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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VIRTUAL PUBLIC MEETING - FDA'S COMMUNICATIONS ABOUT THE SAFETY OF MEDICAL DEVICES

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Via Video Conference

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M E E T I N G

(1:00 p.m.)

MS. CRISTINZIO: Good afternoon. Welcome to our virtual public meeting to discuss the FDA's Communications About the Safety of Medical Devices. I'm Dayle Cristinzio, Director of Stakeholder Engagement for the Office of External Affairs at the FDA, and I will be moderating today's meeting.

To open today's meeting we will first hear from Jeff Shuren, Director of the Center for Devices and Radiological Health.

DR. SHUREN: Good afternoon, everyone, and thank you for joining us for today's public meeting to discuss the FDA's Communications About the Safety of Medical Devices. I want to thank our panelists, who represent patients, healthcare professionals, medical device industry, and media, all of whom are key stakeholders of and audiences for FDA safety communications. I also want to thank the meeting organizers and all of today's attendees and speakers. I'm looking forward to hearing your feedback, which will help us continue to improve public-facing communications about medical device safety.

We're here today because communicating about the safety of medical devices is a responsibility the FDA takes seriously, and we want to ensure we're doing our best to develop and deliver clear and actionable communications. Protecting patients and providing information to help patients and healthcare professionals make informed decisions are part of the core of our mission and have been the focus of several of our strategic priorities over the last decade. The FDA's Center for Devices and Radiological Health's North Star has been our vision that patients in the U.S. have first in the world access to devices of public health importance that are high quality, effective, and safe.

Medical devices play a crucial role in the treatment and diagnosis of illness and injury. As you heard in our pre-meeting video, the FDA currently regulates more than

190,000 different devices of varying complexity. And although medical devices can provide great benefits to patients, they also present risks. We at the FDA take seriously our role in communicating about both the benefits and risks of medical devices to support an informed public and strong healthcare system.

Since its formation in the early 1980s, the Center for Devices and Radiological Health, or CDRH, has issued communications about the safety of medical devices. One of our earliest was a safety alert about problems with electrically powered hospital beds that resulted in the deaths of three children in hospitals in the U.S. and Canada. And since then, we have issued hundreds of communications about device safety under various names, including medical device safety communications, recall notices, safety alerts, patient health notifications, and letters to healthcare providers, among others.

The FDA shares with the medical device industry the responsibility for communicating the risks of medical devices to patients, caregivers, and healthcare professionals. We know to be useful that information must be clear, simple to understand, and easy to receive or find and act on. We consider the medical device industry our partners in ensuring that safety issues are quickly identified, assessed, and communicated appropriately.

Patients, caregivers, and healthcare professionals play a critical role in providing us with feedback about medical devices both by voluntarily reporting adverse events and by contributing their unique personal, clinical perspectives before or after a device reaches the market. These groups, along with members of the media, often play a key role in helping to disseminate safety information and advocating for continued transparency in communicating about safety signals and potential risks of medical devices. We are all patients at some point in our lives and we are in this together. Collectively, we can effectively protect patients and promote public health.

Over the years, CDRH has established many ways of connecting with patients, healthcare professionals, industry, and academia, whether through partnerships, networks, research, or public meetings. This is the first time we've brought everyone together to broadly discuss how best to communicate about the safety of medical devices.

We are tackling this topic from many angles. For example, we recently issued a discussion paper on communicating cybersecurity vulnerabilities to patients, which outlines considerations for the FDA, federal partners, and industry stakeholders to help thoughtfully inform patients and the public about cybersecurity vulnerabilities. The paper is a combination of best practices for risk communication research, message testing conducted by our social scientists, and feedback from the Patient Engagement Advisory Committee meeting we held in 2019. From today's discussions we hope to learn new insights that can be applied across the safety spectrum. We also welcome comments to the docket for the discussion paper, which is open until December 21st.

We heard in the first pre-meeting video how we typically develop public communications about safety. It is a thoughtful process supported by a diverse set of expertise and rooted in the fact that we strive to provide timely public communication when there is a new or increased safety concern that may change the benefit-risk profile of a device. Simply stated, the goal is to support patients, healthcare professionals, and caregivers in making informed decisions about treatments and diagnostics.

CDRH spent many years enhancing our ability to identify, evaluate, and address emerging safety signals related to marketed medical devices. A signal represents a new potentially causal association or a new aspect or increased frequency of a known association between a medical device and an adverse event or set of adverse events.

Following identification of a signal, a team of multidisciplinary subject matter experts is convened to refine, research, and understand the issue, then determine the

appropriate public health and/or regulatory actions to mitigate the identified risk.

Since our current Signal Management Program was established in 2012, more than 220 signals have been evaluated, resulting in numerous public health or regulatory actions taken, with the most common action being the issuance of a public safety communication. To date, the FDA has issued 62 communications and device manufacturers have issued 16 communications in place of FDA communications, related to safety signals.

Signal-related communications are a subset of medical device safety communications the FDA has issued when the benefit-risk profile has changed for a device. In addition to public communications, other actions taken to mitigate safety risks include modifications to product labeling, issuance of mandatory postmarket studies (also known as 522 Orders), product recalls, development of regulatory guidance, recognition or development of national and international standards, public advisory committee meetings, and clinical research.

In recent years, CDRH has updated and refined its policies and internal processes to enable more timely communication around identified signals so the public has information to act on sooner. We believe that transparency and communicating about the safety of medical devices is paramount to patient safety. That's why in 2016 we established a policy for when we would communicate an emerging signal. Knowledge is powerful and we firmly believe in putting that power in the hands of patients and healthcare professionals. Of the 14 emerging signals for which we issued a safety communication, none of the signals were later shown not to represent a new or increased known risk.

In 2018, CDRH published the Medical Device Safety Action Plan which described key actions we committed to take to help assure the safety of medical devices on the U.S. market. Ensuring the FDA is consistently first among the world's regulatory agencies to identify and act on safety signals related to medical devices is an important milestone in the

FDA's continued work on the Medical Device Safety Action Plan. Robust oversight of safety also requires timely public communication about safety issues and effective interventions to address concerns. Today's public meeting is another step toward achieving the objectives of the Medical Device Safety Action Plan.

Our goal today is to hear from you about ways to improve our communications to ensure that all patients, caregivers, and healthcare professionals in the U.S. receive the information about medical device safety they need in a timely, clear, and consistent manner. We hope to engage in a rich dialogue with you on this topic through a series of moderated panel discussions, open public sessions, and questions using the tool Mentimeter, which you'll hear more about in a few moments. We want to receive as much feedback as we can during the meeting.

However, today is not your only opportunity to provide feedback to us. We've opened a public docket for today's meeting topics on regulations.gov, which will be open until January 19th, 2021.

On behalf of CDRH, I thank all of you for your contributions as we strive to improve the FDA's communications about medical device safety. And now I'll turn it over to Dayle Cristinzio, our moderator for today's meeting. Thank you.

MS. CRISTINZIO: Thank you, Jeff, for setting the tone for our discussion today.

For our agenda today, we have four public sessions. During each public session we have members of the public slated to speak for 2 minutes each, followed by a moderated panel discussion. We will have a brief 5-minute stretch break between Public Sessions 2 and 3.

As Jeff mentioned, we provided a pre-meeting video in advance to help set the table for our discussion today. A link to the video was included in the announcement and registration page, and I encourage all of you to watch this video after we conclude, if you

haven't already seen it.

During this unprecedented time, we made the decision to hold this public hearing virtually, after it was originally planned to take place in April of this year. While we wish we could all be in a room together for this important conversation, we have worked hard to ensure our stakeholders' voices are heard today.

During today's meeting, we will be using a survey tool called Mentimeter to enable us to see real-time responses from our audience to questions related to our discussions. These questions will be asked throughout the meeting and will appear on your screen. To participate in this real-time feedback collection, you will need to use an internet browser on your computer, phone, or tablet and go to www.menti.com, and that's spelled m-e-n-t-i. We will display a code for you to enter before you can begin. But I encourage you to take the time to respond to all the questions as they appear throughout the meeting.

I have a few more housekeeping announcements before we start with introductions. We have a limited time for our discussion today, but a lot of important topics to discuss. I ask that all members of the public who are registered to speak to be mindful of your 2-minute time limit so we have adequate time for discussion. I will give you a friendly reminder as you near the end of your time.

I also want to remind everyone that the purpose of today's meeting is to discuss the development, content, and format of the FDA's communications about the safety of medical devices. It is not intended to inform the criteria for when the FDA would issue a communication.

The goal of this meeting is to share the FDA's current practices for medical device safety communications and to hear from our stakeholders, including patients and caregivers, healthcare providers, medical device industry, and media about ways to improve our safety communications to ensure our stakeholders receive the information they need in

a timely, clear, and consistent manner.

And finally, I want to encourage everyone to submit written comments on this topic to the docket. The docket can be found at www.regulations.gov and it is number FDA-2020-0096. The link to the docket is also on the registration page for this meeting on the FDA's website. The docket is open until January 19th, 2021.

And now I would like to turn to our panel to do brief introductions. I will call on each of you to introduce yourselves. Representing regulated medical device industry, we have three panelists. First is Diane Wurzburger.

Diane.

MS. WURZBURGER: Good afternoon, Diane Wurzburger. I'm the Executive for Regulatory Affairs from GE Healthcare, and today I'm representing the Medical Imaging and Technology Alliance. Thank you.

MS. CRISTINZIO: Thank you, Diane.

Next we have Mark Leahey.

MR. LEAHY: Good afternoon, Mark Leahy. I'm president and CEO of the Medical Device Manufacturers Association. We represent nearly 300 primarily small to midsized medical technology companies, and I look forward to the discussion today.

MS. CRISTINZIO: Thank you, Mark.

Next we have Danelle Miller.

MS. MILLER: Hi, my name is Danelle Miller. I'm the Vice President of Global Regulatory Policy and Intelligence for Roche Diagnostics, and I'm representing AdvaMed today.

MS. CRISTINZIO: Welcome, Danelle.

Next we have three representatives from the hospitals and healthcare professionals segment. First we have Barb McCarthy.

MS. McCARTHY: Hi, good afternoon. My name is Barbara McCarthy and I am the enterprise risk officer at Beverly Hospital in Massachusetts, and I am representing the risk managers nationally. I am the president elect of the American Society for Healthcare Risk Management. Thank you.

MS. CRISTINZIO: Thank you, Barb.

Next is Bobbi Jo Hurst.

(No response.)

MS. CRISTINZIO: Bobbi Jo, you might be having some problems hearing. We'll come back to you in a moment.

Next I'd like to call on Kathleen Blake.

DR. BLAKE: Yes, good afternoon. I'm Dr. Kathleen Blake. I am Vice President for Healthcare Quality at the American Medical Association.

MS. CRISTINZIO: Thanks.

Any chance, Bobbi Jo, you're able to speak yet?

(No response.)

MS. CRISTINZIO: Okay, we'll come back to you in a moment.

Okay. Next, representing patients and caregivers, we have Brian Herrick.

MR. HERRICK: Good afternoon, my name is Brian Herrick. I work for JDRF in research communications, but I'm here speaking on behalf of the Type 1 diabetes community.

MS. CRISTINZIO: Welcome, Brian.

Next we have Scherika Perry.

MS. PERRY: Good afternoon. I'm Scherika Perry and I'm actually a parent of a patient who had multiple medical devices.

MS. CRISTINZIO: Thank you.

And next we have Danielle Dass.

MS. DASS: Hi, good afternoon. My name is Danielle Dass, I'm here on behalf of the International Foundation for Autoimmune & Autoinflammatory Arthritis, and I'll be speaking on behalf of patients, especially those living with chronic illness.

MS. CRISTINZIO: Thanks for joining us.

Next we have, representing the media, Danny Al-Faruque.

MR. AL-FARUQUE: Good afternoon. My name is Ferdous Al-Faruque, I go by Danny. I'm a senior reporter at Medtech Insight, and we typically report for the medical device industry and other stakeholders in that arena.

MS. CRISTINZIO: Thank you.

And we also have Kris Pickel.

MS. PICKEL: Hi, everyone, I'm Kris Pickel. I'm an investigative reporter with CBS Live in Phoenix, Arizona, and I have investigated a number of medical devices that are regulated by the FDA.

MS. CRISTINZIO: Thank you, Kris.

Finally, we have another category. Representing risk communication science, we have Cynthia Baur.

DR. BAUR: Hello, I'm Dr. Cynthia Baur. I'm the director of the Center for Health Literacy in the School of Public Health at the University of Maryland in College Park, Maryland, and I'm here speaking about health literacy and risk communication.

MS. CRISTINZIO: Thank you so much for joining us. And representing the FDA's Center for Devices and Radiological Health, we have two panelists. First is Alicia Witters.

MS. WITTERS: Good afternoon. My name is Alicia Witters and I'm the director of the Division of Communications here at CDRH, and my team is responsible for developing and distributing many of CDRH's communications around the safety of medical devices, and

we're really looking forward to today's discussion.

MS. CRISTINZIO: Thank you, Alicia.

And finally, our last panelist is Ron Yustein.

DR. YUSTEIN: Good afternoon, my name is Ron Yustein and I'm the associate director for Post-Market Issues, Office of Device Evaluation and Quality in CDRH, and my team also heads up the Signal Management Program in CDRH.

MS. CRISTINZIO: Great, thank you. So that takes care of introductions.

Now I'd like to move us along into our moderated panel discussion. For this panel discussion we have 35 minutes set aside. We have six questions that we'd like the panelists to discuss, so quite an ambitious agenda, and I'd like to just kick things of by posing and reading the questions that we have listed, just as a reminder for everyone.

So the first is:

- How do you learn about any concerns the FDA may have regarding safety issues with your device?
- How do you prefer to receive information about the safety of medical devices?
- Where else can you go for information about the safety of medical devices?
- How often do you expect a follow-up communication from the FDA about the safety of a medical device?
- How would you want to be informed that an issue is resolved? And
- For how long should this type of information be available on the FDA's website?

So I'd like to open up our panel conversation and kick it off to our panelists.

MS. MILLER: I guess I'll go ahead and start. As an industry member, we learn both formal and informally from the FDA all kinds of information. It could be electronic with respect to websites, social media feeds, e-mails, a lot of e-mails, or direct communication between a manufacturer and FDA. We also hear through trade press and other public

media. And during the public health emergency, I think there's been a lot of different forms of communication that FDA has used which has been, I think, very effective. More formal communications we get, mainly the *Federal Register* is what we watch for. So that's just an idea of where we get our feed right now.

MS. HURST: Hi, this is Bobbi Jo Hurst. Can you hear me? We are from a healthcare facility and many healthcare facilities get their information from either ECRI or another type of organization that sends that information. We also receive a lot of our information from our vendors and then we look to that and then go to the FDA from there.

MS. PERRY: As a parent --

DR. BLAKE: This is --

MS. PERRY: Hello?

DR. BLAKE: Please go ahead.

MS. PERRY: Oh. As a parent, I guess the information on the devices that I get normally comes from the physicians. At the physicians, they normally give us the product inserts and then I generally do research on the Internet. I will go to the FDA website to see if there is any information on a particular device I get, but generally it comes from the physicians, actually, and the providers.

DR. BLAKE: So this is Kathy Blake and I might go next since I'm the physician who frequently does end up giving that information to patients and their families, and I would echo that I frequently would get information about implanted devices from the vendor; in my case, cardiac electrophysiology devices. And it would be the dreaded list and you would see them come to your office with a hundred patients that might need to be notified. Less often, it will come from the hospital. And then increasingly, I'm relying upon e-mail communications because I signed up for the CDRH daily news briefing.

MS. McCARTHY: Hi, this is Barb McCarthy. I'd like to sort of echo what other folks

have talked about in the healthcare community and I think it is multifaceted, and I think we probably could streamline some of it, but I also think that it is a combination of electronics, it's a combination of regular mail, that we're still getting some hazard alerts and recalls in the mail. We are reaching out to the medical staff when we're in healthcare institutions making sure they're getting the same things, Dr. Blake, that we're getting in the hospital, and making sure that we're covering all the avenues because multiple departments may have a single product or a single device, and making sure everyone across all sites and all departments are getting the same information really can be a task if it's not electronic. Thank you.

MS. CRISTINZIO: And I'd just like to butt in for one moment to let you all know that the first Menti question of the day is up and we'd love our audience to sign on and participate. Thank you.

MR. HERRICK: This is Brian Herrick, and I think there are two distinct categories here and the first of which is when I'm hearing about the safety of a device that I happen to have, in which case it's often you get a full-court press from the device manufacturer, I'm specifically referring to insulin pumps and glucose monitors, which is great because it has information because you have the system. But the other side of that is keyed into the approval process, so there's lots of new Type 1 diabetes devices that are in FDA waiting to be approved and waiting to hear on the safety and efficacy of those devices and when that happens, I think the biggest class I hear from is a lot of the patient advocacy groups and the reporters that are most covering this specific field because they're the most keyed in to the FDA. They're often waiting for these decisions to come out and they're big amplifiers of these decisions when they happen.

MS. DASS: Yeah, I think to echo that, we see in our organization almost two groups of patients. We have patients that have really strong positive relationships with their

caregivers and they're getting most of their information from their physicians. We also have patients who really struggle to find a diagnosis or struggle to find an effective treatment plan and they may not have that strong positive relationship with their providers and they rely a lot on the media, a lot on social media, word of mouth, things like that and it's not -- you know, the information may be accurate or it may not be accurate.

DR. BAUR: So in our research we focus a lot on people with very low or limited health literacy, and so the first step in that is where people are finding information and research is pretty consistent, but there's a lot of people who are not active information seekers, so if they're exposed to this information at all, it would be in a pretty passive way. They're not going to be attending the print information, they're going to look for it to come to them orally, whether that's from a healthcare provider if they happen to be plugged into care, which a lot of people that we do research with, they're not necessarily plugged into a care system or even have health insurance at all. And they might be looking for something to come in the form of, particularly, video communication. That's what we often get asked for, is to provide things in audio or video format. But if it's in print information at all, it has to be extremely basic with just a few key points in it.

MS. DASS: I echo that. Oops, sorry. Go ahead.

MR. AL-FARUQUE: I going to just say to echo that, I mean, we look at all those sorts of information as well, but the three major sources of information for us tend to be e-mail alerts from the FDA, the FDA website itself, and sometimes we also get e-mails and press releases from the companies themselves, stating that they've had to issue a recall. So that will be our main choices.

MS. McCARTHY: This is Barb again. You know, I'd like to bring up one thing that we -- I don't think we've talked about yet and that is sort of the safety information as we're introducing new devices, and I think that there is user safety, there is sort of out-of-box

training, there is how we set equipment up, how we use that device, how we train folks to use that, all contributes to the safety of that device as intended by the manufacturer. And I think we spend a lot of time on that in the healthcare industry as well, to make sure that unintentionally we don't put patients at risk by not using the device as it was intended.

MS. CRISTINZIO: Okay, and I'll just remind you about the Menti questions, there is a new one that is appearing on the screen now.

DR. BLAKE: So this is Kathy, and I might just echo part of what Barb has just said, and I really think back to the principle of the rational dispersion of new technologies. And I think that there is a different approach that's needed when something is brand new and that as information comes out to the broader clinician community, we really do want to know what should we be looking for, because this information that you're disseminating comes from somewhere and the somewhere can be from the healthcare facility, from the medical practice, and the observations that "just don't make sense," you might not have seen the problem before but you know it doesn't make sense, and so knowing also how to share that information is really important.

MS. PICKEL: And I'd like to echo Danny's comment on where a lot of the media gets its information, from e-mails, from the manufacturers, from the FDA. And one of the questions that is asked on the agenda here is how long should the information be available when it comes out, and I would make the case that it should never be taken down when there are updates, because once you start looking at the patterns of problems with medical devices, you want to be able to go back and see when was the last update, what was included in that update. It's the same thing like when you put your labeling on products and the updates are added, we can go back and see at what point did different side effects start developing with the different products. So once an alert or an update goes up on the FDA website, I would say it would need to stay up there permanently. You can update it

and say this has been updated and put a new link to whatever the new update is, but I don't think the information should ever be taken down.

MS. WURZBURGER: From the manufacturer's perspective, to add on that point, I think it is important to have the information, have clear access to that, but it's as important to make sure that the actions that are taken are relevant to what's been updated. So I would just caution to make sure that we are making -- ensuring that there's access to that timely and current and updated information to all because ours, we're looking at the issues and investigating and refining our actions that are important for the public to take. It's just critical to keep that contemporary.

MS. MILLER: Yeah, I would ditto Diane in terms of making sure that the information that's out there is completely up to date and that it's accurate. And one of the things that I think we can look forward to, hopefully, is timely interaction between the Agency and the industry as you're developing the information. I know Jeff made the comment that he sees industry and FDA as partners in this and absolutely, we agree with that. I think the key here is to make sure that the communication with industry is early, timely, and direct, and so that there's that phone call when you're getting in that -- I think he mentioned there's a cross-functional group -- call the industry players who are affected and say what additional information do you have, because we often have information that may not be publicly available because we may already be looking at a trigger or a trend out there or something, if there is one. That way you make sure that the information that goes out is accurate when it goes out and then is updated as needed. So I think just to know direct and timely, that's the best way to, I think, express it.

MR. LEAHY: And just to build off what Diane and Danelle said about this need for collaboration and communication early on, I listened to the video primer prior to today's session and I noted that towards the end they talked about, you know, the whole process

they had and kind of as a footnote, it said CDRH "shortly before the communication will reach out to the industry." And again, I think the patient safety is first and foremost from everybody here and so if there are early observations, then that conversation needs to start immediately so that additional analysis can be done, as Danelle said, that there is understanding in totality that everybody, it's kind of all hands on deck so that you can filter out okay, this is something that doesn't elevate to where there's something that explains it versus those that okay, this requires additional effort and then again, before that communication goes out, obviously, having all stakeholders engaged will make sure that when it goes out, it's timely, it's accurate, and it's actionable.

MR. HERRICK: I really agree with all of that because I think about not just the folks that maybe are getting updated medical devices they happen to have, but the other stakeholders that are in the community that rely on different players in industry, both to bring them the news that is most important and it's from a voice that they trust, and it also helps them to make future health decisions about which products may go to the market having the totality of information, and I think that's a hugely important step when going public, is working with different industry partners, patient advocacy groups, to make sure that whatever the news is, if it's important, is spread as widely as possible.

MS. CRISTINZIO: And I just want to note that there's a new Menti question up for those in the audience. Thank you.

DR. BAUR: So I think a lot of the comments so far are coming from the perspective of people who are very plugged into a lot of information networks and I think that's great, I mean, that's really important, all of -- you know, that's how information flows. But there are a lot of people who are not plugged into those networks, into those channels, they might not be members of patient advocacy groups, they might not belong to lists or -- and I think what we know about the way media, mass media and social media work, is people are

in very narrow channels right now and people, they are in what people are calling information bubbles or -- you know, there's other terms for that.

So I think FDA just needs to be very aware of how narrow some people's information networks are and either think extremely broadly in terms of all of the mass and social media channels and how that information has to go out, or think really about a very wide variety of trusted sources because, you know, I think about some of the groups that we interact with. For example, in Baltimore City, you have to get down into the neighborhoods if you really want information diffusing there. So for example, it might have to come from a trusted person in order for it to be even credible information. So I think it really depends if you're looking at really what your model for information diffusion is and kind of the interplay between mass and social media channels and those interpersonal channels and some of these more formal structures that are represented here today.

MS. DASS: And it's also really important, I think, to consider that not everyone is getting, especially, their durable medical equipment from a manufacturer directly. You know, we have a lot of patients that are on limited financial means, they purchased them used or grandma gives it to them or something like that. They might not even know the make and model of the item that they have much less follow the safety information that's coming out until someone they know and trust in their close bubble comes and says hey, I see you're using a wheelchair, have you checked the recent information that came out or something like that.

DR. BLAKE: One of the areas that we've not touched on yet does also have to do with, basically, the availability or lack thereof, of broadband across the United States. Certainly, people on both coasts, it's less of an issue. I'm based in New Mexico and it's a huge problem, and so many individuals in our state have very, very limited access to broadband. We have 16, I think now, native American tribes and on some of the tribal

lands many individuals do not have electricity or telephones, much less running water.

And so being able to have multimodality communication vehicles. So yes, sometimes it may be printed material that is sent by mail. Other times it may be a communication of enduring material that a child, an adult child, for example, that the patient is able to look at and then be able to share with other family members. So I think that sessions like this are terrific and I'm really hoping that in the docket that you'll be collecting that you'll get those rural and really frontier types of comments and considerations.

MS. CRISTINZIO: Thank you for that, Kathleen, that's a really important comment. And I think it brings me back to our original questions. You know, where else can you go for information about the safety of medical devices? And the other thing that we've not really touched upon in this conversation yet is how often do you expect a follow-up communication from the FDA about safety of a medical device? And I thought I'd just refer to the panelists to see if they have anything further to say.

MS. PICKEL: I will say I'm finding, you know, a lot of times it's not even the follow-up that needs better communication, it's the initial warning. You had a warning that came out on Singulair in -- I believe it was March and granted, we're in a pandemic, but I've been talking to multiple doctors currently and say, about four out of five never heard the original labeling update that came out, the box warning. So it's before jumping to the follow-up, there's still a big problem with getting out these initial warnings and I know that's going to be more the problem and solution that'll be coming up in discussion number two. But when it comes to the follow-up, a lot of the doctors are not even getting -- and patients are not getting the original warning.

MR. LEAHY: And this is Mark. Again, I think certainly, I look forward to the discussion of how we can make the initial communications more broadly accessible. And on

the follow-up communication, I could just say, from many of the innovators' perspective -- and again, this goes back to having collaboration and a more informed conversation with all stakeholders, patients, physicians, innovators, regulators, prior to that first communication going out because I know, in many instances, the first safety communication goes out and actually is not actually correct, there are things that need to be corrected, and from my members' perspective, very often the correction never gets the attention. It's that initial communication that is cited frequently and if there are additional facts or information to better inform the public, those are usually not as widely disseminated. So again, I think that just reinforces the objective of trying to get it right the first time and then certainly, on follow-up conversations and communications, making sure that process continues.

MS. MILLER: Yeah. And I would add to what Mark said, is sometimes what happens is the manufacturer jumps on something and sends something out, particularly in a recall, send something out, it's already been announced, and then the Agency will do a press release or an additional communication and the question comes back to us, is this another one? And no, it's an additional communication with respect to the first one and there's tons of confusion. So it goes back to, again, I think what I said originally, and what Mark and Diane have echoed, which is let's talk about it the first time, let's all agree on it, let's get it out and get in the right channels. I'm hearing a lot of great information about information bubbles which I hadn't heard about previously. But I think getting it to the right place but making sure it's right the first time so that we can -- we don't really need that follow-up because we've got it out there and it's right and it's also -- you know, it's also in the right place.

DR. BAUR: I just wanted to comment also on that initial notification problem because I was reflecting on a medical device that I had in preparation for today and I thought even when I got it, I sat there for 30 minutes with a demonstration from the

technician and his question to me at the end was do you have any questions? Now, I do this for a living and I looked at him and I said I have no idea what you're expecting me to do with this device when I take it home. And he certainly didn't tell me that the FDA would ever be a source of information if I had a problem about this device, either that the FDA would be communicating with me or if FDA would communicate to the office and an office would communicate with me.

So I think there's just this initial problem about -- I mean, it would never have occurred to me, if I hadn't been on this panel, that I should've been looking to FDA for information about this medical device. And, you know, I consider myself a pretty informed person, so I feel like if I did not know that, there are a lot of other people who wouldn't know that. So I think this initial -- this notion that FDA initially has to deal with the issue of how do people even think about FDA as a source of information about this and if they even should, or should it be coming from whoever they get the device from. But then that goes back to the problem that was also raised. It may not be coming from a facility or healthcare provider, it may come from a friend or relative or something you buy off craigslist or whatever. So I think those are definitely some issues to think about because people may not even know that FDA is supposed to be communicating with them about these topics and if so, even what to expect.

MS. WURZBURGER: Yeah, I think that's an interesting point. Diane again.

From the manufacturers' perspective, I think that as a manufacturer, we have the responsibility to ensure that we are communicating that as a first line. But again, to what Danelle and Mark had shared, that early collaboration and partnership with FDA, because for these channels that we cannot reach through our own means as the manufacturer, there are broader ways that a communication can get out to the patients and the healthcare providers that need to have it and I think that, again, early collaboration and

early communication is key.

MS. CRISTINZIO: And I believe that there is a new Menti question up for the panel or sorry, for the participants. And I also believe Ron Yustein has something to ask.

DR. YUSTEIN: Yes, thank you. Can you hear me, Dayle?

(Off microphone response.)

DR. YUSTEIN: Great. So my question goes mostly to Danelle and Mark and industry. I hear what you're saying about the interactions early on. Can you describe what you would envision in a case where our safety signal is what we call a class signal? In other words, the issue goes across perhaps a dozen or 20 manufacturers, how would that interaction ahead of time look in your mind?

MS. MILLER: Well, I think I'll start and you guys add in. I think there's a couple things to do, is one, you guys have us practically on speed dial in some cases. So I'd say give us a call, pull us together, or another way to do it is to go through the industry associations. I mean, you know, I represent AdvaMed and we've got MITA and MDMA here, who can reach large numbers of device and IVD manufacturers. So whichever way is best, but frankly, I love the "pick up the phone and call us" because the sooner we can work with you, I think the better off everyone's going to be.

MR. LEAHY: Yeah, I would just add again, I think the -- certainly in those instances with the class effect, I think the trades are a great place to start and again, we have various working groups usually with already a concentration of particular companies in place. And then you may not be able to get all -- you know, we may cast 80% of the net, but I think it's better than just one or two. And again, I think, as we've heard here today and in talking to our members in preparation for this, no one wants -- you know, it's in everybody's best interest to engage in this very, very quickly with the regulators, with patient groups, with physicians. I mean, the sooner we all can kind of share information, then we can learn from

one another. You know, a company may have access to additional data that will help supplement what FDA has seen.

And so again, just the opportunity to kind of weave that fabric together with the relevant stakeholders is going to make sure that (1) it's a comprehensive analysis here and not just relying upon one segment. And then (2), as we've said multiple times and it's worth echoing, that the quality of that first communication is so important for so many reasons and that, I think, we recognize the limitations are stretched thin at FDA and, Ron, we appreciate all that you're doing all the time and particularly in the public health emergency, but I think there are ways here with a lot of folks who are committed to the same objectives here and if we can just, I think, plug in earlier and have a mechanism where that flow of information is near real time, I think that certainly will enhance the process for all.

DR. YUSTEIN: Thank you for your comments. I just wanted to clarify one thing. Many times, as part of the signal management process at FDA, we often and I would say probably the majority of times, certainly not a hundred percent of the times, we do reach out to the manufacturer that is impacted by the safety issue that we are evaluating and we do ask them for additional information, and we call that our informational request process. And the manufacturers are generally very good at getting us information back in a timely fashion, and we do consider that information as part of our evaluation and our decision-making processes in terms of what our actions are going to be. There certainly are times where time may not permit that to happen or, in the case of a very large class signal, we obviously can't reach out to 20 or 30 manufacturers efficiently, but we generally do do that on a regular basis.

MR. LEAHY: No, certainly. And we appreciate that. And some of the feedback we had from our companies, too, they're -- and again, just providing a couple of examples where maybe there's early communication about a potential signal and again, the company

is very transparent, a lot of interaction over the course of maybe weeks or months and then no interaction for months and months and then they get a call saying in two hours a safety communication is going out and in many -- in some instances, I should say, that communication goes out and if FDA had simply gone back to the company and shared, this is what we found from other stakeholders, do you have any final -- additional information, it would've provided additional context.

So again, this is -- you know, there's no perfect art here. I think there's an opportunity here for -- and if there's a more regular communication throughout, I think that's just going to make sure that, again, you have all the information and it's not all going to come from our members, it's going to come from the physicians, the patients. So just that, start to finish, having a feedback loop, I think, would hopefully assist you and the team in making sure we get it right.

DR. YUSTEIN: Yes. Thank you, Mark, I appreciate that feedback.

DR. BLAKE: This is Kathy, and a couple of things that have not yet been raised. So we're talking about safety issues, but we've not really touched upon how often do we want to be able to get updated. And I would say, for example, very important to find out if there are particular subcategories or subsets of individuals with devices, big people, little people, you know, various categories, to be able to understand who we should be monitoring most closely.

We've not touched, either, on the fact that sometimes there are people who are super responders who do particularly well with their device. That is helpful information if I am trying to decide which device an individual will have. And then a more subtle communication that I've not seen done very often is the communication that says we're dealing with a safety signal or we're dealing with an issue. So if you have the option of postponing, for example, the implantation of a device so that perhaps only your people who

need it on an urgent basis receive it and then others who kind of wait for the dust to settle, that kind of nuance can be very helpful.

MR. AL-FARUQUE: I think, you know, when you're asking the question like when do we expect information on a safety communication, usually the way I look at it is has something changed with the safety profile of that product. So just to give you an example, in the past, sometimes FDA will say hey, we've got a problem with cybersecurity on a product and right now the best thing you can do is go talk to your physician about it and we are working with the manufacturer to try to come up with a patch. I would expect when FDA has developed a patch, the manufacturer has developed a patch, then we'd get another update saying hey, we've got a patch now to anybody who needs to patch the product, needs to come back and get that product patched. And this, of course, also applies to any sort of traditional product where if you find a solution to the product or let's say you -- or even if you find that the problem is larger than you initially anticipated, we definitely would want to know that so we can report it out.

MS. McCARTHY: You know, there are also recalls and alerts which would require us, as healthcare institutions, to pull product immediately and I think that there are nooks and crannies in every single healthcare location where folks horde, store, whatever you want to call it, and I think that those are probably the most problematic. How do we get all that product out of the pipeline? How do we know where it is, how it was distributed, how we get it back, how we account for it. So those recalled products over a course of multiple departments really can be problematic. I'm sure Bobbi Jo can attest to that, as well, as we try to sort of find everything and make sure we've got it all accounted for. And then finding an alternative for some things, as Dr. Baur could identify there, there are some things where this is the product that we have to use and how do we find an acceptable alternative for that on very short notice.

MS. HURST: Yeah, this is Bobbi Jo. We do have that problem and we do have to have a systematic approach to be able to find all of that information and where it's being housed. We also know with some of the recalls and alerts, some of our nursing staff or other staff would get them, as well as our materials management who handles all the recalls. So it does cause an alarm because the materials, it depends on the lot number. So many of the recalls are not for every product in that line, but just for specific lots.

So going back, you know, the manufacturer is telling us what lot numbers are being recalled. I don't know that the FDA has all of that specific information sometimes in their -- when they put out notices, but that is also important because then everybody would have that same information to look what lot number is it, what specific device is it, so it would just be more clear. But you do need a good process to go back and find everything.

MR. HERRICK: And I think that really highlights the importance of the manufacturer's role in all of this, because when you hear, you know, your device, certain lot numbers are expired or not working or are dysfunctional, your most important thing is knowing what those next steps are. So if you have a device where you have a box of something and the next -- that box isn't -- you get a replacement for it, it's really helpful when you're hearing from the manufacturer saying please don't use this, here are Steps X, Y, and Z you can take to remedy the solution and we're here to work with you on it versus just hearing an announcement that some things are defective. So that device manufacturer side is incredibly important in ensuring that you don't need as many communications, you can kind of get it right the first time, you let people know what the problem is and what they have to do, and then that follow-up communication that everything is fine isn't really as important.

MR. LEAHY: I just want to go back to something that was said earlier though, too, about kind of maybe having some communication that if certain folks are higher risk than,

you know, kind of delineating the communication, I think -- and I know this isn't the focus but it is important to today's conversation, but I think that threshold question of an observation and then when it tracks to something that's actionable, because I think there have been instances where a single observation or article can create a real groundswell and then down the road, when there are more eyes and there's kind of more analysis done, there was no -- and so I think that's just part of this whole exercise here is recognizing, again, early observation and early collaboration, work through it because I don't think -- you know, there can be more harm to the public, too, if something goes out prematurely and that, in fact, could prevent folks from getting access to the care that need.

MS. WURZBURGER: Yeah, Mark, I'll echo that. I mean, I think what's important to understand, too, is that while the FDA has their cross-functional team internally working on the signal investigation, we too, on the manufacturer side, have our risk management process and when we're seeing these trends or spikes, we have a cross-functional team of clinical experts and engineering experts and quality and regulatory experts, etc., that are also looking at it. So again, the collaboration and getting it right the first time and having a more comprehensive view as to what's going on and what actions are to be taken, that consistency, I think, is really critical not to create confusion and perhaps actions that are not really going to solve the problem quickly.

DR. BAUR: Well, this is on a different theme, but I want to loop back to something that I believe it was Scherika said that when she does internet searches, right, she uses a search engine and looks for things. So I went to the safety communications page and took just the top notices there and did internet searches just to see what would come up and the CPAP safety, that did come up in the top results, but then when I looked for deep brain stimulator safety, I had to go halfway down the page, which we know a lot of consumers will not do when they're looking at search results. And then on the dental amalgam safety,

that was near the bottom of the page and since most consumers and patients are probably not going to use amalgam, they might use dental fillings or mercury fillings, those don't even show up in a search.

So I think that just FDA should be very mindful that people will do online searches for information and being mindful about where their safety communications are going to show up in those search results because otherwise, if you're not probably in the top three to five and if you're definitely not on the first page, people are not going to see your communications.

MS. PERRY: I'll echo that and say that, on a couple of times, I have frustrated my physicians with information that I received from the Internet that was not specific to the specific product that they were going to use on me. And so it did take a lot of time to drill down through the World Wide Web to figure out exactly what it was. So there is a lot of disinformation out there, as well, so I definitely will echo that. And it makes the patient and the parent more frustrated when we can't find it easily. And I'm sure that that goes back to the doctor. Dr. Blake, you know, I'm sure that it must frustrate you when we come in and we have all of this disinformation that's out there that's not from a credible source. But I also, as a parent, find the FDA website a little bit hard to navigate. Sometimes it seems a little overwhelming at times.

DR. BLAKE: I just have to say that it is far better to have someone bring in too much information and to share their concerns than to have that unexpressed or unaddressed. It really is a -- I think of it as a dyad or when it's a child who's care is involved, it's really the physician, the patient, and the parent or caregiver because everybody is getting information from different sources.

MS. CRISTINZIO: Thank you so much for this really great conversation. That concludes the end of our first session for our panel discussion and I wanted to move now to

hear from some of our public speakers. So first we have on the line Sammy Noumbissi. Sammy, your 2 minutes begins now. Thank you.

DR. NOUMBISSI: Okay, I'm going to go ahead and speak. Yes, I'm Dr. Sammy Noumbissi. I'm a dentist in Silver Spring, Maryland, and my area of expertise is dental implants and I've been doing dental implants for 23 years, most of it. About half of that time I've been doing implants that are made of titanium. And we have been seeing in the last decade or so, although there have been earlier reports, a lot of issues with dental implants.

And as I was listening to one of the panelists when I was on hold, there is a lot of -- it's very difficult to navigate the FDA's website to find out information about any implant, let alone dentists or patients aware of the facts that there is information available about the implant they're about to receive. So what this has caused is not only in the last 10, 15 years the number of implant systems and brands and manufacturers has exponentially grown, not only the amount of dental implants placed in patients has gone up, we're looking at around five to six million implants, five to five and a half million implants placed per year in the United States alone, okay, and we know the statistics show that we have about a hundred and twenty million Americans that are missing at least a tooth, 36 million Americans that don't have any teeth at all, and the implants are getting more, and more affordable; more people are getting them and the information about how these implants perform is very hard to access.

So I'm going to say something here that's probably going to edge a little bit out of this topic about labeling, we're probably going to have to have also the manufacturers have the information about their systems and the materials in their implants readily available. You just don't know how difficult it is for me, as a clinician, or let alone a patient, to get information about the content of an implant, which is a potential source of an adverse

event.

MS. CRISTINZIO: You're toward the end of your 2 minutes, thank you. Okay. Sorry about that, I wanted to go next to our next public speaker, which is Richard Perrin. Richard, you should be live.

MR. PERRIN: I appreciate the opportunity to make some comments today to the group, and my name is Richard Perrin with Active Innovations, and this is an extremely important topic to the nation's healthcare supply chain. I have had the privilege of working with leading manufacturers, distributors, and provider organizations on identifying best practices to enhance timely and efficient responses to medical device recalls. There are three things that I would ask of the participants in today's meeting to consider.

First, please encourage the use of the unique device identification (UDI), particularly the UDI-DI, device information and product information (UDI-PI), as essential information to be included in medical device recall communications to enhance safety. When the UDI rule was first issued, the value of managing recalls was specifically called out in the Paperwork Reduction Act review by OMB.

Second, please request that information submitted to the FDA/CDRH for recalls be submitted in a standardized electronic data format so that the information, when disseminated from the FDA to end users, can be interfaced and integrated electronically -- digitally, into their existing information systems. This will enable enhanced safety and efficiency of tracking recalled items and eliminate re-keying of data manually to prevent inadvertent errors in transcription.

Third, please add evaluation of cost and impact on providers and users, as well as manufacturers and distributors of medical device information for recalls, as part of the evaluation of enhanced regulations or future regulations to be promulgated.

These are my brief comments for today and I will work with my colleagues to provide

additional details on these comments to the docket by January 19th. Thank you for your efforts.

MS. CRISTINZIO: Thank you so much, Richard.

Next we have William Reynolds. William, you're live.

DR. REYNOLDS: Thank you. I'm Dr. Bill Reynolds, President of the American Optometric Association. Doctors of optometry prescribe a majority of contact lenses for patients in the United States. We know the value that these FDA-regulated medical devices can have on patients' lives. We also know that without appropriate care and oversight, patients can be harmed by inappropriate use of medical devices. Today we currently have doctors of optometry from across the country listening in to this important session. Our doctors are privileged to serve millions of Americans by providing high-quality health and vision care, and we appreciate the work that the FDA does to keep Americans safe. Getting accurate and reliable information to the public about medical device safety is a critical function of the FDA. The FDA has recently been given the challenging task of regulating the many medical mobile apps that have come to the market. We understand that the Agency works to apply its regulatory oversight to only those mobile apps and medical devices that could pose a risk to public safety.

Last year the FDA took action to prompt a voluntary recall from the online vision testing company named Visibly, formerly known as Opternative. For more than 3 years the AOA had raised concerns with the FDA with the online test, marketed by Visibly, could potentially pose serious health risks to the public and did not comply with federal law. There are now, however, similar products that have entered the market since the recall was issued and AOA has reported these companies to the FDA and is awaiting action. The AOA is calling upon the Agency to partner with doctors of optometry and to develop clear and specific information to the public about the risk involved in these type of apps.

Claiming to be able to renew a contact lens prescription outside of the established doctor-patient relationship gives patients a false sense of security that their eye health has been examined. Through an examination, a doctor of optometry is able to assess the health of the eyes, potentially identifying sight-threatening and maybe overall health-threatening diseases. Today, 25 states have patient protection laws in place to serve the doctor-patient relationship and ensure that these apps cannot undermine patient care. Attorney general offices in North Dakota and Georgia have issued patient warnings.

MS. CRISTINZIO: Thank you, you're a little over. Thank you so much, though. I'm sorry to cut you off. I just want to remind everyone that as you're trying to get through all of your comments, you're so welcome to submit any additional things to the docket.

Next we have Joan Melendez.

MS. MELENDEZ: Hi. Thank you for your time today. And hello, my name is Joan Melendez, I'm the president of Xcelrate UDI. I work with healthcare workers and medical device companies. I see the challenges resulting from the lack of a UDI and inability to communicate recalls by e-mail every day. This blocks timely, actionable medical device communication. My recommendation for the FDA is to amend Title 21, chapter I, subchapter H, part 810.4 and 810.15 to include e-mail and other electronic communication as a means to share medical device data.

Patient safety. The FDA must require the use of UDI and communication for recalls and adverse events and IFUs. Patient safety. The FDA must expand use of UDI to include biologics. The inclusive use of UDI and allowing -- health communication will result in timely access to medical device changes, recalls, and adverse events. As simple as a scan, think of that, as opposed to the weeks, if not months, currently seen in notifications of a recall. Patients are harmed.

Part of the challenge is -- in a federal registry that was first the approved form of

communication of recalls, to mailgrams, telegrams, and mail. This restriction adds unnecessary healthcare operational costs and negatively impacts our environment. More importantly, it significantly delays access to critical medical device data that healthcare providers need as a point of care. As a result, it is the patients who suffer. It is the patient that is injured. Patients put their trust in the FDA and their healthcare providers to do no harm and yet, due to limitations of how field notification and recalls can be communicated and the lack of UDI usage, faulty and life-threatening medical devices are implanted in and used on our patients every day. Thank you so much for your time.

MS. CRISTINZIO: Thank you so much, Joan.

And last from this segment we have Jeremy Elias. Jeremy.

MR. ELIAS: Good afternoon, everyone. Thank you for the time today. I appreciate the work the FDA and manufacturers do daily. My name is Jeremy Elias. To qualify why I'm talking today and for transparency, I'm speaking as a patient and an impacted caregiver first. A loved one in our family is no longer with us due to a recall of a defective pacemaker and the lack of a timely notification. As a result of this experience, I am the founder and CEO of a healthcare IT company, TrackMy Solutions. We offer a solution that's free to our patient population to track implantable devices for recall. We do this through a point-of-care integrated solution and issue an electronic implant ID card for the patient for ongoing monitoring based on UDI. We feel our service is vitally needed across the healthcare ecosystem to improve how patients are receiving recall and safety information from the FDA and device manufacturers to help prevent my family's experience. My discussion is not to promote our technology or company, rather to talk about the following gaps we see daily in this space.

Information received today does not go directly to the patients and in a tech-heavy world -- yet the proper processes need to be in place upstream. Today, a patient must

manually sign up or know which social media accounts to follow to receive alerts versus a federally mandated electronic implant ID card, for example, which would positively identify the exact implant within a patient and allow for positively identified alerts to be sent directly to a patient, which we hope to see enhanced regulation to require better tracking down to that patient level, and positive sent alerts.

Information that is received today is very hard to understand and it is not in patient speak. This reality forces a patient into panic mode whether or not the recall information is relevant to them. In reality, patients ignore the recall information, if they ever get it, and suffer health consequences, including at times death, because of never receiving the proper information. This leads to class action lawsuits like we've seen with large and leading manufacturers that are unfortunately contingent. Also, data within a recall announcement from the FDA does not have all required useful recall data elements, for example, the UDI or unique device identifier. All echo what Mr. Perrin and Joan Melendez noted, we must have a standard dataset when recalls take place. We support the need --

MS. CRISTINZIO: Thank you.

MR. ELIAS: -- for a federal guideline to require manufacturers to publish this set, and I request the FDA to review my comments and take action on areas of improvement. Together, we can do better and increase patient safety. Thank you.

MS. CRISTINZIO: Thank you so much, Jeremy.

Well, that concludes our first segment for Session 1 and now I'd like to move to our next moderated panel discussion. Also, I wanted to just take a minute, because she wasn't able to formally introduce herself, Bobbi Jo, I know her speaker is now working because I heard you speak, but you want to just briefly introduce yourself to the audience?

MS. HURST: Yes, I am Bobbi Jo Hurst. I'm a registered nurse and the manager of employee health and safety and I am also the community liaison for the Association of

Occupational Health Professionals in Healthcare.

MS. CRISTINZIO: Great. Thank you so much for being with us today, Bobbi Jo.

Okay, so that moves us into Moderated Panel Discussion Number 2. This is quite an ambitious agenda. As some of you may see, we have about 11 questions. I'm not actually going to read them all, I'm going to read some of the main topic discussions to get us started today and then I'm going to leave it up to our panelists to carry us through, and I might jump in from time to time if I'm seeing that they're leaving anything out.

So first, the three main topic discussions we have, really, the first one is, "Is information the FDA provides about the safety of medical devices understandable?"

The second is, "Does the FDA deliver the right information about the safety of medical devices?"

And the third is, "Can you describe a classification system you think would be most helpful in understanding the severity of safety issue?"

Thank you so much. Panelists.

MS. PICKEL: I can go ahead and kick us off on this one. I feel like sometimes the information that the FDA puts out, it is so vague and confusing, it's overwhelming, it's written in medical or technical terms, when your ultimate goal should be to get the information out in a way that is understandable to absolutely everyone. I know as a reporter, I get multiple e-mails a day, hundreds of e-mails, and you end up going through these e-mails and if the topic line doesn't jump out and grab you and tell you why it's important, you move on to the next e-mail pretty fast to see what's in it.

I want to give you an example of one of the e-mails put out by the FDA. This was a statement. You might say hey, this was a little different than our safety concerns that we put out, but it's actually an example of just the systemic problems that the FDA has in actually communicating their information.

So this is the actual headline of it, right here. Statement from FDA Principal Deputy Commissioner Amy Abernathy, M.D., Ph.D., and Jeff Shuren, M.D., J.D., Director of the FDA Center for Devices and Radiological Health, on FDA's new efforts to protect women's health and ensure the safety of breast implants. Looking at that, you have no idea what that is actually going to be covered in that release. So it could have said FDA takes steps to better understand the risk of cancer connected to breast implants. That was in the first two sentences. This is a four-page press release. Buried 130 lines down is the fact that it said -- let's see -- FDA will not ban textured implants based on a lack of science. That actually could have been another headline.

But there were other topics within this. Breast implants, this was the first time that the FDA actually acknowledged breast implant illness. That didn't even get its own paragraph, that was buried halfway down. It could have been headlines that could have said there was so much more information in there, it could have said the five warnings the FDA is considering to improve awareness about the risks of breast implants. There were so many things, there was too much information buried in this. This was more like a historical document on everything the FDA had done in the last couple years to get to this point, when that wasn't really important. What people needed to know is what are the risks and how could this affect me, and these were warnings that were being considered.

Another one which recently came out, FDA issued final guidance for certain labeling recommendations for breast implants. What it could have said is FDA recommends stronger warnings for the risks associated with breast implants, just very, very simple language. And one of the reasons this is so important is because it's this information that's going to get to people. I'll point out that this came out 8 weeks ago that the FDA was recommending stronger warnings on breast implants. None of the manufacturers have put the warning out there. So the information has to come from the FDA and it has to be

simple to understand.

Let me give you two really quick examples of really good information. Consumer update, the facts on tampons and how to use them safely. You're going to know exactly what the FDA is talking about when they're getting their information out for that. Another one was the FDA approves lotion for non-prescription use, this a great headline. These are very simple, those are two really good examples. But for the most part, a lot of the information that comes out from the FDA is very difficult to understand.

I've been a journalist for 30 years, there are a lot of times I have to have other people on the medical programs, I will call them and say can you interpret this information for me, because as a reporter I don't want to interpret the information, I want to know exactly what you guys are trying to get out and it just comes down to -- a lot of it -- of making the information much more simple.

MR. HERRICK: I had a similar experience but it's kind of in two parts. The first is being I think there's a really strong -- when you look at your approval language for one's new product and new -- again, I'm speaking through the Type 1 diabetes world primarily, but when there's a new product that's been FDA approved, you get a long press release and those are -- I think I agree with what Kris just said, it can be really hard to read and understand what the point is that we're trying to get at.

However, on the flip side of that, I find the recall communications to be extremely clear and I'm just pulling up one from this past February on the Medtronic pump, it was very -- Medtronic recalls MiniMed insulin pump for incorrect insulin dosing. Extremely clear. They say this is the most serious kind of recall. The sub-heads are recalled product, reason for the recall, who may be affected, then what to do. And that level of communication, just like the bullet points, what you need to know if you have to take action, how to do it, I think can absolutely be universal across every time there's a

communication that the FDA is putting out regardless of whether it's not a recall, which is something that has the utmost priority of being understood. I just find that level of communications are just -- it's so clear. You know, if it affects you, you know what you have to do and you know where you have to do it. And I just have found those to be very helpful, but on the flip side, approvals for new things can be much trickier to understand.

MS. DASS: I was really struck when watching the video to prepare for this session where they were talking about the intended audience of the safety messages and it was like patients, healthcare providers, manufacturers, and I was like wow, those are really different audiences and they're coming from very different levels of prior knowledge. And I'm not sure it's really a realistic goal to draft a memo that is going to be universally understood by all of those groups. I recognize that it would be a huge undertaking for the FDA to have sort of a patient safety communication and an industry safety communication, but I do question if that's necessary because the overwhelming majority of our patients are not going to be able to understand the safety communications. As Brian said, they get the recalls, that's pretty straightforward, do not use this, here's the name of the product, but anything more technical than that and they're really going to be relying on someone else to interpret that information for them, at which point you have to question what is the utility of it in the first place.

MS. HURST: This is Bobbi Jo.

I do agree with that because if you are making some decisions in the healthcare field, you need a lot of information, you need what information about what happened and it needs to be very particular about the type of device, and you can go after the people that have those devices or look at the devices so you don't utilize them. Whereas for the patients, I think they need it in a different type of language so that they do understand it and they know how to act. So I do agree, there's two communications that could be very

different.

MS. CRISTINZIO: I just want to interject really quickly and remind everyone there's a Menti question up and we hope you're responding.

MR. AL-FARUQUE: I just wanted to say I agree with both Kris and Brian, I think there are times when certain pieces of communication tend to bury the lead and you got to go -- as a reporter, you know, you're digging through the information to figure out is this something you actually need to spend time on to write about or is this something that you can skip for now and you have another story to cover. So yeah, it would be nice to have a little bit more emphasis on getting the nugget of the story higher up in those press releases, especially if they're press releases designed for the public.

And I agree with Brian. I'm often really happy about the way that FDA presents a lot of those recalled data because they are in bullet form so you get to the important pieces of information, which lot was recalled, when were they made, when did the recall take effect, all of that information. But there is also sometimes a little bit of ambiguity and I don't know if that is because of business information being protected or not, but there are times when they'll say because of a manufacturing error or something, and I want to know what that manufacturing error is because as a reporter, I'm looking for trends, I'm trying to figure out, let's say, you know, we saw a number of recalls in the past couple of months for catheters where the tips were faulty and they were either breaking off or falling off and I wanted to know like is there a plastic, you know, an issue with some sort of plastic that's being manufactured? Is there an issue with the process that was used, maybe it was a faulty process, because I think for manufacturers who are reading trade publications like ours, that's important information, they want to know what the other people did wrong so they don't make those same mistakes.

So I think, in terms of whatever you need to send out to the public to summarize,

yes, I think you could do a little bit better job of not burying the lead and I do think that in a lot of these recall alerts that if we could get a little more detail that would be great.

And another thing is I would love it if FDA made the inspectors or the folks who are working on that more available to the press so that we could talk to them and say hey, you know, give us a little bit of history about why this happened, that would be really, really helpful to us, as well, because we're not just looking at a recall, we're looking at trends.

MS. CRISTINZIO: I'll just pose one of my probing questions, which is really when should we provide the data and how much should we include? You know, if it's helpful to see that, we would love to know.

MS. PERRY: I think it's dual fold, as everyone said, you have different audiences; as Danielle said, you have different audiences. And what's funny to me is, as you guys were talking, I was just thinking, I got a recall for my Ford Fusion in the mail and it literally said steering wheel bolts not safe, bring to manufacturer, could cause crash. It came in the mail, it was from my manufacturer, it told me exactly what the issue was, it told me exactly what to do, I was clear, it's done. I drive my car down to Ford, I get it fixed, it's over. And I think that I don't need a lot more information than that. So as a patient, as a consumer, I don't need to know that 35 -- this happened to 35,000 cars; it's my car, I need to take it in to get it taken care of. Now, if I'm in trends or if I'm in, as -- I can't say your name and I apologize, Federos's (ph.) business, then okay, sure. But that should be something --

MR. AL-FARUQUE: Just call me Danny, it's okay.

MS. PERRY: Okay, Danny, thank you. Sorry about that.

Then have a separate area for that. But if we're talking about the general public and what we need to do it, needs to be simple, clear, and concise. And I can tell you that Ford does a great job. I know every recall that I ever needed to do with my car, it comes directly to my house, it's stated important, I open it up and I know what to do. End of story.

MS. MILLER: You know, I think there's two distinctions a little bit. One is the recall communication, and I think the other is what Danny and Kris were talking about, which is sort of a more broad communication, maybe emerging signal, maybe a number of other safety types of communications that may come out. When it's a recall, particularly a Class I recall, the manufacturer and FDA are working very closely together to make sure that the information is clear, it's concise, the recommendation is there, etc.

Danny, there may not be some information there that you really want because it might be proprietary processes or something like that, but generally, the manufacturer and the FDA are trying very hard to get that information out. I think you raise a really good point in terms of the distinction, though, between those that go to patients -- and Roche happens to make blood glucose monitoring systems as well as the lab systems that go into the big laboratories. So different, completely different types of audiences, so we've had to really think about how do we communicate to those audiences. When you have something that is more of an emerging signal, though, it sounds to me what would be helpful is if you can include things like how early is this information, what's the source of the data, is the evaluation ongoing, especially if it's an announcement that we're looking into whatever the product happens to be, you know, but is this an ongoing evaluation, when do we expect to say more.

And if there's a benefit-risk analysis that a physician should be doing with a patient because, let's face it, this is all -- in most cases, it's going to be a decision between a healthcare provider and their patient, and we all want to make sure that the right decision is made for that patient. So the more information that can be provided up front, particularly in a situation that is not as clear where you've got -- you don't have a recall but you've got an emerging signal, that you have that information available. So anyway, hopefully that would be helpful.

MS. CRISTINZIO: Great. And now there's a new Menti question up for everyone. One of the probing questions that hasn't really been addressed yet is really, do you think we need to describe what a device is or does when communicating about its safety? And I think that drills down a little bit into what Scherika was talking about, what she's getting from Ford. Do you think we need to actually spell it out in our communications?

MS. PICKEL: Absolutely. And I will give you an example that is not necessarily a safety device, but a recall the FDA had was on hand sanitizer and I think this goes in perfectly to different ways of informing people depending on what they are. Maybe something for the manufacturer, the distributor, the consumer, because there was just one press release that went into it and it had just charts and graphs of here's the name of the hand sanitizer, here's the lot, but what it didn't do was show me if my product was recalled. There were not the pictures, I know it's a lot more work, but it would be a much more effective way to show people what is being recalled and that is something you just have to make the information easy to understand, describing it, showing it, that is one way.

I jumped in on that, but what I wanted to go back to is when should you make concerns more known about a device, I would say as soon as possible. Earlier, well when the FDA dropped the fact that they had hid -- dropped all the data from six million problems of reports from manufacturers that were in the MAUDE system, that is where people go to -- where to go to report problems with medical devices. Over the years I have been told, as a reporter, to go there to look up any information on reports of problems with medical devices. What the FDA did not disclose was that manufacturers didn't have to put their reports of problems in that system. There were six million reports of various medical problems in that system that were not made public until Madris Tomes with medical --I'm sorry, her company is Device Events, she's a former FDA employee and she had to spend 40 million -- I'm sorry, $40,000 to develop the software to actually go through all the data that

was dropped.

And I bring this up because of the gentleman in the public comments who said he was looking for information on dental implants and there were -- let me see, there were more than two million reports of problems with the dental implants. The first problem was failure to integrate, basically. And I really still haven't seen any of the warnings from that data that came down.

So there are people -- there are a lot of warnings the FDA should be getting out there that at this point still aren't. Like, if you're looking into the safety of things, great, but we're hearing from that one person in particular that they're not being informed, they can't find the information and the FDA has this information, so it should already be coming out. And so when do you put the safety information, the warnings, out? It should be as soon as possible and put it out with new policies -- as needed. There is the gap.

MS. CRISTINZIO: There's a new Menti up before we move on. Go ahead.

MS. DASS: I think that with regard to identifying what the device is and what it does, it's critical, it's absolutely critical, and also identifying what demographic or community is likely to be affected by the product would be helpful, as well. You know, patients are only as informed as their providers tend to make them and when we go through the informed consent procedures, a lot of times the physicians are using very lay-term analogy and trying to make things very understandable and very approachable and they may not be using the actual device names.

I recently had a liver biopsy and when they went through the informed consent, they said, you know, we're going to put in a foam, we're going to put a gel in you, they never gave me the name of the actual device. When I was researching to prep for this panel, I discovered there was an FDA safety update on that specific device. But I would not have known -- had I seen that safety update prior to my biopsy, I would not have known that

that's what they were using because they didn't tell me the exact name.

So for the safety updates to be understandable by patients and to be useful, I think it needs to identify this is what this device is, this is what it does, also this is when you may have encountered it. Otherwise a lot of patients could, even if they saw them, which is a whole other hurdle, they may not realize that they're applicable to their situation.

MS. PERRY: Danielle, to your point, my daughter has had several different devices, she had a monolateral fixator which was in body. She's had a double hip replacement and two different materials for the hip replacements. So for the one, for the hip replacement, the doctor came in and he said this is going to be the manufacturer, this is what it is, and he gave me the manufacturer brochure, right, so I had that. For the other one, I got no information. So he was like she needs a fixator, we're going to drill in, we're going to put these screws in, we're going to do this, this is what the complications could be, blah-blah-blah, but the information about the device itself, I got no information on that. So when the FDA does or if they do send out a recall, I am a patient, I'm not prepared to do that, so I think that there is some work that needs to be done on the other side of this, in the profession itself, to help patients so that they will be knowledgeable when the FDA does send out something.

DR. BAUR: So I wanted to make a couple of comments. I think you're hearing from many different angles that people are asking the FDA to tackle what we call the nature of the risk, right? You've heard very clearly that people want to know who's affected, they'll probably want to know a little bit about why they're affected, and then certainly what are the implications, like what are they supposed to do. So I think those are sort of the three minimum criteria to address the nature of the risk, there's certainly other things depending on what the risk is.

But, you know, people have a really hard time figuring out how to respond if they

don't get some signals about the seriousness of it, right, because risk is on a spectrum, right, there are some super, super risky things in life and there are some things that have a little bit of risk to them and people make those judgments all the time. I mean, for 9 months we've been living in a world where people are running all of their personal risk assessments on a minute-by-minute basis and we're seeing what happens when you have a whole society doing that. So I think really understanding what the nature of the risk is related to different products and devices and procedures is really important and it's going to probably vary, the amount of detail is going to vary based on the device and the nature of the risk.

And the other thing is I'm sure many people in this meeting and listening in know that the FDA has to follow the Plain Writing Act. The Plain Writing Act requires all executive branch agencies to use plain language in their public communications. And so I think FDA already needs to meet that standard in terms of following plain language techniques. There are certainly additional things that they can do, I mean, there's a lot of research on numeracy and some of the challenges that people have in understanding data, and unfortunately one of the conclusions that many people have drawn is "don't include any data." But your question is actually very appropriate, people do need data. The question is how is that data presented, is the data actually answering useful questions for them, and assessing whether or not the data are helping them make the informed decisions.

So I think those are some of the things I would want FDA to consider when you're thinking about data. So I would not draw the conclusion that "for simplicity's sake don't include any data" because there's a lot of research that shows the data are important information for people, but it's really going to depend on the presentation and how it helps them understand what to do next.

MS. CRISTINZIO: And on that point, if we are providing data, would you want us to

have it in the safety communications or is it okay for us to provide a link to that for more information? What are your thoughts?

MS. PICKEL: It depends on the format you're putting the data in. If it's very understandable, it can go into the original communication or you can expand on it in a link and it all depends on how it's broken down and how understandable it is.

MR. LEAHY: And this is Mark.

I also think if the data is included that it's a comprehensive overview of all the data, not just simply one report, because the robustness of that, the methodology, all of these things matter. So that goes back to, again, I think as long as all the stakeholders are engaged early here, data transmitted absolutely makes sense but it has to be comprehensive, you can't just cherry pick one analysis and ignore the other body of evidence out there.

DR. BLAKE: But I'm also hearing something a little different than what I expected, but something that is, I think, very important which is I'm hearing that yes, the focus of this conversation is about safety issues that arise after individuals have received or been exposed to a device, but I'm also hearing that there is a need for plain English information before they receive the device so that it does go into part of the informed consent process. And as I think back on the many devices that I've implanted, the patient brochure or booklet comes in the package of the device, so by that time they have received it. So having some plain English information, a lot of which we use to develop ourselves in my practice, would perhaps allow people to really think it through before they make a decision to proceed.

MS. PERRY: I'd like to 100,000% quadruple -- there's no words that could get you to understand how important that concept is before, because speaking as a parent whose child was going through a bone marrow transplant, was in a lot of pain and agony, and if it's

not clear at that particular point in time, all I wanted was my kid to not be in pain. That's my personal thing, that's all I want. So you could tell me just about anything and I'd probably believe you if I was a little bit less naive. But simple is better, simple is better.

And then someone mentioned about having a link to more detailed information, I think that that's always the best idea, present the information clear, concise, bullet-pointed, this is what the information is for, and then if you want more information and you need to delve deeper, here's the link to go to that; that can be in the jargon that, you know, the medical professionals communicate in, because there is a big divide between how patients communicate and doctors communicate in the medical profession. I'm a pharmaceutical sales rep, as well, and I do find myself, even in my pharmaceutical sales rep role, talking over people, and I've had that comment come to me from multiple doctors, hey, you're just talking in a language that I just need you to bring it down to like -- to English, like every day, I don't have time to go to the thesaurus to look up what you're saying. So that's my comment on that.

DR. BAUR: And I'll just add that a lot of times projects that we work on out of the Center for Health Literacy, what we're asked to do is develop materials that clinicians can use to talk to patients, right, so I think that's also something to keep in mind, is there's an assumption that the clear communication is only for the patients or the caregivers and everybody else can deal with the technical information or the jargon. And you've heard from the media's perspective, you just heard an example of how clinicians are saying that's not true either, you know, they're pressed for time, they need to have a couple of really key pieces of information to relate to their patients. You know, their staff also needs very clear communication to be able to answer patient questions.

So I think there's this assumption that "just segment the clear communication off over here for this one audience" and everybody else can do that. So I would really

encourage you to think about clear communication techniques running across all the audiences, but then thinking about that layering technique to provide more detail or more technical information when it's needed.

MS. MILLER: Yeah, I mean I would agree with that, I think there are a couple of things there that that you said. I mean, I think when you're looking at the communication and how detailed it is, how like technical it is, for lack of a better word, we have some very sophisticated patients who want to know it all and so you provide that information but you provide it in a way that's understandable. And I think to Mark's earlier point, it needs to represent the full gamut. Even if it doesn't have all of the numbers, all the data, it needs to represent the gamut of the data.

I think another piece that you said earlier that I didn't want to get lost, because the communication really should reflect the severity of the safety issue, and so how you communicate, when you communicate and to whom you communicate in some parts really depends on how severe this communication is. Do you need to put a press release out on every potential, no, and FDA doesn't. But is there some criteria for when you communicate based on risk? That would make sense to me.

I think the other thing that -- to your point earlier, I think there was discussion on finding things on the website. Would it be easier to find if it's either based on risk or divided by patient communication versus healthcare provider communication or something like that? So that might be a helpful breakdown, as well.

MS. McCARTHY: And I want to go back to the original question which also was does the FDA need to include in these what the device is used for, and I would say yes and the reason is, is that a lot of the names of these devices are very marketing generated and they don't really tell you what the device does and the headline doesn't really say that. So to have something that says yes, okay, I get it, this device is used by interventional radiology

or it's used by the OR, it's used by cardiology, gives everybody in the healthcare sort of world a feeling for what that device is actually used for. Sometimes the name just doesn't -- it's not intuitive at all. So yes, we do need to know what the device is used for.

MR. AL-FARUQUE: I agree with what Barb just said, there are times when I'm reading a recall notice and it has all the medical lingo in there and I'm not a doctor, so I don't know how to interpret this. So I have to go back, do my research to figure out -- I mean, it's not that big of a deal, really, but I want to make sure I understand it and so I got to go back and do some research to figure out what the device does, what kind of conditions it treats, stuff like that. So the less medical jargon or even if you include medical jargon, to add like a layer of layman's terms, that would be very, very helpful, especially for reporters who don't have a medical background.

MS. CRISTINZIO: So I wanted to ask one more question that I don't think has been addressed yet in this session, and we've got about a little less than 10 minutes left before we are going to take a break. If the FDA cannot provide any recommended actions, would you still want us to communicate about the device's safety issue?

MR. AL-FARUQUE: Yeah, absolutely.

MS. McCARTHY: Yes.

MR. AL-FARUQUE: Yeah, I think that just knowing that is very helpful.

MS. PERRY: Knowing it gives you -- if the FDA can't make a recommendation, at least I know that there's something that is wrong and I need to go talk to my doctor or go and find someone who can make a recommendation that's specifically relevant to me. So absolutely.

MS. McCARTHY: You know, and that puts the whole healthcare community on alert for us to watch. You know, if you have a question mark in your head, then we're going to tell clinicians to also be on alert for signals and to please let us know if they find anything

that looks out of the ordinary.

MS. HURST: It is so important because then the clinicians can start making decisions looking for alternatives, seeing how they can keep their patients as safe as possible. So it needs to be sent out.

MS. DASS: But I do think any time a safety communication is issued it should be very clear, both to the person drafting it and to the audience reading it, what the actionable item is here, what you're supposed to do with this information. And so if the FDA is unable to issue a recommendation, it should say that. It should say if you are a patient impacted by this, please watch for adverse events or if you encounter any, report them to this person. I find that way too often safety information, whether it's coming from manufacturers or the FDA or whomever, will say discuss this with your physician. Well, some of my physicians have a 6-month wait for an appointment and there are a lot of patients that don't have regular access to a physician unless it is an absolute emergency because of financial reasons. So just have a chat with them to find out if you should take this seriously is not a useful recommendation.

DR. BLAKE: I have to say it's the communication has to come across in a way that says here's what we know and here's what we don't know. And I realize that that may create all kinds of other challenges for FDA and for manufacturers, but it then opens up the opportunity for people to report something if they observe it. It's sort of that, you know, see something/say something as opposed to wondering if maybe you're the only person or if it is due to something else. So we are talking about health literacy and about the fact that we are going to have to grapple with uncertainty that we don't have absolutely all the information the first time we communicate.

MS. PICKEL: Kathy, I think that's a really -- that's an important point. I want to give you one example of a safety communication. The FDA warned that gadolinium-based

contrast agents are retained in the body, that's the contrast in MRIs. But I went back and read the 400-page transcript from the panel looking at it and that came out -- the warning came out, but it didn't say what the possible side effects were to report to the doctors. It just said report anything to the FDA and talk to your doctor, but it didn't lay out what those potential side effects could be.

In the panel discussion that was had on gadolinium, people reported having severe speech ataxia, tremors, seizures, Parkinson-like symptoms, cerebral atrophy, but none of that was put out in the FDA warning of hey, where it was in the safety communication, none of that was put out of what the potential side effects were to look for. So it also comes from how things are phrased; you want it to be understandable but you don't want it to be so sanitized that people don't understand what they're looking for.

MS. CRISTINZIO: Thank you for that, Kris.

I want to just touch briefly on one last thing before we end this session because I don't think we've touched on it yet. The last question that I mentioned was "Can you describe a classification system you think would be most helpful in understanding the severity of a safety issue?" And would it be helpful to see a classification system such as a red/yellow/green or low/medium/high on messages about the risk of severity or urgency of a safety issue related to a medical device?

DR. BAUR: So I just want to comment on that quickly because we haven't uttered the phrase "risk perception," but that has to be part of this transcript and discussion, is because risk perception really varies and there's a lot of research that shows when you get into some of these interpretive schemes, there's a wide range of interpretation of some of these classification systems.

So I think that that's -- so there is some research that says you have to get back to what we've been talking about, you have to give people information in multiple formats. So

you could give it to them in the form of a number, a little bit of text, and then a visual, because people are going to key in on different types of information. So I would not rely on any one type of presentation to really address that range of risk perception. You're going to have to think about a scheme that allows for different types of presentation of similar types of information.

MR. HERRICK: I would also add to that, the way I've seen it currently that is you're defining whatever the -- you're defining what the level of the risk is anyway, you're saying this is the class which is the most serious. So I mean, you can add more things on that, but I feel you're going to have to define it like you do now, anyway. But along those lines, I think what is helpful is -- I'm just beating a dead horse here, but the more -- in regards to recalls, the more you can do to work with everyone in the community to help distribute the message because of the wide breadth of ways that people get their information, the different channels people are tuned in to, I think just could not be more important.

MS. CRISTINZIO: Great, thank you so much.

I'm sorry, we're at the very end and I know we probably could talk about this issue for quite some time, but I want to be mindful of the time. We have a number of public speakers set up to talk to us for 2 minutes each on the phone and I would like to go to our first one now. The first one is Phillip Drum.

Phillip, your 2 minutes begins now.

DR. DRUM: Thank you very much for having me. I'm a pharmacist/clinician and I have concern about the classification scheme being used currently. I'm referencing in the August 24th, 2020 -- the Medfusion syringe pump recall of over 46,000 pumps throughout the United States. This is used, as was clearly pointed out in the recall notice, in neonate pediatric patients, it's their workhorse pump, and it's also being used in anesthesia. And so currently there's a lack of a timeline for resolution of a Class I recall without recalling the

product from the market. Class I recalls, as designated, are the most significant type of recall and may cause serious injury and death. A pharmaceutical Class I recall results in withdrawing of the offending product from the market. Why is there a difference? And I'm looking for consistency here from the FDA for a Class I recall response between a device that delivers a dangerous pharmaceutical potentially in excess or under-dosing and a pharmaceutical product.

So my recommendation is that you set a timeline limit that if you're going to have a Class I recall, you set a time limit for this to be either rectified within a certain timeline, and I would say 6 months when we're talking a workhorse pump like this, or withdraw it from the market -- maybe having a lower-level classification for this recall, but it's very concerning and confusing to me. I'm currently -- you know, I would request that you have a March 1 deadline for this Medfusion recall. That gives them 8 months since they identified this in June. I think we really need to -- you know, if we're going to call it a Class I recall, let's act like it's a Class I recall. Thank you.

MS. CRISTINZIO: Great, thank you so much for that.

Our next caller is Gabriela Salas or Saylas (ph.). Sorry about that, Gabriela.

MS. SALAS: Yes, it's Salas. Thank you for the opportunity to provide oral comments. My name is Gabriela Salas and I am the health policy fellow at the National Women's Health Network, a nonprofit -- organization that has been bringing the voices of women to the FDA for 45 years. We are supported by our members and do not accept financial support from drug or device makers. I have no conflicts of interest to disclose.

When it comes to clinical trials of new drugs and medical devices, all too often it's still a man's world. For decades, most biomedical research focused on men, specifically white men, even though it's for medical devices intended for use by both men and women. The FDA has encouraged device makers to include women and people of color in clinical

trials, but without any consequences for failure to comply, progress has been slow. Women are now included in most trials of new drugs -- but they are less likely to be included in sufficient numbers -- and trials of medical devices and when they are included, the data can be difficult to navigate and information on how a medical device impacts women is not always accessible to patients. A critical part of communicating medical device safety information to patients is letting them know if those devices have been tested in people like them.

The network strongly urges the FDA to replicate the successful drug trial snapshots and publish a clinical trial snapshot for every FDA-cleared medical device. This will provide the necessary data and information needed for patients to make proper and informed decisions for their own health and safety in an accessible and absorbable manner. Thank you again for your consideration.

MS. CRISTINZIO: Great, thank you so much.

Our next is Nancy LeMaster. Nancy, you're live.

MS. LeMASTER: Thank you very much. I'm Nancy LeMaster and I'm speaking on behalf of the Association of Healthcare Resource and Materials Managers, known as AHRMM, learning UDI community. This is a collaborative that includes healthcare providers, manufacturers, distributors, software application providers, standards organizations, and the FDA, and we're really looking at ways to increase the adoption in the utilization of the unique device identifier.

And in order to make the safety information more understandable, I think one of the best examples was the Ford Fusion and the reason that that recall information could be transmitted so well was because of the use of the vehicle identification number, the VIN. We need to use the unique device identifier in the same way, that's what it was created for, and it needs to be included in all communications whether it's to the general public,

healthcare providers, and it must be included in all recall information from every single manufacturer.

In order to make this information then more usable, it's really important that all recall information be communicated in standardized electronic format so that that data can be actually queried by healthcare providers. Right now, providers need to be the ones that are working with the physicians and identifying patients who have had implantable devices that have been recalled and we need that information electronically, not in PDF forms. We also need it standardized so it's not different from every manufacturer and that the FDA requests are not different by regions.

So we think that if we use this information in a standardized format, it will be accurate, it will be actionable, and we would encourage the FDA to use its various databases to connect one to the other, to use something like the GUDID to auto-populate the manufacturers' recall submissions so we eliminate all of this re-keying in this manual information that is going back and we're finding great inaccuracies in information that's transcribed by the FDA from the manufacturer versus the original information the manufacturer sends out to the providers. Thank you for the opportunity.

MS. CRISTINZIO: Thank you, Maria. Oh, sorry. Sorry about that. Thank you, Nancy.

Next we have Maria Gmitro.

MS. GMITRO: Hi there, my name is Maria Gmitro and I'm an organic advocate. My involvement began when I was harmed by an FDA-approved medical device. I'm currently president of Breast Implant Safety Alliance and director of community outreach for TrackMy Solutions.

A quick example. When I started to have a bad reaction to a medical device, the doctor told me that the FDA said there was no connection. Since that time, we had a hearing on safety, a device recall, a new guidance document with a black box warning;

however, there's not been much done as to awareness. The FDA made a great video about breast implants, but who is actually seeing the video? The FDA is lacking in communication provided to patients and doctors. Patients are not even aware that they can report problems to the FDA. No doctor informed me and I had learned from support groups on social media.

Also, the recent Class I recall of breast implants which can cause serious injury or death is confusing to patients because the device went by several names and the UDI was not provided to patients. The manufacturers lost patients, patients lost implant ID cards, doctors retired, destroyed medical records, the patients are scared, and these are the patients we work with.

Now that I have been speaking out about medical device safety, people come to me for safety information when they should be coming to you. The average person has difficulty navigating MAUDE and finding information about specific devices. Today, many folks are getting information from social media. I checked the FDA social media accounts and there's very little engagement or sharing of info. I think the FDA needs to get this information prior to the patients getting the devices. We need more patient-speak, we need more use of their healthcare provider letters, use social media to reach diverse populations, utilize UDI, digital implant ID cards, recall alert system. Similar to the auto industry, communicate adverse event -- current adverse event data, promote adverse event reporting with MedWatch, and medical device advertisements should include risks to watch for.

Thank you for allowing me to speak and your consideration of my suggestions. I will follow up with written comments, and together we can do better. Thank you.

MS. CRISTINZIO: Thank you so much.

And last for this segment we have Jamee Cook.

MS. COOK: Hi, my name is Jamee Cook. I'm speaking on behalf of breast implant victim advocacy and breast implant lymphoma advocates. To focus on section two, the FDA safety alerts are not always clear or accessible, and the reader may not fully understand the next steps they need to take after that alert. In relation to breast implants, many of our patients rely on news media journalists and social media to get these alerts. Advocates may follow FDA e-mail alerts, but we do not believe that the general public does.

We consistently reference auto issues and the number of phone calls or letters that we get related to vehicles or airbags, yet a similar aggressive approach is not taken in relation to medical devices. The letter to healthcare providers about breast implant cancer was helpful in raising awareness, but how else can the FDA assure that the medical community is being notified of these safety concerns? As it currently stands, most of our patients are educating their doctors.

It would be helpful to include data in safety communications if the FDA data were up to date. Unfortunately, we know that the FDA site is not updated as frequently as it needs to be. Patients may not even understand why the FDA data is unreliable or outdated. When we look at adverse event reports through MAUDE or data on breast implants and breast implant cancer, we know that there are limitations to those reports and we know that real-world evidence does not match the FDA communication. A link to current data might offer a good solution if available and accurate.

If the FDA cannot provide any recommended actions, we do still believe communication about the safety issue is important. We would also agree with Kris Pickel that this information needs to remain accessible indefinitely. It should be up to the reader what to do with that information, but the FDA should be required to outsource that info to the public.

Thank you for the time to speak. Our groups will be submitting written statements

to the docket to expand our concerns.

MS. CRISTINZIO: Great, thank you so much, Jamee. And that's a really good reminder to everyone listening today that we do have the docket open until mid-January and we hope that everyone that has additional comments will submit to the docket.

At this point we are halfway through our program today and we have a scheduled 5-minute bio-break. I hope everyone stands up, gets some water, and we'll see you back here in about 5 minutes. Thank you so much.

(Off the record at 3:01 p.m.)

(On the record at 3:08 p.m.)

MS. CRISTINZIO: Welcome back to our public session. We will now begin Session 3, which is a moderated panel discussion. Hopefully everyone got a little stretch break. I'm going to kick us off by reading some of the questions to get our panelists' brains working, and here we go.

So what challenges do you face with the FDA's communications about the safety of medical devices? And there are some other probing questions under that such as with respect to internet access, with respect to language and translational services, accessibility, assistive technology, and 508 compliance and/or comprehension.

And then also, what are your recommendations to improve the FDA's communications about the safety of medical devices?

So panelists, let's kick it off.

MS. PERRY: Okay, so let's -- I guess the challenge would be complex jargon. So if a febrile is a fever, just make it easy so that patients don't have to use a thesaurus or other resources to just understand what the article is about. I think Kris made a very good point that when an article's title is so long and so complicated, the information is buried. So just bring and highlight the information up front that you want people to know about. Make it

clear, concise, and to the point.

MS. CRISTINZIO: Great, thanks.

And I'd also just like to remind everyone that we have Menti questions up again. They appear about every 2 minutes. I'm going to try not to jump in regularly. Thanks.

DR. BAUR: So in Session 1 there had been some comments about internet access, both broadband and then also mobile access through Wi-Fi, I think that is a really important consideration. But even when people do have that access -- so we do research on smartphone health applications and one of the things that we see is that even when people have smartphones and Wi-Fi access, there may not -- there might not be a lot of experience or a lot of understanding sort of how to use apps, for example, or to use their phones in particular ways to access different kinds of information. So I would say that internet access is definitely part of it, device access is definitely part of it, but I think it's also really understanding the usability issues related to smartphones because we just see that among some populations we work with, there's very limited understanding of how to use their smartphones, even.

DR. BLAKE: So I think this gets into the question of how bi-directional the communication is. And so when someone is admitted to the hospital, they are asked how do they prefer to receive information. So I think we can learn from other domains within healthcare how that information can be used proactively so that someone receives the information the first time in their preferred mode.

I'm also struck by this list of including translation and issues related to language, and I'm particularly struck because physician offices are required to have translation services available for all of their patients. The same is true for hospitals. And if you don't have a qualified translator on site, you typically engage with a remote provider. So the disconnect, if we think about the information going from FDA or from a manufacturer to a physician, I

then need to engage the translation service to be able to have it explained to the patient. So I think it merits consideration to have some of that translation already done for our patients.

MS. DASS: I think one of the most significant challenges in the chronic patient community in terms of getting this information is that it doesn't seem to be very targeted in its approach, it's sort of put out into the ether like "Okay, here. We've published it and hopefully you'll find it." And that's not really how patients get their information. If it's a story that affects a lot of people, we may read about it in the media and that's very effective.

But when you're looking at rare diseases especially, or devices that really only impact a small community, those stories are not necessarily going to get picked up by the media and so I'm looking then at things like social media, which is the next place that a lot of people get their information. And even if you follow the FDA, you're not necessarily going to be reading everything that comes out, going "Oh, wait. Does this apply to me? Oh, no. Okay. Does this one? Yes, so I'll read this one." Most patients, if they are really active in a patient community, are going to get their information from a Facebook group about their illness or they're following certain hashtags on Twitter that apply to their illness. And so the information, if you want to reach them, really needs to be targeted to that patient community that is impacted by the safety communication, not the whole patient community, because the overwhelming majority of them, it doesn't apply to them and so people are not really paying attention.

MR. HERRICK: And something else that I think is helpful to keep in mind is for a lot of folks with chronic illnesses, often they have a caretaker who's making their health decisions for them, but they may not often always be in the same place. Like, I'm thinking about when I went to college. If I had something -- something happened to one of my

devices, it would have gotten mailed to my parents, who didn't live where I was, and that that communication would have to get filtered along to me eventually and I would, depending on my mood, either regard it or ignore it as many 18-year-olds do.

So I think this just gets back to what we've been talking about so many times, which is just it needs to be in a diversity of channels when you're trying to communicate to people in a way that can be very easily understood, whether it's someone that may be taking care of someone for a disease that they don't have or if it's someone that is way in the weeds involved with these patient advocacy groups and is super involved.

MS. PICKEL: When it comes to improving communication, the whole thing is you have information and how do we get that information out to groups of people who aren't plugged in at all, who don't even know that they need this information? We've covered a lot of the "let's make the press releases more concise and the information to doctors" and all that trickling down to patients, but there's this large group of people out there who don't even know that they need this information, so how do you reach them? When I was looking at the list for all the panelists, the one thing that wasn't on here was marketing, how do you market this information that is the product of the FDA?

Now, I'm lucky enough to be related to Sandy Barger with Chief Outsiders, she's really great with marketing, and I went to her and said how do you get this information out there, what do you do, and she pointed out in a day in our daily lives we are bombarded with tens of thousands of messages every day, you have so many messages coming at you between social media advertisers, radio, television. And so the FDA has to find a way to get their information past all those things and make sure that people understand that they know that they need this information. And it's true, you have to be concise, that is a really big part of it.

But how we now relate information has changed so much, I do want to give you an

example. This was what the *Wall Street Journal* looked like in 2000, you see it's all text. That is not what communication is about now. This is what the *Wall Street Journal* looks like today. Pictures are a great way to reach people, they're going to get that visual. They say a picture is worth a thousand words. Well, then a video is worth a thousand pictures. You want to find ways to make the information as easy and as digestible as possible.

The FDA has access to a lot of things, you have the panels typically where people are in person and you have these just impassioned stories, and you could put out these 30-second videos, find ways; you see them all the time. When you're scrolling through social media they just start playing, and you put the warnings out instantly or the communications out instantly in the top of the video. You make it something where it goes viral for people, they're like "oh, I could use that information" and then they share it with other people.

And videos are really so important. I watched the video that the FDA sent us about how they have all of the social media channels and how they're using them. I've been doing investigations with the FDA since 2015, I've never once seen their Facebook page, I did not know that they have it. So being on social media doesn't mean that you're necessarily using it in the best possible way.

You need people with you, not just the public information officers who are really good at putting out some of this stuff, you need to find ways to reach the categories of people affected by your product or the product that you're talking about, the medical device. There are ways on Facebook to target people across the country. Say for breast implants, most likely to be used by to 18- to 60-year-olds, you can specifically target those warnings and sponsor these videos and put them out to target the people you need to reach the most. And also when it comes to the warning, the videos are really what's going to make it understandable and digestible. And why not have these videos made by the

FDA? You can do QR codes, put it out with the warning information, the written warning, so all people have to do is click on their phone, scan a QR code, it takes them to the video with the information that the FDA thinks is important. It takes out that middleman of say, a doctor who wants to use the device going -- playing down the side effects, going "well, these are the potential side effects, but don't worry about them." It would take you right to the actual warnings, a video that the patients can understand.

And one more thing, this is more specific for television. When it comes to a very specific warning that you want out there, something really important, make five phone calls to the different networks: CBS, ABC, NBC, Fox, CNN. Do the main networks, call and say "hey, this is important, pay attention to this." They will then put it out and it trickles down to the affiliates across the country. It's a little more effort, but if you want it to actually get out there if it's that important, you got to take those extra steps.

MR. HERRICK: And Kris, I don't disagree with anything you just said, but I think it is worth noting that the average user of Facebook is what, 40 years old? I think it's just different people and different audiences are in different places and I think that's something we've really learned at JDRF when we're trying to communicate things, whether it's about the Medtronic recall that I mentioned a few months ago on behalf of the community, it's not just Facebook, it's on Twitter, it's also on Instagram. I don't think we've delved into Tik Tok yet, but I could be wrong. It's e-mail groups to different organizations, it's working with our peer organizations to also amplify the message, it's just because people are just in so many different places and absorb their information so many different ways. It's not "spray and pray," but it's knowing that different things work for different people in different places.

MS. PICKEL: Oh, absolutely. There are so many different apps right now, you have to include them all: Twitter, Instagram, Tik Tok, and Parlor. They're all out there, there's

like 40 main social media apps that people are on and that's the thing, you have to figure out where people are. And it also doesn't rule out the just good old-fashioned paperwork with letters to people who don't have access to the Internet.

One of the problems is a lot of people don't even know what medical devices they have. They either have had them for so long or when they actually got the medical device it was not stressed of, keep this paperwork, this is important. That goes back to a lot of what we were talking about earlier, describing the medical device, what does it do, why is it important. If you have it, you have to find out what you have. And one thing that I've run into a lot in reporting is people don't know what their medical device is and because it was put in so long ago, the doctors no longer have those records, either. So you really have to get people more engaged and more active and for a lot of people, they don't even know how to find out what medical device they do have.

DR. BLAKE: So I'm going to chime in and maybe talk about the audience that I'm representing, which is the physician audience, because I think you've already got -- you've gotten a lot of ideas about how to reach laypeople, patients, families, caregivers. So I'm just going to share some of the research that we did as we were revising our educational programming at the AMA and we reached out to a variety of different organizations. We looked at what was being done in the marketplace, we did focus groups, we did surveys.

So what we found was that physicians, for sure, they don't go to conferences anymore or they go to fewer of them and certainly right now, not any. They want micro-learning opportunities and that, by micro, it might mean somewhere between 5 to 15 minutes and it could be a podcast, it could be a webinar that becomes enduring material, but it will be very focused. The second thing that we found is that physicians wanted to be able to tell the source of information what they were interested in so that I can put in that I'm interested in topics A, B, and C and so that gets fed to me on a regular basis and I can

adjust those interests and that I do not declare myself as an interested recipient for topics X, Y, and Z. So then in my field, it would have been cardiac electrical devices, probably some valves, some stents, a few other things that I would say I absolutely have to have this information. But if it is, let's say, gastric bypass, pretty unlikely that I would need directly to manage that information.

The other thing that I'll share is -- really, our premier publication is *JAMA*, the *Journal of the American Medical Association*, and we've done surveys about what do physicians like most about *JAMA*, the print version of *JAMA;* it is the last page, which is the patient page, and why is that? It's because that is a one-page synopsis frequently done in bullet points and also with some pictures. So you're then able to be, I would say, knowledgeable at a certain level so that you have something you can share if a patient asks. So I think also being able to say what am I hyper-interested in, what am I less interested in but I'd still like to know, and then what are the things that I don't need to know probably at all. So just some of what we've learned as we've revamped all of our educational products.

MS. McCARTHY: And if we take that one step further, as we're moving patients in and out of our healthcare system, one of the things we frequently ask folks along the way and especially at discharges is, do they understand what we're telling them. It's an important part of -- we give a lot of education. Sometimes that discharge packet is 17, 18, 20 pages long, but we really never ask do they understand what's in it. We're in a hurry to move people to the next level of care versus really having them understand what it means to be in that packet.

So anything that we can get as a healthcare industry that will help us communicate that well, that will put that at the top of the patient's list, have them recall it back to us, give us three steps if you understand it. What does this really mean, what is it really for, do you know when to call your doctor, when the next steps are. We can really help folks

understand whether people know it or they don't know it and need more information. So any of those helpful tips from the front end to the back end really help the caregiver with devices and products.

MS. CRISTINZIO: All right. So this is Dayle, I'd like to just chime in a bit. We haven't really talked a lot about the accessibility and the assistive technology aspect of our communications, and I'd love to hear a little bit more from you on that.

MR. AL-FARUQUE: So I think a couple of folks who have chimed in today, Richard Perrin and I think Joan Melendez, who both spoke in the public comment section, they emphasized the need for UDI and I think FDA also understands that and I think there's been some questions about how fast has FDA moved on it, some of the barriers it's faced, there's been questions about the different agencies and the lack of consistency between how they're issued from those agencies. But at the end of the day, like if the UDI system goes into effect, that only takes care of one part of FDA's vision, which is now we can trace and track where different devices are.

But there is no way beyond that really, that -- at least that I know of, where FDA can reach back to the people who have those devices. So people can change addresses throughout their lifetime, they can change physicians, they can change caretakers. So I think there has to be some sort of a database where when you get that device, that you have some sort of contact information. Typically, I would say things like cell phone numbers and e-mails are less likely to change. You know, you might still include primary caretaker information, you might still include physician information so that when there is a recall or if there is an issue, that you can reach back directly to the physician, caretaker, and patient themselves to say hey, there is an issue that you should be aware of. So I think maybe that's something that FDA and -- you know, I'm a reporter, I only observe. I'm not supposed to give opinions but, as a future patient, I would say that might be a way to get in

touch with people and say here's what you need to know about a device because Danielle earlier, when she was saying hey, you have to target your message to the population that actually cares about it, she's absolutely right because no one's going to sit there all day long and look for FDA recall notices unless that recall notice specifically applies to them.

DR. BLAKE: I might just add a comment. HL7, which does a lot of the standards work related to exchange of electronic information, is going through the process of developing a standard for, I think, exactly what was just described including use cases of somebody who moves, somebody who has multiple devices. So I would direct people's attention to that. It is an arduous process to develop the standard, but I think there's a great deal of interest in doing that.

MS. MILLER: Now, one of the things that I would point out, because I think we're focused a lot on implantables or that's what it sounds like, implantables and those that perhaps a physician and a patient are talking a lot, too, but you have -- I guess FDA has a broad breadth of types of devices that they have oversight. And so if you're thinking about, for example, those that are bought over the counter, very hard to track who has that device. You have those that, for example, with an in vitro diagnostic, I guarantee neither you nor your doctor knows what IVD was used because it's not on your diagnostic report and the UDI is probably not programmed into the electronic health record.

So I think that there is -- there's certain flexibility that I think FDA needs to have in terms of how they communicate. I think somebody talked earlier, and maybe it was Danielle, not only about multiple audiences but really multiple channels depending on the type of device, depending on who's the audience, depending on what's the risk; I mean, all of these various things, and those are decisions that I know FDA makes all the time, often in collaboration with us.

And I think that there's also a distinction between the type of communication.

Where it's a recall, it has got to be very clear "this is a recall." If it's an emerging signal, be clear "this is an emerging signal" so that there are distinctions that are made and so you're not only looking at who am I communicating to, what channel, what's the best pathway, but also what is that format that I'm going to use based on the risk and the type of communication that it might be.

MS. CRISTINZIO: Great. All right, so I want to bring it back to our main couple of topics because we only have 4 minutes left before we go to the public speakers. I do want to touch -- try and maybe rephrase my question again about assistive technology and accessibility and what challenges you think we may be having with FDA communications. You know, is it hard for screen readers, for example, to process some of our communication materials? Are there other accessibility issues that you are encountering? And I think that's something that we're sort of lacking in this conversation.

(No response.)

MS. CRISTINZIO: No?

DR. BAUR: Well, I'm not sure that you have people in this crowd where that's their specialty but also, I mean, again, federal agencies have certain requirements, accessibility requirements you have to meet. So if you've been getting complaints that the approaches you've been using are getting in the way, I mean, I'd be responsive to those complaints, and there's certainly a lot of organized groups that you could reach out to and have them -- you know, FDA does have the ability to do usability testing and with different groups that might be using those devices. So I mean, to me, that's the best way to answer that question, is to do the usability testing and see whether the methods you've currently got are meeting the accessibility and 508 requirements or not.

MS. CRISTINZIO: Okay, great.

DR. BLAKE: I might just add one brief comment, which is that we don't have that

perspective necessarily represented here. I know from clinical practice, our approach is because it's we have to solve a problem right here and now, is to figure out some kind of workaround and those are not always optimal.

MS. CRISTINZIO: Okay, got it.

DR. BAUR: Before you cut away, just to pick up on the marketing comment earlier, I mean, there's an opportunity potentially with point of sale for a lot of the over-the-counter things and so that's one topic that hasn't come up but could be considered by the FDA in terms of reaching people. I think it was Danelle who commented on the large number of over-the-counter products that people might be coming to on their own and I think it's really the thing about what are the opportunities at point of sale.

MS. CRISTINZIO: Yeah.

Okay, well, I think that we're almost at time right now and need to go to our public session, and I think we have five speakers lined up to continue this conversation. The first one is Robyn Towt and I believe she is on the line for us.

Robyn.

MS. TOWT: Hi. My name is Robyn Towt, I'm from Breast Implant Safety Alliance. And one thing that I haven't heard mentioned today is communicating with other government agencies such as CDC, NIH, and CMS to share important information about devices with each other. This will ensure that patients and healthcare providers have access to the most recent information and our government agencies should all be on the same page in regard to having this up-to-date information that might change the benefit-risk profile. It will also help in developing ICD codes to help capture data to study medical devices. An example would be the FDA's recent acknowledgment of the many risks, complications, autoimmune diseases, and cancers that are caused by breast implants. The FDA should communicate this information to other organizations so that healthcare

providers can properly monitor patients who have become sick. This applies to all medical devices. We would also recommend specific communication in a letter to healthcare providers that outlines the adverse events, systemic symptoms, and autoimmune issues that are associated with implanted devices. Many patients are being overlooked or misdiagnosed because their doctors in many different specialties aren't informed of this new information. The device manufacturer representatives are not informing doctors and therefore patients are not receiving the proper medical care.

As Sam stated earlier, in his experience as a dentist, many physicians are not even aware of the ingredients in the device that their patient is having the reaction to. Healthcare providers in all specialties need to have this knowledge to assist in making informed patient management decisions and we need accountability from the manufacturers as well as accurate labeling to definitively outline these risks.

I want to piggyback on what Kris Pickel mentioned about using public service announcement videos. This is a great way that the FDA and the implant manufacturers can relay information to not only medical providers but to the public, as well. Most healthcare specialties have societies and other member organizations that meet regularly at conferences and annual meetings. PSAs would be an effective way to implement communication with these groups. It's imperative that doctors of every specialty are aware of adverse effects that are associated with implanted devices so that we have proper data collection and surveillance of patients. As mentioned earlier, patients in rural populations do not have access to the information and they rely on their medical doctors to keep them informed.

By working collaboratively, that's our path to providing patients with the highest standard of care. Thanks for allowing me the opportunity to participate today.

MS. CRISTINZIO: Thank you, Robyn.

Our next speaker is Jason Elliott.

MR. ELLIOTT: Yes, thank you. Good afternoon. And I really appreciate the opportunity to offer feedback and comments today. My name is Jason Elliott and I represent Greenville County in the South Carolina House of Representatives and I was first elected in 2016.

I know the challenges that we all face in ensuring that the public is well informed of health risks. The FDA does great work, especially now as the COVID-19 pandemic continues to impact so many aspects of our lives. The FDA is asking great questions to determine with whom your Agency should engage before communicating about medical device safety.

In my role as a state rep, I'm well-served and better informed when I engage directly with my constituents and those individuals that are closest to an issue. Before I was elected, the South Carolina General Assembly passed the Eye Care Consumer Protection Act to promote medical device safety. This act specifically enacted guard rails and safety guidelines for the prescription of contact lenses, a regulated medical device. Our legislature recognized the need to hear from both doctors and patients in the development of this legislation. I urge the FDA to use this same approach and call upon your usual stakeholders that are involved in official advisory panels and to engage physicians who provide frontline care to patients receiving medical devices.

I also encourage the FDA to look at legislation passed in South Carolina and across the country, aimed at ensuring that the public is well informed concerning the safe use of prescribed medical devices such as contact lenses. Physician supervision of those devices is critical to their effectiveness and can't be circumvented.

Again, I thank you for this opportunity and look forward to assisting in any way I can on behalf of the public so the FDA continues its important work. Thanks so much.

MS. CRISTINZIO: Thank you so much, Jason.

Next up we have Madris Tomes.

MS. KINARD-TOMES: Hi, my name is Madris Kinard-Tomes and I'm the founder of Device Events. I previously worked for the FDA on UDI and adverse event reporting. I am not a harmed patient and I want to tell you why.

In March of 2014, my orthopedic surgeon suggested I get a shoulder replacement. I walked down the hall and talked to the adverse event report specialist and asked should I get this device and they told me to wait a few years. They said that they didn't recommend the device I mentioned and they specifically said they were receiving a lot of reports around these types of shoulders.

I left the FDA around that time. Three and a half years later that device was recalled. I had not gotten it. The FDA knew of the issues long before the recall took place and 3800 of these shoulders had to be recalled. The FDA needs to move faster on signals. The FDA needs to provide numbers and severity of adverse events when signals are found. Care providers and patients deserve to know the data so they can make informed decisions like I did.

If you try to search the adverse event database at the FDA, you'll only see 500 reports at a time. With over 10 million reports, this is simply not doable. Imagine if you also are trying to use a screen reader, that search would be insurmountable for you.

A year ago I had the opportunity to present at an FDA meeting on metals and devices. I spoke about titanium alloy dental implants because there have been 1.5 million serious injuries. Since then, more than 200,000 additional adverse events have arrived for more than 20 different brands. These are the second most reported device to the FDA, yet no safety communication has been made yet.

The FDA needs to push out data and not expect patients to know to look for it. Physicians and patients need to know the material content in their devices: Are they metal,

polymers, alloys? This should not be a trade secret. Any material implanted in the human body is no longer inert and therefore needs to be on the label and in UDI. Thanks so much for your time today.

MS. CRISTINZIO: Thank you so much.

Our next speaker is Bill Fertig. Bill.

MR. FERTIG: Hi. Good afternoon, this is Bill Fertig, Director of the Spinal Cord Injury Resource Center of the United Spinal Association, also the executive council as a delegate of the North American Spinal Cord Injury Consortium, and I've lived with paraplegia for the last 21 years from a motorcycle accident. I thank the FDA for this opportunity to present the SCI perspective today.

SCI, spinal cord injury, does not discriminate. Anyone in this audience can become paralyzed tomorrow due to a spinal cord injury from a car accident, fall, sports accident, or a spinal tumor. SCI affects a wide range of ages and socioeconomic status levels. Our SCI population is highly dependent upon medical devices from point of injury forward for daily mobility and personal care like catheters, pressure relief seating, Baclofen pumps, diaphragmatic pacing systems, DPS, and other assistive medical devices. Over 72% of recent survey respondents cited their continuing hunger for information from the FDA regarding medical devices in a clear layman-friendly reporting format.

Regarding device safety, the SCI community recommends the following: creating a layperson-friendly medical device reporting portal, possibly via phone app -- let's use the new technology that's available -- SCID social media platforms or through existing Better Business Bureau portals, especially for rural and underserved communities where that's their connection. Our advocacy groups, like United Spinal, the North American SCI Consortium, etc., can play a pivotal role to disseminate safety information to this population. We feel that FDA should embolden and enable the specific disease-specific

organizations to help disseminate the information and get it right out there quickly.

Due to information overloads, please concentrate on devices approved for secondary conditions such as osteoporosis, pressure source, spasticity, bladder and bowel dysfunction, and communicate this in a multilingual, accessible lay language and provide links to access more in-depth data for more information. Thank you.

MS. CRISTINZIO: Thank you, Bill.

Next up we have Sue Francis.

MS. FRANCIS: Sue Francis, public sector.

The public is looking for medical device accountability. Device identifiers and discharge packets are essential. Last fall, over five million Biolox delta femoral heads were recalled on one single event. I saw nothing about it on social media. Other recalls only listed generic titles like "medical device recalls" with no specific product name. Some recalls existed not even listing 510(k) pathways. The FDA should not be selectively omitting any information.

Packaging recalls and commingling of orthopedic products has been a long ongoing issue. Every recall is important if it's a device that impacts you. No matter what the medical literacy level of a patient is, each patient deserves a complete information packet and access to electronic records pertaining to all information for his or her implants. Social media giants have shown unprecedented censorship of information. Understandably, the FDA does not want to unnecessarily panic the public on recalls, yet it should be noted that patients can decide with their doctors what is and is not important about their implants. The FDA has listed Linkedin, Twitter, Flickr, Facebook, and Pinterest as their vehicles for targeting communications with specific audiences. Yet social media is a strategic marketing and sales tool. The FDA is building heavy reliance on social media communications; however, specific attention must be given to platforms which cannot be censored by big

tech, already demonstrating that it leans in unilateral ways. Big tech and big device companies undoubtedly favor their customers, the manufacturers. Alternative platforms such as patient portals, MyChart, and others could and should be used. Healthcare systems already have electronic patient-doctor interfaces. The FDA needs to step up and require implant registries and mandate adverse event filings. Notifications specific to implants placed in patients' bodies should be located inside electronic medical record portals. I urge a more planned communication through medical portals to address the big issue of silent recall of medical devices.

Thank you for your time today and your considerations in those matters.

MS. CRISTINZIO: Thank you so much, Sue Francis.

Now we are taking -- we're taking us to our final and fourth session where we have a moderated panel discussion followed again by a public session. And I will read the questions for everyone on the panel to get them going and starting now.

So the first question is:

- With whom should the FDA engage before communicating publicly about the safety of medical devices?
- Under what circumstances should the FDA engage stakeholders when communicating publicly about the safety of medical devices? And
- At what points should the FDA engage stakeholders when communicating publicly about the safety of medical devices?

So with that, I'll leave it to our panelists.

MR. LEAHY: Maybe I'll start off, and I said this, I think, in the first session but it's worth repeating and I think it probably fits more naturally in this section. You know, from our members' perspective, as I said, I think the sooner the better. This is in everyone's best interest to engage quickly, again, with the innovators, with patients, with physicians, with

FDA, and that should be an ongoing feedback loop to get that information assessed, better equip ourselves to have that communication be comprehensive.

I think two other points I'd like to make, try to make, and I think they all fit together. Again, Dr. Shuren started this off about -- and it's been referenced with other speakers as well -- again, the observations. If that tracks to kind of an emerging signal and again, I think in those instances, too, immediate and active engagement with the company is important because there are probably datasets that FDA has visibility on they can track across the landscape. There are probably datasets that the companies have, too, that help provide a more full picture; so again, with all that information.

And then assess again, not just a single observation or single study, we've seen this happen periodically where there's one study reported out and there's kind of hysteria out there, and then when you look at the totality, it turns out, in many instances, there was no "there" there. So again, you know, we just want to make sure that we have a comprehensive assessment here and that the patient is equipped with all the information.

And then finally, I think it's important that we have a conversation that if we evolve, there's enough information, safety engagement, safety communication goes out, what's the process and the timeline and the data threshold that if additional information comes to bear or if corrective actions are taken and the safety communication or the underlying issue is resolved, how does that get communicated out to the public in an effective and timely way, as well? So I think those are, I think, the three kind of legs of the stool here, that if we're having an enhanced communication process that enhances the public and the patient information all need to be addressed in a comprehensive way.

MS. HURST: This is Bobbi Jo.

I agree that everybody needs to be notified. I also think that the healthcare professionals need to have the information and need to have a lot of detailed information

so that they're prepared to speak to the public. The public needs to be made aware, but it's a cooperative effort than before between the healthcare provider and the patient so they can have a crucial conversation about the follow-up and the care following. So it is important that the manufacturers reach out, as well as FDA, so it's very understandable information and action that needs to be taken.

MS. PERRY: I echo that sentiment, I literally was going to say the same thing. The first person that the FDA should notify are the physicians themselves. They are the ones that we're going to turn to and call to. As soon as I get a notice, the first person I'm going to call is my doctor and if my doctor has no idea about this recall, then it questions the validity of it, it questions -- it puts into play like "okay, is this real, what should I do, is it nothing, what's going on," and it draws in to question the FDA's validity with it with patients. So definitely the doctor.

MR. HERRICK: And along those lines about trusting the validity of how you -- fact check is a wrong one, but verify that something is accurate, I think it's super important to bring in the patient advocacy groups, the few organizations that are out there that have these giant networks of people that are specific to these diseases because they're going to help you amplify your message, they're going to have a scientific staff on hand that's probably going to decode it and write their own bulleted-point e-mail communication or Facebook posts about what it means and it can't do anything but help. Especially when you're talking about recalls of medical devices, it just -- it affects a lot of people and the sooner you bring those folks into the tent, they can also help with their -- it can help with your communication strategy to make sure it's reaching all the people. We've touched on this many times, that people get their information in so many different ways and there's so many different problems and subsets of the population, it's just the more folks you engage in a way that can be confidential and needs to not be confidential, it's just really the way to

go, I think.

MS. MILLER: Yeah, I think to magnify that is that you really need to be communicating and building the communication with the impacted members of the healthcare ecosystem and that's going to include the patients, the healthcare providers, and the industry players, as well as FDA itself and often others, as well. And I mean, part of what the industry brings to the table in addition to the data, and you might be seeing data around the world, is the patient engagement. And we're engaging with our customers where it's patients or with our customers where it's healthcare providers or laboratorians or whatever it might be, and that's something that we can bring to the table, is how to communicate that.

And I think, again, there's a difference between a recall and an emerging signal and making clear when that difference is and making sure that the information is clear on that, if it's an emerging signal, that it is an emerging signal, we're continuing to evaluate or FDA is continuing to evaluate and that we'll get back with more information. So that, I think Scherika said it earlier, is if you're talking with your doctor, your doctor needs to know that this isn't a recall yet, this is something -- especially for something like an implantable, this isn't a recall, we're not going to take action yet, that gives you risks, as well. So let's talk about risk-benefit for the individual patient and the more information that you can provide all of those within the healthcare ecosystem, the more likely the patient's going to get what they need.

MS. CRISTINZIO: Great. And I see we do have new Menti questions up and participation has gone down, so I'm just giving one last plug, make sure you're going online.

DR. BLAKE: So as someone who got many, many, many of these notices, more than I would necessarily have expected or wanted, I would say one group to seriously communicate with early, because they have a huge network, is the affected medical

specialty societies. So going back to it might be the American College of Cardiology or the American College of Surgeons or different organizations whose members then are, quite frankly, fairly accustomed to getting almost daily updates on a variety of topics.

And I don't think it's been said previously, but what can help with those communications is to have a standard sort of frequently asked questions, you know, what should I do with this information right now; do I need to do X, Y, or Z; things that will then just sort of tell me how to act at that point in time. And then I'll get an update perhaps through my specialty society that says with this particular issue we have found that radiology studies don't need to be done every 3 months, you can do them every 6 months or every year, things like that. I call it kind of news you can use, real nuts and bolts practical stuff.

MS. McCARTHY: You know, I've also found that there's so much information coming across all of our desks that what we monitor and measure is what people also pay attention to. We monitor a lot of things, we publicize a lot of things. Do we ever say -- in our industry, do we ever say you know what, last year we had 10 food recalls, we had 15 device recalls, we pulled back 15 products, we had five that were Class I, we had four patients that were impacted, we still need to hear from you, make sure you're letting us know, there are reports we make to manufacturers and to FDA if things go wrong. I think that if more of us on the healthcare side would measure and monitor, it might help the industry, you know, all boats raise everyone at the same time and it just needs to get some air time, given all the noise that we're all talking about and everything else we measure.

MS. PICKEL: I do think that there needs to be an early signal, much earlier than what is happening with the various devices. With breast implants, the doctors said for years "oh, we keep hearing about it and there's nothing to it." There is something to it now, there is a box warning on these implants, but you couldn't find all the MDRs. You can't expect the

average person to be able to go look at what's on the FDA's website and says there's no proof of any of that. You should have a link or something to say this is the emerging trend we're seeing.

With gadolinium, the MRI contrast, there was enough for the FDA to hold a panel on the discussion of gadolinium and the problems that MRI contrast can cause and yet that information, you really can't find it as a possible emerging trend. And I talked to a neuroradiologist, actually an endocrinologist asked a neuroradiologist regarding is this safe, is it not, and their response was there's no proof what gadolinium does once it gets deposited.

But for people looking, could this be a problem? They don't have a place to go to find out what is the information the FDA hasn't put out. You have to have something. It's like all right, what should we be looking for? So yeah, it doesn't need to be a full-blown warning, but it can't be so difficult to find the information, you shouldn't expect the average person to know how to use MAUDE.

MS. WURZBURGER: Yeah. You know, I don't disagree with anything that everyone has said here just now on this panel. I think we all have a mutual goal of patient safety, ensuring patient safety in our communications, and that the information is there. More information is not necessarily better, but I think if we work collectively across the ecosystem to ensure that we are all contributing to what that information looks like and it's complemented through our various investigations and the analyses that we're doing, I think what we can put out there for the patients and for the providers can be as complete and accurate as possible and of course, timely is critical, as well.

DR. BAUR: I want to come back to people, though, who aren't plugged into any of these information ecosystems, though, and who might be buying these over-the-counter, others are coming into contact with these devices in other ways. And I think one option,

you know, you're still going to end up with a more informed consumer if you go through some of the organizations, the patient advocacy organizations, that's still going to be a more informed and engaged group than you probably would get just with a sample out of the public. But that can still give you some feedback, some initial feedback.

So to your questions about with whom and under what circumstances, again, I would just reiterate sooner rather than later and see if you can get some early feedback on draft materials. I know that there's sometimes some reluctance to let draft materials go because you're concerned about them getting -- you know, circulating widely and being misunderstood because they're not the final word.

But at some point that's a cost-benefit analysis that the FDA has to do as an agency, is the trade-offs that you're making in putting out information that people don't understand versus the risk of potentially asking for that feedback early and maybe the occasional early release of something. But I think there's also other opportunities to get feedback on your draft materials, I mean, it's a best practice. I know many FDA communications staff well, I know they know it's a best practice.

So I think it's getting the FDA leadership above and beyond the communication experts in-house to kind of also buy into this notion that you're going to have to have feedback on your materials, pilot test them, have some templates, know some of the key things, because you've heard repeatedly over the last few hours about how complicated and confusing and jargon-filled your information is, and the only way you're going to get better is to pilot test and correct and get feedback on it. You know, we can recommend all day long to get rid of the jargon, but you've got to engage with the people who are going to use the information to find out what that jargon is, why it's so technical, and what the level of information is. So I would just really encourage you to think concretely about how you can get sort of an early warning system going with the people who are supposed to use this

information, particularly in that space outside of the healthcare delivery system.

MS. CRISTINZIO: We have a few minutes left in our discussion and I just want to remind everyone that we still are running Menti questions online and we're still looking for feedback from our audience members.

Sorry. Carry on, panelists.

MS. DASS: With regard to the feedback, I also think it's really important to ask people, if they've looked at a sample or a draft, what they understood from it because one of the problems that we run into in trying to disseminate information with patients is when they believe they have understood it but they have not taken what we wanted them to get from it, or they've misunderstood it and now they're going to go and potentially even spread this misinformation, and that's a huge problem. So it can't just be did you understand the draft, it also needs to be tell me what you understood from the draft and let me make sure that that's what I was trying to convey to you.

MS. CRISTINZIO: Any other comments from the panelists?

MS. PICKEL: A really quick question for Scherika. How's your child?

MS. PERRY: What did you say?

MS. PICKEL: You said your child had a bone marrow transfusion.

MS. PERRY: Yeah, but she is completely cured, she had haploidentical experimental bone marrow transplantation for sickle cell and lupus and what's really interesting is that she was only one of four people throughout the United States at that particular point in time who was diagnosed to have both diseases concurrently and information was painful to get, but she's cured.

MS. PICKEL: Glad to hear that. And I think that highlights the importance of putting out information and just making sure everybody has access to it, but doing it in a way that doesn't scare people off from using things.

MS. PERRY: Yeah, that's right. Thanks for asking that, Kris.

MS. PICKEL: Thank you.

MS. PERRY: And that's why someone mentioned on this panel about diversity. You know, I was looking at the panel and thinking about it's very -- and getting diverse people involved. One of the callers talked about getting more diverse people in clinical studies and it is so very hard to do. It is very, very hard to do to get -- as an African American female talking to my family, black people don't want to participate in clinical trials or do these kind of things. So I find it very interesting, the caller who mentioned that.

MS. CRISTINZIO: Great. I just want to kind of go back to our initial conversation about sort of with whom should the FDA engage before communicating publicly about the safety of medical devices, and I think we heard pretty clearly that physicians and the medical professionals obviously are first on most people's minds. Are there others that disagree or want to add a comment to that?

MR. LEAHY: Just make sure that the innovators are part of that conversation, as well. Certainly, the clinicians are important. Certainly, the patient community groups are important, as well. But again, going back to the primer, the video, the fact that the current SOP that CDRH has is that "shortly before" the communication, the company is alerted and that seems far too late in the process and I think, again, we all collectively, as Diane said, have the patient interest paramount here. And so the sooner that innovators, physicians, and patients can get involved, it's critically important and I don't think anybody should be -- you know, should be contacted "shortly before." And again, I think there's a way to manage this through technology platforms like this and others where information can be shared and again, this is all to better inform FDA so that they can determine what that threshold is in which it warrants additional communication publicly and again, the key is once that goes out that it's well informed, it's comprehensive, and it's most useful for all that's receiving it.

MR. AL-FARUQUE: I would also make the selfish pitch, you know, I'm from a trade publication so I'm slightly different, but for people like Kris, if you're trying to get a message out to the wider public and you're not ready to put it out to the public, it's always a good idea to reach out to reporters and talk to them about it before you make it public so that we have a better understanding of what the issue is because oftentimes when you put out press releases about safety issues at the last minute, we're running on deadline, we're trying to figure out, you know, we've got to get the story out. So it helps us a little bit even if you want to embargo that information to have a conversation to figure out that we are understanding the information correctly and any sort of question that we might have unanswered gets resolved before the information goes public. So I just make that little selfish pitch.

MS. CRISTINZIO: Thanks for that. So we're wrapping up this last panel discussion and before we cut to our public session, I just thought I would give our panelists one last chance to make any other final remarks on this topic. Or just a closing remark for the whole of our conversation. It doesn't have to just be this.

MS. McCARTHY: Dayle, I have a comment. You know, I think that it's unusual for me, as a nurse and a risk manager, to be part of conversations within my healthcare institution regarding supplies and products and recalls and choices and some of those sorts of things, it's not a common place, and I think that it's a discipline within healthcare that I think is maybe underutilized and could help with a seat at the table for some of these conversations as well, whether it's working with Dr. Blake as a physician or whether it's working with the industry or our supply chain folks or even patients and patient and family groups, our PFAT (ph.) groups are really also helpful in some of these things. So I think it's another source for the industry to think about, as well.

MR. AL-FARUQUE: I'd actually like to ask the FDA a question. You know, we're

asking a lot of the FDA here, I think. Over this whole meeting there's been a lot of suggestions on how the communication process can be improved, but does FDA have enough resources? Do you guys struggle, especially considering that you're dealing with COVID and a lot of your resources had to be channeled in a different direction? And do you feel like you have enough congressional authority to go through with a lot of these requests? On those resources and authority, where do you guys feel you stand?

MS. WITTERS: So I can attempt to respond to that multifaceted question there, Danny. It's certainly a challenging time for everybody, particularly in the communication field. You called out some of those unique challenges that FDA is facing in particular. You know, bandwidth is always a challenge for us here, not just in the communications realm, but I would say across the Agency.

So it's definitely something that we have gotten a lot of support from our leadership around being able to fill those positions, both the communication boots on the ground within the centers, as well as our press office, our Office of External Affairs, which Dayle and her team work closely with us to help get those messages out. So again, I would say resources are often a challenge for the federal government, particularly in the communications realm when you're a regulatory agency.

But the Agency does recognize the value of communication and it's a big part of what we're doing here today, wanting to really get the feedback to make sure that we have the strongest system possible and that we're taking into account all of the various perspectives. And I'll take a moment to just thank you all for providing the perspectives today. The way that we have approached some of the resource challenges is putting together that network of partnerships across the Agency and across federal agencies, not just at FDA but also our partners at other agencies, as well. So again, I mentioned the Office of External Affairs and Dayle Cristinzio's group, in helping us get the word out.

And so we are this specialized network that really comes together around communicating about safety issues, but also new approvals and more positive messaging that keeps the patient in mind and we all have a different specialty to play. So I think, in putting together those resources we've been able to be fairly successful, but obviously room for improvement, which is part of why we're here today, a big part of why we're having this particular meeting and have opened up the docket because we certainly want to get as much feedback around these topics that we're discussing today as possible.

DR. YUSTEIN: And this is Ron Yustein. So I just wanted to go back to something that Dr. Shuren said in his opening remarks when he referred back to the 2018 Medical Device Safety Action Plan where we put out the goal that it was our intent to be the first in the world to find and act on safety signals. So this is communicating and acting on safety signals and of course, communication being a big part of that is certainly a prime focus of where we're heading as a center. So this is something that we're serious about and that we're going to put the right resources and time into.

DR. BLAKE: This is Kathy, and I might just have just a few closing comments. So number one, physicians and, I think, patients will continue to rely upon the FDA for this kind of information. We're not capable independently of evaluating each and every signal, in part because there is just so much that is coming before you. Secondly, I think there is the importance of intermediaries so that you achieve your communication goals, and we've mentioned a number of them, and I would say just continually assess them in terms of what the uptake is and if you find that there's no uptake on one, go find something else but don't get absolutely stuck maintaining multiple, multiple channels. The third part is to keep it simple, and I really go back to the phrase, you know, the frequently asked questions, the news I can use, you know, that's what I need right here and now. And so whenever you're communicating with me as a physician or my physician colleagues, think about the fact that

we will be likely the first person that a patient calls. And so, though you might be writing to me, include the "this is what you need to tell your patients" because then you've covered a lot of the interactions that are going to have to take place.

MS. CRISTINZIO: Great, thank you for your feedback, Kathleen.

MR. HERRICK: I have one thing to close, which is that, you know, we all have very similar goals here. I think we all want people to do better and communicating on different devices that are helping people do better is such a big part of that. The more that we can -- FDA can really acknowledge that it's a huge area in this complex ecosystem, but it's just one part of the system, and the more they can continue to engage and encourage collaboration with patient groups, all the folks on this call which represent a huge array of different players in this field, the more we can all work together to better get this news out; it's going to make things better for people who we're ultimately doing all this work for. And erring on the side of more communications, better communications, sharing more, I think, is always the way to go.

MS. PICKEL: And I would add, this was a great start to have a panel. The reach here is only so far throughout the communities. Journalism, our stories only make it so far and you might look at bringing in outside marketing that has no financial ties to any of the devices that are used, whether they're implantable or over the counter, and figure out a way to get the information to people who can use it, like professional marketers, and you really want to take out the financial incentive for any information to not make it out, just have somebody completely separate and figure out how to reach the general public who we're not tied to, the ones that are a little more disenfranchised from the constant source of information.

MS. HURST: And this is Bobbi Jo. I want to thank you for the opportunity to be part of this, it was a great discussion. And I want to thank the manufacturers who actually do

usually reach out to the hospitals prior to the FDA alerts that come out. And I do think that the risk assessment would be great, that we could have the degree of risk. Additionally, FDA can then monitor devices that also provide safety for our healthcare professionals. So not only are we looking at the patients because we want to keep them safe, but we also want to keep our healthcare professionals safe as they work very hard. So I have that take on it. So thank you. And the more information that you can provide for us and the safer you can keep all of us, the greater it is.

MS. CRISTINZIO: Great. Well, thank you for all of that really valuable feedback. I think this concludes our final moderated panel discussion and we still have our final public session left where we have five speakers signed up for 2-minute increments, as well, so stay tuned for that. I believe all of our callers are on the line and ready to go.

Our first speaker is Mark Estes. Mark.

DR. ESTES: Thank you very much. I appreciate the opportunity to address the FDA's Communication About the Safety of Medical Devices. And in the way of background, I'm a physician for pacemakers and devices, and I've had experience and wanted to really represent perhaps the patient's perspective here most vocally.

A fundamental principle, I think, that we all agree with is that patients are entitled to timely disclosure of product information. And having dealt with many pacemakers and defibrillator recalls over a 30-year career, the patient's perspective needs to include very clear, targeted, concise information with specific recommendations about how it affects them. Most patients want to hear from their physicians, most physicians want the information, but they also want to be able to give them the simple message, as Dr. Kathleen Blake says, they want simplicity which is, I think, a real virtue here. Simplicity is the ultimate sophistication and what the patients want is the signal, how does this affect me? What do people I trust, my healthcare providers, recommend for me?

So physicians get their information from multiple sources, obviously the FDA and from manufacturers but importantly, as also was mentioned, professional societies play a key role here. They serve to place the information in context and much like the advisory boards for the manufacturers, use the most sophisticated risk management decision-making tools to give recommendations to physicians who commonly are looking for guidance, not only to manufacturers and the FDA but professional societies, as well.

So my simple message is involve all stakeholders as soon as possible, focus on the patient communication. And I'd like to thank and commend the Agency for considering my comments and addressing ways in which we can all get it right for the patients with the right message at the right time, communicated by the right individual. Thank you.

MS. CRISTINZIO: Thank you so much, Mark.

Our next speaker is Laura Mauri.

DR. MAURI: Thank you. Thank you for the opportunity to speak. I'm Dr. Laura Mauri, I'm Senior Vice President and Chief Clinical and Regulatory officer for Medtronic.

Medtronic is a mission-driven company developing medical devices that's focused on alleviating pain, restoring health, and extending life and as such, patients have always been at the center of our mission. And like me, many of Medtronic's employees are also physicians or are researchers and scientists. As a physician, I know how important it is to have clear and reliable information to provide the best care for patients and we really want to thank the Agency for investing the time and attention to this topic, it's very important, and for reviewing its process openly. We share FDA's commitment.

And I think you're hearing that communicating information in a way that best supports patients, the healthcare practitioners, and hospital staff and that's also based on reliable scientific data provided in a clear and timely manner, that's one of the reasons that we support robust systems for monitoring our postmarket performance data for our devices

and in many cases, we compile clinical evidence related to safety and effectiveness in that setting. We encourage FDA to reach out to us whenever conducting these critical risk-benefit assessments of safety signals so that we can provide FDA with the most complete and current information, and to support scientific and medical discussions.

I think it's important to note that, as you've heard today, medical devices can be complex, they're designed often and manufactured by very specialized teams, and are often selected or implanted by physicians for patients who may have complex or multiple chronic medical problems. And by including input from experienced scientists and physicians who are involved in the design or the use or assessment of these products, it increases the opportunity for producing a response that's most helpful for patients.

FDA's noted that it's interested in continuing to engage stakeholders to better define the process for safety communications and we at Medtronic are prepared to support the Agency in this effort. We believe that getting this right is what's best for patients and we join FDA in the shared purpose. I want to thank you for the opportunity to participate in today's meeting and thank the panel for their very important discussion.

MS. CRISTINZIO: Thank you. Thank you, Laura.

Next we have Lori Grover.

DR. GROVER: Hi, good afternoon. I'm Dr. Lori Grover, I'm the co-director of the Center for Eye and Health Outcomes. I'm a doctor of optometry with a Ph.D. in health services research and policy from the Hopkins Bloomberg School of Public Health, and I value the FDA's willingness to examine the current processes and where stakeholders complain -- increased role in device safety messaging. I appreciate this time to share some of the first clinical research investigating the national landscape of eye-related apps and patient engagement with reported online eye tests used to generate contact lenses, which is a Class II and higher prescription with a focus on the patient perspective.

Peer-reviewed findings have been presented at two national conferences and we've systematically reviewed 34 different apps with an end-user focus on two apps that are heavily marketed by the device industry to the public. Our large cohort findings demonstrate a concerning lack of user ability, health literacy, and understanding of risks to health across all ages, specifically with apps supposedly delivering a safe and accurate Class II and higher med device prescription. These apps are marketed as standalone online vision tests with an end goal of a new contact lens prescription and there is no other parallel process for determining another new Class II or higher medical device prescription. None of the 34 apps followed a standard of care for evidence-based clinical guidelines.

Of the two apps investigated in depth, neither met the FDA's criteria for relatively harmless app or for software as a medical device. Throughout the study, one app continued to offer a contact lens under FDA recall. We found little scientific or analytical validity or reliability in the final medical device outcome. Our findings on patient understanding and use of the mobile health app was concerning, as well. Fifty-two percent of research subjects did not properly follow instructions. This included initial user errors to quantitative inaccuracies to questionable results in prescriptive medical device findings. Over 82% of users of either app demonstrated confusion during the app process. Additionally, the public does not leave these online engagements with confidence in their eye- and vision-related health decisions.

When assessing impacts relative to health literacy and safety, such as risk of corneal ulcers and other relatively potential vision-impairing outcomes, over 96% of patients indicated confidence in decision making following an in-person eye exam, but by sharp contrast only 36% of those using an online app indicated confidence in their decision making.

So when helping the FDA formulate more effective public health communications on

medical devices, we stand ready to assist in helping to make the landscape safer for the public. Thank you very much.

MS. CRISTINZIO: Thank you.

And our next caller is Danielle Valoras.

MS. VALORAS: Yes. Hi, my name is Danielle Valoras and I really truly appreciate this discussion. Thank you for allowing me to be a part of it. I'm a general practitioner as a physician assistant and I am frustrated with the lack of timely transparency and accountability, and frustrated with the lack of information on medical devices. If received, this information would be pertinent to the care of my clients.

For example, I have clients that will ask about specific surgeries and what risks there are associated. I can easily look those up. I can even look up the ratings on the different surgeons performing the implantable device surgeries. Oddly, I don't have easy access to a tool to look up which device has the lowest adverse event rate or failure rates associated with them. Why is there not a type of consumer report safety rating tool for the different implantable devices out there?

We do not have transparency and I do not see the FDA holding the manufacturers accountable. For example, the public should have ongoing information as to when a company has issues, whether emergent or recalled. It takes an unacceptable amount of time for the public and practitioners to be informed. It can be many years from the time the FDA is aware to the time issues are declared. During this time, this is a public safety risk. When a manufacturer breaches their conditional approval, they break their contract, they fail to represent and put forth a safe product. Why is there leeway on this? Why do they get the luxury of having their products on the market when they did not perform the appropriate task? For example, all breast implant manufacturers have failed to meet their conditional approval requirements and yet they are still allowed to sell. For this

implantable device, the history is quite controversial with a moratorium to a conditionally approved product coupled with a significant amount of real-world data and peer-reviewed papers and research to missing AE reports recently being found. All this compounds now by failure of all the companies, not just one but all of them, to meet FDA requirements.

How does the FDA not -- how does the FDA take these -- not take these off the market to keep the public safe? This is just one type of medical device and all the mandates and guidelines have failed to keep approximately 30% of those recipients safe. The least burdensome approach for the manufacturer at times means less safety for the patients. I urge you to rethink the transparency and timeliness of the inquiry and declarations. Thank you.

MS. CRISTINZIO: Thank you, Danielle.

Our last speaker for the day is Johndra Upton McNeely.

DR. McNEELY: Hey, good afternoon. Thanks for allowing me a few moments here. I'm Dr. Johndra McNeely, I'm a practicing doctor of optometry, I'm in South Carolina. I want to strongly encourage the FDA to engage directly with relevant physician organizations prior to communicating with the public about safety of medical devices. With regard to contact lenses, the FDA has provided clear and specific guidance to educate the public about considerations to ensure safe use of contact lenses and that type of messaging should continue.

As additional messaging and campaigns are developed by engaging with physician organizations, the FDA would be able to take advantage of our boots-on-the-ground experience from the physician organization's members to enhance messaging and ensure that communications are reflective of what is really occurring in physicians' practices. In the past few years there has been a tremendous increase in the number of new entrants to the contact lens market and we, as physicians, are thrilled when we have access to

additional high-quality new medical device advancements. However, what we have seen more recently has been too often new products that are using old and outdated medical device technology and are working to completely subvert the doctor-patient relationship by encouraging patients to use medical devices without any real physician oversight. Patients need to be warned about these types of direct-to-consumer approaches that we know have already led to adverse events, as is reflected in the FDA's MedWatch data.

In South Carolina we've taken great efforts to educate the public about considerations related to the use of online apps for generating prescriptions for medical devices. Online vision tests that are set up for just the purpose of generating a contact lens prescription and selling contact lenses are prohibited in the state. The American Optometric Association has developed information for the public concerns about this process for generating prescriptions for medical devices.

Other states also have similar laws in place to connect patients and educate the public about concerns with this type of process. We strongly believe that FDA should develop similar guidance and work with organizations like the American Optometric Association to educate and inform patients about concerns related to online vision testing. The FDA is clear that medical devices must be used under physician supervision. In my own practice, I would never prescribe contact lenses without ever having seen the patient and evaluated their eye health. Additionally, unlike these app-based vision tests, I would never solely rely on patient self-reporting of health conditions or their contact lens behaviors. As all physicians will tell you, there are very often occasions when -- I'm sorry.

MS. CRISTINZIO: That's great. Sorry, you're way over.

DR. McNEELY: Thank you so much.

MS. CRISTINZIO: I apologize for cutting you off. I do want to remind you and anyone else on the line that's listening that we do still have the docket open and if you have

additional comments or remarks that you want to make, we're happy to see them in our docket.

Thank you so much to all of our panelists and public speakers for engaging in a robust discussion about the development, content, and format of the FDA's Communications About the Safety of Medical Devices. We really appreciated hearing from you about ways to improve our safety communications to ensure our stakeholders receive the information they need in a timely, clear, and consistent manner.

And finally, I just want to remind everyone, as I said before, that our docket is open. It can be found at www.regulations.gov and is number FDA-2020-0096. The link to the docket is also on the registration page for this meeting and on FDA's website and it's open until January 19th, 2021.

I really enjoyed my time with everyone this afternoon and I really appreciate your interest in this topic. Thank you so much.

(Whereupon, at 4:31 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:

VIRTUAL PUBLIC MEETING - FDA'S COMMUNICATIONS ABOUT THE SAFETY OF MEDICAL DEVICES

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Via 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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