medical device recall is considered Class II when use of a recalled product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote. Class III means use of the recalled product is not likely to cause adverse health consequences.

a. Are there other terminologies or approaches (e.g. color-coded alert levels) the FDA should consider to convey the degree of risk associated with a specific recalled device?
b. What other terminology besides "recall" should the FDA consider using, in certain cases, for example, with lower-risk recalls?

MR. CONWAY: Great. Thank you very much, Commander.

I know this is an important issue to many of us who have worked in the advocacy field and on the professional side, so why don't we go right ahead and start with Bennet.

MR. DUNLAP: So back to my "who's on first" analogy. Oh, my dog is trying to climb

into my lap. I'm a little confused because a Class III device is the one that gets the most regulatory scrutiny, but the Class III recall is the one that doesn't impact as much and I think you all need to figure out which way you're going to run around the bases and not use the same numbers in radically different ways.

I think that our friends in aviation have some terminology for things like recalls that don't sound like recall. An AD, an airworthiness directive from the FAA can be extremely serious and ground 737s or it can just be hey, the next time you're doing maintenance you've got to do this. So I think there's other regulatory bodies that use different language than we've looked at and I just find it really confusing that the FDA isn't consistent with I through III and III through I.

MR. CONWAY: Great. Thank you very much.

Dr. Parker.

DR. M. PARKER: I agree with Bennet. I think it's easier, since we understand code red means something bad. What's wrong with red, yellow, and green? Simple.

MR. DUNLAP: I knew I'd like her. That was Bennet.

MR. CONWAY: Thank you, Dr. Parker.

Cynthia.

MS. CHAUHAN: Cynthia Chauhan. I just agree that adding color coding is really important. The numbers thing I don't know about. Number I to me means very important, so I'm okay with the current numbering system, but I understand it could be confusing.

MR. CONWAY: Okay, thank you very much.

Amye Leong.

MS. LEONG: I also agree with a color-coded system. In bones and joints and in functional activities, you've got a stage 1 through 4 area where the larger the number, the

more disabled you may be or functionality wise in terms of your body movement. So utilizing a Roman numeral or even a number can be very confusing because we have so many of them used in a lot different ways. You have outline numbers and that gets confusing after a while.

So if we can keep it clean, keep it with what we know, there are red, green, and yellow stop signs at nearly every corner of this country, those kinds of simple kinds of ways. It doesn't mean death, but we'll have to define it, of course, and what that actually means, that it means get to the doctor, get to your provider as quickly as you can. Thank you.

MR. CONWAY: Okay, thank you.

Dr. Parker.

DR. R. PARKER: So one other thing I would add to it is that I totally agree with judicious use of color, color has meaning, so I would agree with those comments. I would also make sure that notifications reflect timeliness and what is known at the point -- at the time of the communication, you're getting whatever. I think part of what we can do through good communication is help educate everyone about uncertainty. We learn as we go. Devices have, for many, a lifetime of being with someone and we learn as we go. And so it's really important for us all to realize that we know more years from now than we do right now. That's certainly played out significantly with the current pandemic.

And so what we do to make sure that our communications do reflect the best available, up-to-date, data-driven evidence about risk and making it clear that that does evolve over time, I think that's part of the clarity of the communication that everybody can be on board with and part of the systematic approach to educating everyone that there's no such thing as an added device or medication that doesn't have both benefits and risk. That's what brought it to market, that those were assessed and we garner, increasingly over

time, more data about those.

MR. CONWAY: Great. Thank you.

Mr. James.

DR. JAMES: Jijo James. I'll keep it short, three points. One, more social sciences research so that we can test some of these concepts. Two, let's look at what other international regulatory bodies are doing and see if we can harmonize. To some extent, things like field safety correction alerts or corrective actions are some of the terms that have been used, but we need to test these. And three, also keep in mind, I think it's been raised before, we've talked about devices and generally we think about implantables. There are a whole other set of devices that surgeons use as part of surgery, that are part of after surgery, and may not necessarily result in an implant, you know, endo cutters and things like that. Is it worth considering different nomenclature for those so that when we're communicating to patients we're very clear about what we're communicating about?

MR. CONWAY: Great. Thank you.

Any other comments before I move to summarize on this?

(No response.)

MR. CONWAY: Great. Thank you.

Ms. Capanna and Ms. Keith, with regard to Question Number 6, the Committee generally believes there are a lot of opportunities here to do many things with clarity and in a way that's easily understood. You heard a lot about color coding as a commonsense approach, but with that you also heard some need for clarification in terms of the context that's used for color and that's in regard to two things: one, context for what is the need, what's the timeliness, what's the sense of urgency that goes with the color coding, and then also the need to actually test out and see if there are alternatives that could be used based

on social science data to get a better insight into it.

And then also in terms of the simplicity of language and nomenclature, it should be taken into account that there are many different types of devices and that perhaps some types of devices need different language and different types of assessment that go with it.

But overall, you've heard an interest in trying to keep it clean in terms of the language that's used, take a look at what other bodies are doing, not only here in the U.S. on the commercial side. Bennet raised the issue of the airline industry but also to see what's being done around the world.

In this regard, is this adequate and responsive?

MS. KEITH: Yes, it is. Thank you.

MR. CONWAY: Ms. Capanna?

MS. CAPANNA: Apologies. I wondered if there was any clarification anyone had on terminology other than "recall" that we should use, consider using, for example, in lower-risk recalls.

MR. CONWAY: Bennet, would you like to take a stab at that?

MR. DUNLAP: Yeah. The aviation industry, for lower-risk things, issues what's called an advisory circular, an AC, that's something that doesn't imply you're going to fall out of the air as a great idea or something that's a critical health issues, you know, a circular. "Well, I think you should be aware of this."

MR. CONWAY: Is that responsive, Ms. Capanna?

MS. CAPANNA: Thank you.

MR. CONWAY: Okay. Thank you very much.

At this point I'd like to thank the Committee and the FDA for their contributions throughout the day. I would also like to thank the public hearing speakers, industry,

healthcare providers, patients, and FDA professionals for their remarks and for their responsiveness and engagement throughout the day.

I wanted to go ahead here and ask the FDA representatives if they have any concluding remarks.

Ms. Capanna and Ms. Keith.

MS. CAPANNA: Apologies, it's taking me a moment to get both buttons off. I really just want to thank you all on behalf of the entire FDA team. It's been very helpful to us to have you all and we appreciate the time that you've spent with us today and in preparing for this meeting. Your expertise and your thoughtful perspectives have really helped us to take a closer look at medical device recall communications through the lens of the patients. And you all know this is our fifth year since establishing this Committee and we fully intend, as with every prior meeting, to carefully consider the recommendations that you've made here for us today and use these insights to look for ways that we can shape our ongoing work. So thank you all, we appreciate your time and effort.

MR. CONWAY: Great. Thank you very much.

Ms. Keith, did you want to say anything?

MS. KEITH: Yes, thank you very much. I just wanted to thank the panel members as well, thank you for your public service today. Your thoughtful deliberations on the topic of recall communications are greatly appreciated. The insights into the patient perspective on recall communications you provided to the FDA will aid us in our efforts to ensure that patients receive needed clear recall communication as we go forward. So thank you again for your time today.

MR. CONWAY: Great. Thank you very much. And I'd like to thank you all for joining us at the PEAC meeting today where we, the patients and care partners, provide our

perspective to FDA's Center for Devices and Radiological Health, CDRH. Your participation today will be an initial step in helping to assure the needs and experiences of patients are included as a part of FDA's communication approach as it pertains to communicating medical device recalls.

On a final note, as Chair, I'd just like to add this, this is an extremely complex issue and I don't think people fully appreciate it, but we've given a lot of insight to the public on how complex the terrain is and the ecosystem upon which so many patients and so many families depend before they actually ever see a medical device or a product. Medical devices are something that people maintain their life on in many cases. I know this well from the dialysis devices that I've lived on for many years and many of my fellow Committee members here, literally, their lives depend on devices. I think the most important thing is to understand multiple means of communications and how communications are sequenced is critical and giving our creative insights to the FDA is vitally important because while it's very easy to point to the government sometimes as being part of the problem, the better part of it and the most honorable part is being part of the solution and that's what we're trying to do here today. Not simply through our own insights, but those that have been given to us by those that participated in the virtual discussions and those who had the courage and the willingness to engage with us in the public hearing process. So it was a very, very valuable thing, I think, for a government to hear directly from people and whether they're a citizen that's simply coming to us or somebody who's been in the advocacy field, I think all voices matter and that has been reflected in the FDA.

As a final note to the FDA, I'd like to say this, it is not easy to serve in government. Those of us who have don't get a lot of thank you's. But from a most sincere perspective

from me, as the Chair, and also on behalf of my fellow Committee members, thank you for your public service. It's not an easy time to serve, but it's one of the most rewarding and we can see it in your work, the thoroughness of the prep for this meeting today and over the course of the past 5 years.

I think I can say for the Committee with great consensus that those of us who have been in the fields of patient advocacy and as providers and as patients and as industry, you had an open door and open ear and what we have done through this Committee has been reflected in the course of your discussions internally and your external publications and communications for the past 5 years and that says a lot about the Agency, and your willingness to work with those who are most involved and especially, to respect the lives and the health experiences of those who have lived through many, many different chronic diseases and life-threatening illnesses. So thank you, FDA, for the opportunity to engage with you. Thank you.

This meeting is now officially brought to a close, so thank you.

(Whereupon, at 5:24 p.m., the meeting was adjourned.)

C E R T I F I C A T E

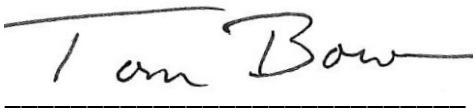
This is to certify that the attached proceedings in the matter of:

PATIENT ENGAGEMENT ADVISORY COMMITTEE

October 6, 2021

Via Zoom Videoconference

were held as herein appears, and that this is the original transcription thereof for the files of the Food and Drug Administration, Center for Devices and Radiological Health, Medical Devices Advisory Committee.



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