U.S. FOOD AND DRUG ADMINISTRATION

Public Meeting

Modernizing Recalls of FDA-Regulated Commodities

Listening Session

Hybrid Meeting

Friday, September 29, 2023

9:04 a.m. to 3:32 p.m.

Meeting Roster

Erik Mettler

FDA/ORA/OPOP

Stewart Watson

FDA/ORMO/OCPM

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Department of Agriculture & Consumer Services

Catherine Alinovi

Next Generation Pet Food Manufacturers

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Amy Barnett

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Stop Foodborne Illness

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Sekhar Chandra

SmartAddress, Inc.

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www.Recalls.fyi

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Align Technology, Inc.

Shannon Davila

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Jeanne Duckett

Avery Dennison

Monica Dudley-Weldon

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Robert Earl

Food Allergy Research & Education (FARE)

Anthony Flood

International Food Information Council

Donna Garren

American Frozen Food Institute

Steven Gendel

Gendel Food Safety LLC

Thomas Gremillion

Consumer Federation of America (Washington, DC)

Kert Gunasekaran

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Roger Hancock

Recall InfoLink

Karin Hoelzer

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Katy Jones

Trustwell/FoodLogiQ

Sharmeen Khan

OpsSmart Global

Madris Kinard

Device Events

Maria Lappin

Canna Consult You?

Justin Leistiko

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Steven Mandernach

Association of Food and Drug Officials (AFDO)

Stephanie Matthews

Johnson & Johnson MedTech

Julie McGill

Trustwell

Farida Mohamedshah

National Confectioners Association

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Joshua Oyster

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Adam Rapp

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Global Patient Advocacy Coalition

David Trosin

NSF

Danielle Valoras

NavWellRx

Roberta Wagner

International Dairy Foods Association

Gretchen Wall

International Fresh Produce Association

C O N T E N T S

P R O C E E D I N G S

(9:04 a.m.)

Opening - Stewart Watson

[Slide 1]

MR. WATSON: Good Morning. You all have passed the first test. You found your way to the Great Room. They did offer several good rooms, but we did insist on the Great Room., so glad you could make it and glad you can be here.

[Slide 2]

Welcome to U.S. Food and Drug Administration's Listening Session on Modernizing Recalls of FDA Regulated Commodities. Thank you for joining us today, those in person and those who are online. This listening session provides us an opportunity to hear from you, our stakeholders, so you can see our information and feedback about topics related to recalls of FDA regulated products. Keep in mind, not all commodities are regulated the same. There are significant differences in recall authority among commodities.

As a reminder, no commercial or promotional

materials will be allowed to be distributed or presented during this session. Also, we are not able to answer questions concerning the topic today and suggest that you go to the docket with any of your comments and concerns. If you need to know how to get to the docket, I've put one on the table right back here, and there are others around. So if you need to get to the docket, you can do that easily with the QR code there.

The views and opinions presented here represent those of the speakers and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration. Members of the media, if you're here and have not already done so, please check in at the media table with Shelly Burgess at the first break.

I'm Stewart Watson. I'm with FDA's Office of Regulatory Affairs, and I'll be your moderator for the day. In a moment, I'll turn it over to Erik Mettler for opening remarks. Erik is FDA's Assistant Commissioner for Partnership and Policy within the Office of Regulatory Affairs.

After Erik's remarks, we will introduce our first speakers. These speakers this morning will have five minutes. There are approximately 25 speakers here in person and approximately 28 speakers online, and we do all appreciate the effort that has gone into making this possible, and we appreciate the FDA for providing this facility and the White Oak production team who has made everything possible regarding the technical aspects of it that we need to make this happen.

We also appreciate those staffing the kiosk outside the Great Room, which is going to be down the hall to the right, and at lunch, there's going to be sandwiches and light refreshments available to purchase if you are so interested.

Each speaker in the room is going to be assigned a number, and you can see the numbers up here on the screen. We request that you first approach the next speaker chair, which is going to be the last chair on the first row over here, so when you are next, please proceed to that chair and the next speaker proceed to the podium, and before

you begin, please state your name and affiliation. There's a green, yellow, and red signal up here when you're speaking. If it's green, you're doing good, when it turns yellow, your time is almost up, and when it's red your time is up.

Speakers on the phone have also been assigned a number. They will be in listen-only mode until they are promoted to panelists. At that time, when it's their turn, they will be able to turn on the camera and unmute their microphones, and be able to speak. They will be sent a message when their time is almost up, and when their time is up, they will be placed back in listen-only mode. Any accompanying materials have been preloaded and will be controlled by our AV team.

All presenters, when it's time to advance your slide, you will please notify the AV team of that, that they need to advance the slide. If you have technical assistance, those on the phone, please write a message in the Q&A function and the audio visual team will work to sort that out.

As a reminder, this session is being

recorded and being livestreamed on FDA's YouTube channel. A transcript of the listening session will be posted on fda.gov as soon as available after this session. FDA has also established a public docket for the listening session that can be accessed at regulations.com and, again, you can use this for that. Public comment period will end on October 27, 2023.

Depending on how quickly we go along this morning, we will have a 20-to-25-minute break this morning and a 20-to-25-minute break this afternoon. We will have a one-hour break for lunch. Restrooms, if you haven't found them all, you go out the door to the right, turn a right again, past the kiosk and down the hall, and follow the signs. It's not too far. Again, the kiosk is available out there for lunchtime if you are interested in purchasing a sandwich or light refreshment. Please make sure all your phones and other electronic devices are muted so as not to be distracting and that we don't interfere with the sound equipment.

I'll now turn it over to Erik for his

opening remarks.

[Slide 3]

Opening Remarks - Erik Mettler

MR. METTLER: Fantastic. Thank you, and thank you guys all for joining us on the last day of the fiscal year, and hopefully we will see you on Monday --

(Laughter.)

-- but that will be dependent.

In that light also, I just wanted to note that the Commissioner and also Associate Commissioner, for Regulatory Affairs wanted to be here, but understandably they have a few issues that they need to address today and are really preparing for an orderly shutdown, if that does happen. Hopefully, it will not, better heads will prevail, and we will be going on as usual.

One of the things I'd like to start out with is just a quote, and it sort of rings true for me and it has my entire career at FDA. It's from Dwight Eisenhower, and it states, "Farming looks easy when your plow is a pencil and you're a

thousand miles away from the cornfield." This is absolutely true with FDA and the federal government, and we know that, and we've known that the entire career, and that's why we have these type of processes where we have an opportunity to reach out to you all to really understanding what's happening on the ground level, whether it be from the medical product side, industry, consumer groups, the consumers themselves, and across the board. We really want to make sure that we truly understand what activities are happening and what the actual impact is at the end of the day.

As we all know, recalls are an important part of the supply chain and the process with everything that FDA regulates, and other commodities as well, and it really is sort of the last line of defense if a product gets out there and really has a problem, and we need to get it out of the consumers hands.

I don't think anyone in this room or anywhere else will underestimate the power or necessary need of a recall process. What we really

want to do is try to figure out how we can simplify it, make it easier, quicker, faster, and make sure that there's the least amount of time that the product is on the market and available to consumers. I truly believe it's not an if, it's when products will be recalled, so we need to make sure that the processes are in place and that everyone's ready for a recall, starting from both at the industry level, all the way down to the consumer, to really make sure that they understand what they need to be doing at the end of the day.

But the purpose we're here today is FDA is really at the beginning stages of a huge broad effort to look at recalls across all the commodities that we regulate, and really look back at what our regulations are, what our actions are, what our guidances are, and then also what our partnerships are with industry and others in how we move forward in our recall activities. We're going to continue to refine our oversight and framework for recalls, but we really want to learn from all of you in moving forward.

One of the things I've really preached my entire time and really try to push out there is that we really live in an integrated public health system, and this is really all of us working together, the regulators, industry, academia, and consumers. We all need to work together to make sure that there are safe products on the market. We all have a specific role in that space.

Recall is no different, and recalls I think are one of the prime areas where this integrated public health system is the utmost of importance. We all have our different roles to play. We all play them a little bit differently. We also all have weaknesses and gaps in there. But I think the key part about this is really working with each other to identify where those are and where we can actually build upon and take that next step, and continue to do what we need to do to get those products off the market.

So over the course of today, I'm really looking forward to seeing everything that you are bringing forward. We'd love to hear more about the

way you are interacting with FDA and what FDA can actually do to help you and everyone else to really make sure that the recalls are working effectively. And also what I would love to hear is any partnerships that you think we can actually leverage that are currently happening: best practices, etc cetera, or potential areas that we can actually partner.

I would also press upon you and everyone here truly looking at the integrated food safety system. You're going to hear a lot of great presentations and recommendations today from folks, and I want you to take that and listen to them carefully. Now, FDA is going to listen to this stuff and go back and forth, but there might be a lot of opportunities for you all to work with each other to really take that next step and improve recalls out of the space that FDA has no control or authority over.

So with that, I would turn it back over and we can get going. Have we gone over who the panelists are? Are we going to?

(No audible response.)

MR. METTLER: Oh, we are?

(Laughter.)

MR. METTLER: And they didn't realize this.

So I'll just have them come up quickly. I really want you to show the representation that we have across the agency here that is not just one commodity; all of FDA is represented up here.

Do you just want to go down real quick and announce it?

Emil, we'll start with you.

MR. WANG: [Inaudible - off mic.]

MR. METTLER: They're going to make you walk up here, a parade. We can't have you sit behind there the entire time.

MR. WANG: Thank you, Erik, and good morning, everyone. Emil Wang, Center for Tobacco Products. Thank you all for coming.

MR. KUNTZ: Hello. I'm Tom Kuntz, CFSAN's Office of Compliance, Recalls and Product Reconditioning Team, and happy to be here.

MS. HUFF: Good morning, everyone. I'm

Lavonia Huff. I am lead CSO in the Office of Compliance, Office of Drug Security and Response.

MS. HONEYCUTT: Good morning, everyone. My name is Cherlita Honeycutt. I'm with the Center for Biologics Evaluation and Research in the Office of Compliance. Thank you.

DR. HODGES: Good morning. My name is Dr. April Hodges. I'm the branch chief of the Complaint Emergency Recall Branch at the Center for Veterinary Medicine.

DR. BITTLEMAN: Hi. I'm Katelyn Bittleman. I'm a policy analyst with the Compliance Equality Program in the Center for Devices and Radiological Health.

LCDR HALWANI: Good morning. I'm Mo Halwani. I am the recall operations branch chief for ORA.

MS. WULF: Good morning. I'm Amanda Wulf, the division director for Division of Operational Policy in the Office of Regulatory Affairs.

MR. TAVE: Good morning. Steve Tave from ORA, director of the Office of Policy Compliance

and Enforcement, which includes both our recall and our policy functions. And I just want to take a moment to thank Stewart for coming here to help moderate, as well as a number of people who are sitting around the room and outside of the room who are really unsung heroes of making today's meeting happen. They won't have a chance to introduce themselves, but we're grateful for their contributions and their presence, just as we're grateful for all of you being here and engaging with us, so thank you.

MR. METTLER: Thank you all. And before we get started, I want to go over some things that will be happening after this meeting. We'll be taking all the information, gathering it together, and really trying to figure out what we can actually do in the short term and long term. We're going to basically be as transparent as possible with all the information that we have. Again, we really need all of you to make this work. Recalls will not work without everyone else in the room, online, and elsewhere. So as we go forward, if you

do not hear from us, please feel free to reach out at any point. We'd love to talk to you.

So thank you, and, Stewart, we'll turn it back over to you to get going. I know Steve is itching to get up here.

[Slide 4]

Moderator - Stewart Watson

MR. WATSON: Alright. Thank you.

Speaker number 1, please make your way to the podium, speaker number 3, if you would come to the next speaker chair, and then our next speaker will actually be speaker number 2 online. So Speaker number 3, if you're present, please come to the next speaker chair.

Speakers

[Slide 5]

MR. MANDERNACH: Well, thank you very much for the opportunity to present a little bit on recalls. I'm Steve Mandernach, and I'm Executive Director for the Association of Food and Drug Officials. We want to begin by just saying a few words about the wonderful staff at FDA that we work

with every day with our state and local programs that we represent at AFDO.

[Slide 6]

They do an amazing job of effectuating and making recalls happen in some of the toughest situations that we see in the food world.

I'm going to focus my comments today largely on the food space. This is an area that we work with a great deal, and it's a little bit more complex area because we have co-regulatory authority with state and local governments, along with public health authorities, so it is a little different, perhaps, than some of the other spaces.

I suspect you might hear those words today more than a few times. Food is a little different in a lot of ways, not to mention it's something every one of you has and uses every day, and it's essential, so that is a little bit different than some of the other products, so we definitely believe that going forward.

With that, I'm going to go ahead and go to slide 2, please.

[Slide 7]

We see two major issues as it relates to recalls. First, when you look at the foodborne illness curve with products that have been recalled for, essentially, some sort of microbiological or chemical contaminant type issue, the illnesses continue going on well after the recall has been effectuated. That's a challenge for us and not something we'd want to see in an optimal system.

The second thing we would say is the issuance of recall communication is typically done later than it probably should be done. When I say that it's often, within the industry and elsewhere it had known for weeks before the public actually gets the knowledge that there's a recall happening, so there's an opportunity there to do better.

The other thing is, all of us have one of these in our pockets today. The last time we updated this regulation was when I was 2. We didn't have cell phones. Faxes were relatively new. Internet and e-mail was basically unthought of. We are not in the same spot and the regulation

has not kept up to date. It is time for a modernization of the regulation to go forward in order to be more effective in how we do communicate with our consumers and our public when we have these significant events.

Ultimately, it's pretty simple. We believe a clear public health goal is to expeditiously remove recall product from the market, not determining if a recall is effective. So what we're saying is perhaps what we're focused on currently in the regulation is determining if it was an effective recall. That's not the important question. When people are getting sick, the important question is, is the product off the market? And that's what we really need to focus on. It's a very different process.

Let's move to the next slide.

[Slide 8]

AFDO issued about a year and a half ago a large white paper on recalls after significant conversations with industry, regulators, public health community, and consumers, evaluating where

some of the pain points are -- I'd urge you to take a look at that; it's available at afdo.org and will be submitted into the record -- but many of the pain points are things that just could be improvements that could make things work better. For example, it's not particularly consistent when a recall is actually triggered. That creates confusion within the industry and within the public about what a recall is and when it happens.

Another challenge is the delay in classification of recalls. This has largely been alleviated when we look at what FSIS has done. That's a near instantaneous classification system and works dramatically better for industry, particularly when much of our industry manufactures both meat and poultry products and food products under FDA regulation. It's a great opportunity to reduce that inconsistency. I would argue the time of figuring out the difference between FDA and USDA probably should not happen in a recall. That consistency is absolutely necessary.

Lastly, we often see that there's a bit of a

lack of urgency in recalls, and they're often thought of as more of a routine matter versus something that's a public health incident. And I'm going to argue, particularly with the class 1 recalls, those are a public health emergency, and we need to treat them as such, and make them an important urgent priority within the agency and within the entire community, including the regulated community. So that's another opportunity for improvement going forward.

We're going to move to the next slide.

[Slide 9]

We did an extensive industry survey at the same time we were doing this work, and we heard some interesting feedback from them as we were doing that. One of them we heard was the regional inconsistencies in how recalls were treated, and the approach was very confusing and challenging in that they found one region -- or essentially at that point, one district or division was doing the recalls differently than the next division and region, and that was very challenging for them and

resulted in great inconsistencies as they worked across the world or a recall. Lastly, I think we would also say that we continually hear the challenge of the lack of early classification of recalls.

I want to hit on one last thing with my last minute that's a giant challenge, and we'll move to the next slide --

[Slide 10]

-- and that relates to information sharing. In food, the food space is unique in that we have co-regulatory authority essentially with concurrent jurisdiction, or in other words, lots of folks have jurisdiction at the same time in that space; yet, we are unable to successfully share information due to restrictions within some of the FOIA laws and records laws within the federal government.

This has to be corrected. This is not effective public health. It is not doing what our consumers expect. I guarantee you there's no consumer in this country that thinks we are not communicating amongst the government because we

have some sort of technical requirement within it that says that we can't share information such as distribution information during a public health event. That is not what our public expects and is not acceptable.

With that, I thank you for the opportunity to present today and look forward to the conversation.

MR. WATSON: Thank you.

Virtual speaker number 2, please unmute yourself, turn on your camera, and you're ready to go.

[Slide 12]

MR. EARL: Good morning. We thank FDA for the opportunity to provide the food allergy perspective --

[Slide 13]

-- related to FDA recall modernization. I'm Robert Earl, Vice President of Regulatory Affairs at FARE, Food Allergy Research and Education.

[Slide 14]

On our next slide, FARE is the leading

nonprofit engaged in food allergy advocacy, as well as the largest private funder of food allergy research. FARE's innovative education, advocacy, and research initiatives transform the future of food allergy through new and improved treatments and prevention strategies, effective policies and legislation, and novel approaches to managing the disease.

[Slide 15]

On the next slide, food allergen recall information is critical to over 33 million Americans with food allergy, as well as their caregivers. Food allergy is a disease, not a diet, and cross-contact or inadvertent exposure to a food allergen is regularly a matter of life and death.

As health equity is integral to everything FARE does, food recall information must reach the substantial portion of our community that is underserved and underresourced. Low income households have a higher rate of food allergy than the general population, 10.7 percent compared to 8.3, and Hispanic and Black individuals have the

highest rate of food allergy emergency room visits.

[Slide 16]

On our next slide, our community requires timely food recalls to save lives and prevent inadvertent ingestion of food allergens. One food allergy death from anaphylaxis is one too many. While FDA's current system informs, in several ways it could improve. FDA has its recalls website and posts on social media. We support that it includes both voluntary recalls and FDA recalls. FARE also maintains a page on our website that includes voluntary manufacturer recalls, FDA and USDA recalls, and alerts from manufacturers about ingredient changes that add or delete a food allergen. Comprehensive food recall communications requires buy-in across the food supply chain, and FDA should encourage this.

[Slide 17]

On the next slide, food recalls must reach our community, reach everyone with food allergy fast, and be comprehensive. As we noted, some in our community may not be aware of FDA recall

information, particularly those with limited resources. That's why we communicate both agency and USDA recalls, as well as product formulation changes. A modern technology-driven, rapid outreach system from FDA could reach our community faster, as we must rely on published recalls.

[Slide 18]

On our next slide, FDA could improve communication about recalls to be faster, use all social media platforms, especially those popular with younger audiences like TikTok, that will increase reach to our full food allergy community. FDA could urge greater recall collaboration between manufacturers and retailers, sharing recall information via e-commerce, purchasing and delivery platforms, and reach food banks and pantries.

As part of looking for, subscribing to, or following FDA, FARE recommends that the agency utilize text alerts that can be customized by an individual or family's food allergens by opting in for alerts and allowing filtering by those relevant from the top nine.

[Slide 19]

On the next slide, in addition to FARE's recommendations about modernizing recalls, we believe that FDA can demonstrate additional leadership about the presence of the top nine food allergens beyond foods and dietary supplements. Our community would benefit from food allergen information on other FDA regulated categories and in recalls. The risk for food allergy reactions and fatal anaphylaxis extends to ingredients in prescription drugs, OTCs, cosmetics, personal care products, and pet foods. Also, we recommend close coordination by FDA with USDA and urge TTB to declare food allergens on beverage alcohol.

[Slide 20]

On our final slide, FARE appreciates the opportunity to share our views to modernize and increase the reach of food allergen recalls to our community to prevent reactions and save lives. We will submit these and additional comments to the FDA docket. Thank you for the opportunity to speak this morning.

[Slide 21]

MR. WATSON: Thank you.

Just one note. I want to make sure everyone is aware that we will be sharing the recording and slides from today's meeting as soon as possible.

Speaker number 3, please make your way to the podium --

[Slide 22]

-- speaker number 5, please make your way to the next speaker chair up here, then virtual speaker number 4 will be the next.

Go ahead.

MS. DAVILA: Good morning. My name is Shannon Davila, and I am the Director of ECRI's total systems approach to safety. Thank you for this opportunity for ECRI to provide public comment on this important issue.

Next slide, please.

[Slide 23]

Over the past 50 years, ECRI and our colleagues at the Institute for Safe Medication Practices have partnered with providers,

manufacturers, and organizations such as the FDA to improve the safety and quality of care across all healthcare settings. As a trusted partner, we have worked alongside and remained in alignment with the FDA to innovate and advance recall identification and management processes and practices, creating solutions that address the ever evolving needs of providers, manufacturers, and patients in the process.

Next slide.

[Slide 24]

There has been a growing call for greater action and transformation around patient safety. ECRI, along with 26 other organizations, created the National Action Plan to Advance Patient Safety, calling for a total systems approach to the redesign of healthcare's safety operating systems. Earlier this month, the President's Council of Advisors on Science and Technology released bold recommendations in the Report to the President, calling for a transformational effort on patient safety. These recommendations specifically call

the need to improve the safety of medical devices through the interoperability of data, including the inclusion of unique device identifiers in claims and in electronic health records to improve data availability. The recommendations urge the federal agencies to collaborate for advanced learning and accountability around safety.

Next slide.

[Slide 25]

Now, as we look towards the next phase of recall modernization, we believe that it is critical to focus not only on innovation but also collaboration and adoption. Positive change is only successful if it is embraced by all relevant stakeholders and sustainable in action. A total systems approach can provide a more holistic methodology anchored in system design, human factors engineering, health equity, and advanced safety science to consider how factors such as staffing, technology, workflow, and the physical environment affect interoperability, as well as the care delivery and outcomes. When we assess and

analyze the interactions of these elements, we are able to identify weaknesses in existing systems, as well as develop pathways towards improved and standardized systems.

Next slide.

[Slide 26]

As a trusted partner throughout the healthcare industry, our goal is to work alongside the FDA and industry to help convene this diverse group of stakeholders to develop and implement a holistic system-based model that can propel and sustain recall management in its next phase of modernization. It is through this collaborative effort that we will tackle the most pressing issues related to recalled modernization, which include a trusted industry collaboration to help engage healthcare providers for better reach to patients and their caregivers.

Key to this will be ramping up efforts to provide better clinical guidance, a more effective and sustainable and nationalized route to patients with greater economies of scale versus the

fragmented reliance on manufacturers, which could further increase product costs, and working alongside manufacturers and industry to help improve the connectivity to providers, and the integration of unique device identifiers and automation of the recall notification process.

A significant portion of the work within ECRI and ISMP focuses on engaging providers in the early identification of and communication about hazardous and unsafe products and medications. By convening pertinent stakeholders, we can help establish better pathways from the FDA to the bedside, which extends to those in underserved communities and home-based care.

Next slide, please.

[Slide 27]

In closing, ECRI stands together with the FDA and industry to register our support for modernization, and we are ready to partner in driving actionable change. Thank you.

[Slide 28]

MR. WATSON: Thank you.

Virtual speaker number 4, please unmute yourself, turn on your camera, and introduce yourself.

MS SAUNIER: Thank you, and good morning. My name is Brittany Saunier, and I'm the Executive Director of the Partnership for Food Safety Education. The Partnership for Food Safety Education develops and promotes effective education programs to reduce foodborne illness risk for consumers. We thank our long-term partners and the FDA for holding a listening session and soliciting comments on modernizing recalls. We'd like to address the topic of creating successful recall strategies, including methods to reach underserved communities in our remarks today.

The Partnership for Food Safety Education has unusual origins and a track record of public-private collaboration for nearly 26 years. Working with industry experts, consumer groups, and our federal agency liaisons, the Partnership developed the original consumer food safety education campaign, Fight Back, and the four core

messages of safe food handling practices: clean, separate, cook, and chill.

The Partnership was created in 1997 through a memorandum of understanding between the U.S. Department of Agriculture and the U.S. Department of Health and Human Services, including the FDA and the CDC, along with leading food industry associations and the Consumer Federation of America. Twenty-six years later, we still work in this cross-sector collaboration with about 40 partner organizations representing manufacturers, retailers, industry associations, scientific associations, consumer groups, and e-commerce.

With a rich history in collaboration and a commitment to science-based guidance, the Partnership is uniquely qualified to support the FDA's efforts in modernizing the recall process by activating the educator network we serve as information disseminators. The Partnership convenes and stewards 13,000 community-based health and food safety educators across the United States.

These educators are in public health agencies at local, county, and state levels. They're in the nutrition sector and cooperative extension, in schools, and in nonprofits that serve vulnerable populations.

The Partnership supports these educators with free access to science-based consumer food safety resources that they disseminate to their communities in urban, rural, or suburban to help them prevent foodborne illness. We estimate that 8-and-a-half-million people are served in the U.S. with safe food handling guidance through this educator network. They have direct connections with their community and they are a trusted source of information. We also know that they are often the first point of contact with food safety questions from their communities.

From a 2022 needs-based assessment survey of educators, nearly 55 percent of respondents listed people with lower incomes as the primary audience they serve with consumer education. The second highest audience served is older adults, 65 years

and older, followed by caregivers of young children up to 6 years old. When asked which audiences are most underserved in their community with food safety information, 51 percent indicated people with lower income as the most underserved, followed by non-English speakers and older adults, 65 years or older. When asked about which tools they find the most effective at influencing behavior change in safe food handling with consumers, nearly 56 percent indicated direct person-to-person contact as the most influential, followed by print materials and classes.

Community-based educators are powerful information disseminators. They know which strategies are effective at influencing behavior and they are predominantly serving people with lower incomes. Our partner organizations, alongside our network of 13,000 community-based health and food safety educators, stand ready to work with the federal agencies to research and test consumer messaging and materials that influence safe food handling behaviors and to bring

understanding of the recall process and actions that help to prevent illnesses.

As the FDA considers strategies for modernizing the recall process, the Partnership is ready to provide leadership on helping underserved households understand recalls by activating our educator network as a trusted information disseminator. This can and should be done through the Partnership, consistent with the collaboration that resulted in the original evidence-based consumer campaign called Fight Back.

I appreciate your time today and for the opportunity to share the importance of considering community-based educators as essential information disseminators to reach underserved communities. Thank you.

MR. WATSON: Alright. Thank you.

[Slide 29]

Speaker number 5, please proceed to the podium, speaker number 7, please proceed to the next speaker chair, and speaker number 8 will be our next virtual speaker.

MR. FLOOD: Good morning. My name is Tony Flood, Senior Director of Ingredient Safety with the International Food Information Council.

[Slide 30]

As a 501(c)(3) nonprofit organization, we serve the public good by effectively communicating science-based information on food safety, nutrition, and sustainable food systems.

Next slide.

[Slide 31]

Our comments today are rooted in more than 20 years of consumer insights on food safety and the core principles of effective risk communication. Specifically, we will address the following FDA interest areas: successful recall communication strategies, including methods to reach underserved communities, and public warning strategies, including press releases, social media, and other communication tools.

Next slide.

[Slide 32]

Building successful recall strategy and

reaching underserved populations requires consumer research and community partners. A successful recall strategy must build on trust and confidence among all Americans, including underserved Americans.

Next slide.

[Slide 33]

IFIC's latest food and health survey reveals that only 70 percent of Americans are confident in the state of the U.S. food supply, with just 17 percent of consumers expressing that they are very confident. This lack of confidence is more pronounced among some underserved populations.

HHS defines underserved communities as populations that do not have access to medical care. This includes rural, elderly, blue collar, and poor populations. IFIC's consumer research notes that of those that lack confidence in the safety of the food supply, upwards of 30 percent, include demographics that are parallel to the HHS underserved population, and includes younger, rural, white males and females without college

degrees. For me personally, I might add to the HHS definition of underserved communities to include communities with limited access to safe, nutritious, or affordable food.

How do we inform these communities about the risk of consumer recall products when they, one, are not confident in the safety of the food supply in the first place; or they may not have access or transportation to begin with; or their current or next meal is somehow connected to that recall product? It is imperative that we conduct comprehensive consumer research to better understand the similarities and differences among the attitudes, beliefs, and behaviors of these Americans, as well as develop culturally sensitive and dignified communications that not only impart recall information but also build trust.

Next slide.

[Slide 34]

Public warning strategies should incorporate effective risk communication principles and should be inclusive of experts in community life. Food

recalls are only effective if the intended behavior is achieved. Perhaps the risk was not clearly defined or the recommended actions were not easily available. These are perils of ineffective risk communication.

As stewards of risk communication, our duty is to, first, be right and be credible, but we do not say be culturally sensitive or even aware of your target population's needs. This will include understanding the intended audiences through safety and literacy, spheres of influence, access to health, or even access to technology and credible sources of information. As communicators, we know that one size does not fit all, and we strongly encourage the best and most effective risk communication principles be incorporated into practical recommendations for consumers.

As the purpose of this FDA listening session is to modernize recalls for the FDA regulated products, we must acknowledge the fact that there are cultural challenges and barriers to an intended behavior. As food safety and nutrition

stakeholders, and risk communicators, we must emphasize the core principles of culturally sensitive message development such that we can successfully reach targeted communities with credible information that is relevant and respectful of them. Outcomes can then be measured by behavior.

One way to achieve this is identifying and partnering with trusted community leaders and individuals that are unique to the community. In my home community, in rural southern Virginia, a blue collar town, barber shops, hair salons, and clergy remain mainstays of community knowledge and information. How might we empower them as value-based experts in the community with tools, resources, and science-based information to become stewards of food recalls and public health alerts?

The opportunity now is to include these value-based experts as contributors to the development, dissemination, and assessment of these efforts. One way this can be done is by providing an environment to convene thoughtful discussions

among food safety experts, regulators, and consumers, along with other public health leaders, stakeholders, including the media and journalists.

IFIC supports the FDA and the efforts being discussed, and we would like to put forward the following recommendations: 1) conduct consumer research to understand Americans' perceptions about food safety and recalls, with an emphasis on cultural sensitivities and behaviors among diverse populations; 2) utilize best practices when communicating risk versus hazard during recalls; 3) equip stakeholders and experts in the community with tools and resources to support successful recall strategies; and 4) reconvene FDA's Risk Communication and Virus Committee, consisting of external industry, academia, and consumer groups.

As we submit these as written comments, IFIC welcomes the opportunity to collaborate and serve all Americans with consumer insights, stakeholder engagement, or thought leadership in your quest to modernize recalls of FDA-related products.

Next slide.

[Slide 35]

MR. WATSON: Thank you.

MR. FLOOD: Thank you.

[Slide 36]

MR. WATSON: Speak number 7, please proceed to the podium --

[Slide 37]

-- speaker number 9, please proceed to the next speaker chair.

MS. BRAYMEN: Good morning. First, I would like to thank you for what you do to protect us and keep us safe. As a fellow food safety professional, I know there are many outbreaks that are prevented due to your diligence. I'm here as a a member of the Alliance to Stop Foodborne Illness, which is a program of Stop Foodborne Illness, and we consist of manufacturers, retailers, government officials, survivors of foodborne illness, and I'm one of those.

When my child was 17 years old, she contracted *E coli* from baking cookies and eating cookie dough, which is something almost everybody

has done, and it seems like such an innocent thing for teenagers to do. Both she and her older sister became violently ill, and the younger one became so sick that I had to rush her to the hospital, and she had a seizure in my car and she turned blue. So I pulled into a fire station asking for help, and they rushed us to the hospital.

Her temperature was 106, and they dumped her body into a barrel of ice water to try to bring her temperature down. She spent a week in the hospital on a cooling bed. I don't know if you know what that is, but it's where they strap your arms and legs, your extremities, and circulate cold water over them to try to bring down your core temperature.

It was such a horrific experience that I remember sleeping on the hospital floor so I could hold her hand, as there was nothing I could do, and she would cry, and then when she slept, I would cry because we didn't know what was wrong and we didn't know how to fix it. We did not know how to help her.

The doctors didn't even test for *E coli* until they ruled out all other possibilities, so she was sent for an ultrasound to check her kidneys, and by that time she had developed HUS, hemolytic uremic syndrome, that can be a side effect or a result of the disease *E coli*, and it attacks your kidneys, attacks your brain, and attacks your entire body.

They were doing the ultrasound, and the sonographer said, "I can't find it," and left to get the doctor. So when the doctor came in, he said, "I'm so sorry, but her kidney has shrunken to the size of a bean; it's 6 centimeters. The other one seems ok." So to this day, by the time we got her home, she is on anti-seizure medication to this day. She has anxiety, post-traumatic stress, and she has panic attacks, and ongoing care is required.

As a direct result of that, I became a food safety auditor, so I am trying to make a difference, as are you, and I am in the facilities that are manufacturing. I am in the distribution

centers that are shipping the finished product. My goal, if I can do anything that will stop one person from having to experience that, then I feel that I've done something. I think that this process can be improved by better recall. I'm not saying it doesn't work, but it's outdated. There are better ways to communicate these days, and I think that's been reiterated a couple of times, to get the message out sooner.

We found out about the recall a month after she went through this. We heard from the retailer before we heard from the manufacturer or the FDA. So I believe that through due diligence and training, I believe training is important for prevention because it's not all on recall; it's also a matter of what do we do to prevent it. That's the auditor in me talking. We have to find a way to prevent that, and as an auditor for the past 12 years, many times I get into a facility and find that training is just a matter of checking a box and not a meaningful training.

The other portion, I believe, is modernizing

our recall plan. There are ways that we monitor hotspots. People will monitor websites and look for key terms for foodborne illness, and you can predict where a recall is going to possibly take place -- or an outbreak; excuse me for that. So my hope is that by hearing our stories and putting a face to these invisible pathogens, it will bring more awareness for people to understand that a pathogen outbreak or a manufacturing failure can result in the death or critical illness of somebody at any age. My kid was a teenager, almost a grown-up, but at that moment she was just a little girl and crying for her mom.

I haven't met anybody who hasn't had some kind of food poisoning, but it's food poisoning on steroids. Imagine that for weeks or months at a time. I believe that modernizing the recall system is a very vital part of that, and I also believe that training -- more training, especially in manufacturing facilities -- needs to take place. Our manufacturers have the means and the obligation to train their own people, their employees, on food

safety. I know it can be done. I've been there. I've seen it. Sorry. I'm very nervous to be here in front of you.

My final comment is that this took place 14 years ago, and to this day, we're still seeing just as many illnesses, and deaths, and outbreaks, and we're currently dealing with -- how many? -- two, three, or four, college outbreaks, and high school. It's all over the place, and I hope that we can find a way to prevent it.

I want to thank you again. I thank everybody for your time and appreciate you.

MR. WATSON: Thank you.

(Applause.)

MR. WATSON: Before we proceed to speaker number 8, is speaker number 9 here? The name would be up here. If you are, please proceed to the next speaker chair.

(No response.)

[Slide 38]

DR. AGHARAHIMI: Hello, everyone. Can you hear me?

MR. WATSON: Yes. This is speaker number 8?

DR. AGHARAHIMI: Alright. Good morning, everyone. This is Dr. Maryam Agharahimi. I'm an analytical chemist with Department of Agriculture and Consumer Services, and I'm also a toxicologist. I'm working with this department, running the food products for the last 22 years. We are the agency that's protecting the consumers, which means that we are analyzing the food products just to make sure whatever they are claiming on their labels are true and correct. If we find something that has not been claimed on the label, then we're going to call that adulteration, and we're going to communicate with FDA.

One of the most important ingredients that I have been testing and, unfortunately, found so many violations is sulfite. And I'm proud to just announce that my analysis, my work with the Department of Agriculture and Consumer Services, has caused so many recalls, nationwide recalls, because I found these ingredients that were not claimed on the label.

Sulfite is the ingredients that manufacturers are using as a preservative to prolong the shelf life of dried fruits and vegetables, and if someone -- a consumer, a consumer product, by reading the label and they don't see or they don't find these ingredients on the list of ingredients, then it's going to cause anaphylactic shock, and in some severe cases can cause death.

So as the primary analyst who is doing this for public safety and has been involved with the communications with FDA and recalls, I decided to speak today just to talk to everyone about how communication is important in the recall of the adulterated food products, and it can save lives.

If you find the ingredients, like sulfite, that can cause anaphylactic shock, or in mild cases could cause skin rash, or itching, or it can cause many other physical problems, and the severe cases can cause an anaphylactic shock, if we promote the communications in the case of finding violations, we can issue the results immediately and recall all

products as soon as possible, and that would be great. We can save lives.

I also want to mention that as a primary analyst who is involved with these recalls, I can do my part to provide everything that FDA needs. In order to expedite the processing of recalls, we need to provide everything -- as a primary lab, we have to provide good information about the product, including a very clear label, a very clear lot number, and all of the data that we have done to prove that that product is adulterated.

Unfortunately, I just see so many products, the same product, with the same label, with the same nutrition fact panel, but a different lot number, and they have a different amount of this preservative or sulfite. For example, like jackfruit, I have run jackfruit so many times, and all times, the labels are the same, and all are products of Sri Lanka. Every information like the nutrition fact panel, the weight, the statement of identity, the manufacturer, everything is the same, but they have a different lot number. I found

sulfite in some lot number that the other lot numbers didn't have that much, which means that as public safety, we have to be careful and communicate with manufacturers, too.

I think if we can promote recall faster, or at the time of manufacturing, to prevent mass production and putting them in the market, that would be greatly better, and we can save much more lives, because by the time we find a violation, and then communicating and producing the paperwork, and processing the paperwork, and communicating with the FDA, and then they can issue the recall from those dates, so many consumers can consume this product, and God knows how many of them are going to be affected because, for example, the sulfite preservative is hidden. They may not know their sickness is because of the product that they consume because they probably --

MR. WATSON: Maryam, I'm going to need you to wrap it up. Your five minutes is up.

DR. AGHARAHIMI: Oh, yes. Thank you so much. I just wanted to thank you for giving me the

chance to talk for this topic. Thank you.

MR. WATSON: Thank you.

[Slide 39]

Now, if speaker number 10 would unmute yourself, turn on your camera, and introduce yourself, please. Speaker number 9 is not here.

MS. TOWT: Are my slides up?

[Slide 40]

MR. WATSON: There we go. Now they are.

MS. TOWT: Thank you.

Good morning, and thank you for having me here today. My name is Robyn Towt. I am co-founder of GPAC, which is the Global Patient Advocacy Coalition, and we advocate for safe medical devices.

Next slide, please.

[Slide 41]

In preparation for today's topic, I researched some other organizations that oversee products that are subject to recalls in the United States. I looked at the Consumer Product Safety Commission that overseas baby cribs, and furniture,

and toys; the National Highway Traffic Safety Administration, which overseas automobile safety; the FAA, for air airline safety; and even the FDA's food safety division.

Next slide, please.

[Slide 43]

I have a posing question for today that I would like everyone to consider, and it's about reasonable probability and what is considered reasonable. How many injuries or deaths from a medical device is considered reasonable to the FDA before they take action?

Just a couple of quick examples, the National Highway Traffic Safety will issue a vehicle recall, and the dealerships will repair the the cars at the manufacturer's expense, holding that manufacturer accountable for their unsafe product. The FAA has very rigorous and detailed preflight inspections, and they will ground planes if there's a problem with the aircraft. They'll deem them unsafe to depart until it's repaired and safety is proven.

The FDA will recall lettuce due to foodborne illness outbreaks, but not medical devices that cause cancer or severe harm, and I have some grave concerns about medical devices such as breast implants and surgical mesh that aren't necessarily life-saving devices but have extreme problematic complications with them and lack proper FDA oversight.

Next slide, please.

[Slide 44]

I'll use breast implants today as an example because I was personally harmed by breast implants after having breast cancer, and I didn't know that since the 1990s, early in the '90s, the FDA was aware of multiple cancers that are caused by breast implants. We have breast implant associated ALCL, which is a lymphoma, and the FDA has known about this since the '90s, yet they didn't issue a statement about it until 2011. They also issued a Healthcare Provider Letter in 2019, alerting all medical professionals about this breast implant-related cancer.

Just last year, in 2022, the FDA issued a statement about breast implant-associated squamous cell carcinoma. This is a highly aggressive cancer. It metastasizes quickly, it doesn't respond to chemotherapy or radiation, and it has a very high mortality rate. Fifty percent of patients are dead within 6 months of getting this cancer, and the FDA knew about this cancer in the early 1990s, and didn't issue a statement about it until 2022.

Still, I got an e-mail last week, after asking the FDA if manufacturer labeling has been updated since this announcement, and it has not. We strongly feel that medical device registries should be mandatory and reporting should be mandatory so that we can better track and monitor the safety of implantable devices.

Virtually, the FDA reports that that MAUDE database are unusable and inaccessible. It was found in 2019 that over 446,000 reports of breast implant complications and harmed patients were missing and not available for the public to see.

So we have hundreds of thousands of injuries from breast implants, over 1400 cases of cancer, and almost 75 deaths. For non-life saving devices, what is considered reasonable probability?

Recommendations we have for the FDA today -- sorry. Next slide, please.

[Slide 45]

The recommendations we have today for the FDA are to utilize software programs like Device Events. This is a program that was developed specifically to analyze, extract, and utilize adverse event reports in the MAUDE database, and that will give us a better understanding of medical device complications. It is also crucial for the FDA to hold manufacturers accountable to update their patient labeling to reflect the current scientific data. This is essential for patients to have proper informed consent so that they can make an educated and informed decision about having a medical device.

We believe that the FDA should consider mandatory medical device registries that will alert

patients about any new safety updates or recall information and also issue Healthcare Provider Letters to all specialties of the medical community. This will not only improve patient outcomes, but it will enable us to diagnose and treat patients in a timely manner.

We would like to see the FDA issue public service announcements, or PSAs, to alert the public of critical information. We saw this a lot during the COVID pandemic. We saw hundreds of commercials on TV and listened to radio commercials, and even social media ads, talking about COVID protocols.

Next slide, please.

[Slide 46]

It is the FDA's duty to protect patients and prioritize safety, and we really hope that you consider our recommendations today to improve the standard of care and also to improve efficiency in recall measures. Thank you for having me today.

[Slide 47]

MR. WATSON: Thank you.

We are going to adjust a little bit. We are

going to have a couple more speakers before we take a break since we are ahead.

Speaker number 11, please proceed to the podium, speaker number 12, please proceed to the next speaker chair, and speaker number 13 will be our next virtual speaker.

MS. BAUM: Good morning, everyone. Good morning, Erik and the panelists. Thank you so much for holding this meeting and for being here today. My name is Mitzi Baum. I'm the CEO of Stop Foodborne Illness. We are known as the voice for safe food, and that's because we work with individuals and families that have been impacted by severe foodborne illness, like Suzie Braymen, who you've already heard from, and you'll be hearing from Scott and Richelle Shields later today.

We exist because of the 1993 outbreak due to *E. coli* O157, associated with hamburgers where 4 children died, and parents were angry, and they formed Stop Foodborne Illness. Almost 30 years later, we're still working on these same issues, and I appreciate the opportunity to speak to you

all today because over the years, we've supported a variety of initiatives by FDA and USDA. We supported FSMA, and FSMA was a promise of a culture shift to preventive, and prevention is important. Recalls are preventive, and we believe that they are an essential part of our system.

In July 2020, FDA put out the New Era for Smarter Food Safety and called out recall modernization. In September 2020, Stop Foodborne Illness convened a multifaceted working group to focus on recall modernization. On the year anniversary of the New Era, we published a white paper and shared it with FDA -- and it's still on our website, and you're welcome to read it, stopfoodborneillness.org -- and we outlined how we can modernize the system to benefit consumers.

Let's be honest, recalls are meant for consumers. We need to remove these items that could potentially harm us and our children, our families, from our refrigerators, our freezers, our pantries. The recall system is not working for consumers. The current language is to communicate

via telegram and press releases, and I hear some laughing in the audience. That's the language, and we all know that this is out of date. And as a previous speaker shared, there are many new ways to communicate this information to consumers. All of us have phones in our hands today.

There are three things that I want to focus on with regard to the modernization sense of urgency, and I believe there are a few things that are emerging. A sense of urgency; we know FDA can act with a sense of emergency and we appreciate the work they do on behalf of the American consumer every day. When there's an outbreak, we see action with a sense of urgency. Recalls need to have that same sense of urgency in the application in which they're initiated as prevention.

Consumer-friendly language. Consumers that don't have the same information as those of us in the room, or that are listening today, that are food safety professionals, don't understand voluntary. They don't understand abundance of caution. It essentially means that it's not really

that important or this isn't an emergency. This isn't going to impact me or my family, when we all know -- and we'll hear some more stories about how recalls have affected families -- that they do. We need to use consumer-friendly language that's very clear and concise, and everyone can understand, including my parents, your parents, and our kids.

And communication, the technology is there. As the previous speaker shared, there are PSAs throughout the pandemic. We know there are AMBER alerts. There are ways to better communicate and get the information into the hands of the consumers to protect themselves. And finally, I believe that FDA can support our organization and the work that we're doing and the work of the working group. Stop Foodborne Illness has been able to raise funds for research to identify what is that language that is important to consumers that will get them to act?

We appreciate all the work of Erik and his team and the time that they've put into working with us. We hope to continue the conversations and

the action together. We are focused on consumer-centric solutions, and I think that should be the core message of all of the work we do around recalls. Thank you so much.

MR. WATSON: Thank you.

[Slide 48]

Speaker number 12, please proceed to the podium. Speaker number 13 will be our next virtual speaker, then we'll take a 25-minute break. Just a reminder, the kiosk will be open for purchase of refreshments during the break.

Go ahead.

MR. GREMILLION: Hello. Sorry to get between everyone and the break.

Good morning. My name is Thomas Gremillion. I'm the Director of Food Policy at Consumer Federation of America. Consumer Federation of America was established in 1968 to advance the consumer interest through research, education, and advocacy, and today, more than 200 of our member groups participate in the federation and govern it through their representation on the organization's

Board of Directors. My comments are quite simplistic, really, and they focus on one aspect of FDA's food recall process. I'm blissfully ignorant of devices and the other things that you may be recalling, but this morning, I want to talk about FDA's policy of disclosing retail consignees of recalled foods.

Consumer and food safety groups have long advocated -- I've been at CFA for eight years. Before I got on, we had been hounding FDA and USDA about publishing the distribution list of retail consignees of foods subject to class 1 recalls, and this is something we succeeded with USDA. In 2008, the Food Safety and Inspection Service, FSIS, explained in the Federal Register how they were changing their policy, and since then has been publishing the distribution list.

In 2018, FDA issued this draft guidance that got us a little bit closer to the USDA policy. Now, foods that are not easily identified by retail packaging, or lack thereof, and are still likely to be in the consumer's possession, for those foods,

FDA will publish the identity of the retailers selling the recalled foods. But that guidance that was published in 2018, I look back at it, and it's like, what's the rationale exactly? It continues to perpetuate what, with all respect, is, frankly, a myth, that the law does not allow -- the guidance says in some recalls, identifying retail consignees may reveal confidential business relationships between suppliers and customers, which may be confidential commercial information, the disclosure of which is restricted by law and FDA regulation.

That's a myth. The same law applies to USDA. USDA has nearly identical regulations implementing that law and providing for the protection of confidential commercial information. In 2008, again, FSIS explained in the Federal Register why the law does not prevent the agency from identifying retail consignees in class 1 recalls, and since 2008, FSIS has required recalling food companies to provide distribution lists, which the agency has posted on its website. This policy has led to greater transparency.

In a 2020 research study on that consignee disclosure policy, it reports, quote, "The proportion of recalls with retailer information increased over time, from 17 percent of recalls in 2010 to 89 percent of recalls in 2015," which, quote, "suggests that policy compliance improved," with respect to FSIS.

FDA would benefit from a similar compliance improvement; we know that. According to the Inspector General's report back in 2018, quote, "FDA did not always assign audit checks consistent with the audit check levels in the audit plan, in part, because," quote, "both the consignee distribution list that FDA obtained from recalling firms were not always complete or accurate." And and as a result, the Inspector General recommended FDA, quote, "take steps to ensure the completeness and accuracy of consignee distribution lists," and one surefire away to improve the completeness and accuracy of these consignee distribution lists, make them public. Let the public be your verification team.

Other reasons this policy makes sense and we need to abandon this myth that Congress has not given FDA the same authority as USDA, information about retail consignees of recalled foods can help to generate local media attention and increase the odds of recall information reaching a consumer.

We heard from Steve Mandernach at the beginning earlier this morning, AFDO has complained about how the state regulatory partners, local health departments, aren't able to get the distribution lists or don't get accurate distribution lists. It's public. You eliminate these barriers.

So just to close, protecting public health involves many tough trade-offs, and very, very complex subject matter here, but this is a very simple issue, and this is a way that FDA can come out of this. I'm so grateful that you are initiating this process and figuring out ways to improve recalls, and this is an easy step forward that will benefit consumers, and I appreciate your time.

MR. WATSON: Thank you.

Speaker number 13, please unmute yourself, turn on your camera, and introduce yourself.

[Slide 50]

MS. BARNETT: Good morning. I'm Amy Barnett. I am a graduate nurse turned patient advocate. I nearly died last year due to the development of type 4 metal allergy caused by my untracked and undocumented surgical clips. I'm grateful to represent my Facebook community and speak for the thousands of others harmed by standard-of-care medical devices that were implanted in their bodies without explicit consent or documentation.

Recalls encompass more than just creating a centralized alert system. It's about addressing the underlying issues that will render it useless. How can anyone identify the need for a recall when the patient, who is most likely to report device problems, is unaware they have them and there's no documentation in their medical records? We need mandates, not guidelines, regulations that require

the gathering of essential data for determining when a recall is necessary. Why can I get more information about my food than a permanent implanted device I didn't consent to have?

Your recall system doesn't just need modernization, it needs accountability. For starters, patients not only need mandated risk checklists and implant materials, they have a right to explicit consent for the device that they are receiving. Current consent laws allow standard-of-care devices to remain undisclosed. If we pay for a device, we deserve to know what it's made of, including trace alloys, because for some of us, that's our peanut dust.

The majority of my Facebook community has zero information about their surgical clips, and therefore, zero accountability across the board. You must mandate and simplify adverse event reporting to ensure comprehensive postmarket surveillance. In 18 years, I've had three different types of surgical clips and none of my doctors have filed an adverse event report on my

behalf. This shouldn't be the sick and dying patient's responsibility. You must mandate documentation of all foreign materials used in or on a patient's body, regardless of risk or permanence, using a unique device identifier in patient medical records.

Even temporary materials can cause reactions. Patients should be autoregistered using barcodes and given implant cards they are instructed to keep for the life of the device. Barcodes should enable smartphone scanning, providing easy access to implant materials and recall instructions via your website. They should be sent annual reminders through their providers and e-mail to keep their contact info updated.

End the 510(k) process. The National Academy of Medicine recommended ending it over a decade ago and current predicate recall analysis confirms it. Manufacturers should be mandated to prove device safety rather than patient suffering thanks to a predicate loophole. Mandate uniform pre- and post-implantation protocols. If a surgeon

is trained to put it in, they should be trained and required to order tests and take it out; otherwise, they shouldn't be allowed to use the device.

Prescreening can begin with basic questions about allergies or past implant reactions, and additional data can be collected through various methods such as lab tests, predictive modeling, clinical trials, tissue analysis, allergy testing, and computational modeling. Establishing dedicated contingency planning teams involving data analysts and AI experts can help create predictive algorithms for early problem detection and proactive recalls.

Offer tracking cookies on the recall website to monitor device events and guide patients to relevant information, much like commercial targeted ads. Leverage cell phones and wearable devices, offering biometric tracking for real-time monitoring. Create straightforward press releases at a 5th grade reading level, explaining the recall, the reasons, risks, and recommended actions using a color-tiered classification system.

Distribute them to local and national media outlets.

Use all social media platforms for real-time updates and engagements, including polls and Q&A sessions. Alert community centers and health departments while providing webinars and visuals like infographics and videos. Create user-friendly multilingual apps or websites with symptoms checklists and virtual town halls. Collaborate with influencers and health professionals for effective recall communication.

Mandate a standardized reimbursement process for holding manufacturers accountable. They must be mandated to cover removal costs and train the patient's chosen surgeon, because not everyone is well enough or can afford to fly across the country for care. Actually impose penalties and public reporting of manufacturers and healthcare facilities that fail to notify all affected patients. They should be subject to fines, exclusion from government programs, and held accountable for recall-related costs.

Noncompliance should result in the suspension of operating status, not a warning letter.

Today, I've chosen to focus on representing my clip community as a whole rather than the details of my 18-year struggle with 23 surgical clips. I understand you've probably been informed of all of my points before; however, it's crucial for my community to know that we've made our concerns known. The key to preventing recalls is to establish regulations that prioritize safety and comprehensive documentation from the very beginning. Thank you for having me today.

MR. WATSON: Thank you.

We'll now take a 25-minute break. Since I was not a math major, and I like even numbers, and I like breaks, we will come back at 10:50, and after the break, we'll resume with in-person speaker number 14. Thank you.

(Whereupon, at 10:22 a.m., a recess was taken, and the meeting resumed at 10:51 a.m.)

MR. WATSON: Thank you for a good morning so far, and everybody's doing a good job in keeping

their presentations on time.

A couple of notes, we are going to go through to noon to make sure the kiosk is staffed and ready to go. So we will push through until noon, so if we have speakers that have come after lunch, you may be before lunch. Also, I heard there's a delay sometimes, if you have a presentation, of your slides showing up here, so just wait for your slides, and don't feel like you have to start until your slides are showing up here. Again, we're doing five minutes, and like I said, you all have done a great job so far.

We are going to start with speaker number 14, and then after that, we'll go to virtual speaker number 15.

[Slide 51]

So if speaker number 16 would go to the next speaker chair, then we'll have speaker 14 come on up. Thank you.

[Slide 52]

DR. HOELZER: Fantastic. Thank you so much to FDA for holding the meeting and for all of you

for being here. I am Dr. Karin Hoelzer, and I represent NORD, the National Organization for Rare Disorders.

Next slide, please.

[Slide 53]

We are an umbrella organization for about 330 disease-specific patient groups in the rare space. We were founded 40 years ago after we played a key role in getting the Orphan Drug Act passed because we realized that if we speak across the rare disease space with one voice, we can move mountains, and I'm really excited to be here and present the rare perspective.

Next slide, please.

[Slide 54]

I thought I would start with just a really brief summary of what rare diseases are and how our patients intersect with FDA. In short, in the U.S., a rare disease is any disease that impacts fewer than 200,000 individuals. And that might sound like not a lot, but we know that there are more than 7,000 known rare diseases, so by and

large, more than 1 in 10 Americans are impacted by rare disease, so many of you in the room probably know somebody, or yourself, affected by a rare disease.

We know that the vast majority of our rare diseases have no FDA-approved therapies, and many of our diseases are genetic and occur very early in childhood and lead to debilitating impacts and premature death. All patients tend to be what we call medically complex, which means that they require a lot of different therapies. So if you think about the types of products that FDA regulates, chances are that, pretty much, each of them is used by a rare disease patient that includes your traditional small molecule drugs, your more traditional biologics, and your cell and gene therapies. Most cell and gene therapies have been developed to date for rare diseases. It includes medical devices and, of course, it impacts food and pet food as well.

Oftentimes, our patients use more than one product at the same time, and because we have small

populations, a lot of our use is off label, which means that when it comes to recall communication, our communities and our off-label users are easier to forget. Then for us, the medical products that we use tend to be really important for managing our health, so if there's a recall, there's not just the direct physical risk of the tainted product, but there is also the impact of supply chain disruptions and the fact that it might be very difficult for our patients in the month after recall to get the product that they need to manage their health.

Many of our diseases are degenerative and progressive, and they oftentimes start in childhood, so not being able to get the products that are needed to maintain health or reduce the impact of the disease can be really stressful and really debilitating for us.

Next slide, please.

[Slide 55]

So what are some of the challenges that we're hearing from our community with recalls? The

first is that oftentimes our patients aren't even aware that there was a recall. If they are aware, oftentimes it is really difficult to decipher the recall notices because they're usually not written with the patient or caregiver in mind. Then, most recall notices really miss some very actionable, tangible information, and whom to reach out to for more information or what to do. And again, our patients usually don't have a lot of treatment options, so if their product is recalled, it becomes very difficult for them to figure out how to continue to manage their health.

So very often the very first call is to alert treating physicians, and oftentimes with things like implanted devices, it is very hard for our patients to even know if their products are impacted by the recall, and I know we heard about that this morning already.

Next slide, please.

[Slide 56]

Let's start to think about some of the ways to change this. First, our patient communities,

because they're so small, tend to be really tight-knit. Facebook I know was already mentioned this morning. It's a wonderful way of getting the word out. Working with the patient groups and working with the patients to really spread the word, those are very tangible ways to make sure that at least patients know when a product is recalled.

Pilot testing with messaging with our community, speaking for our community here, we would love to help. We would love to look at these messages. We would love to do pilot testing to make sure that what you are putting out there for a recall notice actually is understood the way you intended it to be understood and it was actually helpful.

One of the biggest challenges that we hear from our patients over and over again is give us a place to call or reach out for more information, so really having a tangible person or address to reach out to that is accessible to our patients, and they can give them helpful advice for how to continue to

manage their health if their product is recalled is really important. Then, as I said before, usually our patients have very long-standing relationships with their treating physicians. They oftentimes travel across state lines and fly across the country to see the specialists that have seen their disease before, so they will be the first person that the patient with a recalled product will reach out to. So make sure that these physicians have the information they need to be helpful. Support them, give them the information, and give them the tools to help their patients.

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[Slide 57]

Just a word about diversity, equity, and inclusion, these are some general findings from work that we've done trying to better engage our whole patient community, but I think many of them are really important if we want to make sure that recalls are equally accessible to and understood by everyone in the patient community.

First, we know that our patients usually

face more than one challenge to equitable access, we know that a long-term view and partnership is really important and, again, we know that the barriers to equitable access are not the same for everyone in the patient community, and that's for each of our 7,000-plus rare disease communities, so again, partnership is really key.

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[Slide 58]

If you don't take anything else from my presentation today, the two points I want you to take home are, first, rare disease patients are probably using almost every product that is impacted by recall, so please don't overlook us and partner with us. Partner with us in preparing for recalls in getting the word out and in figuring out how to be more effective. We are here to help. Our lives and our patients' lives depend on effective recalls, and I really appreciate FDA's recognition of the need to reform recalls and the opportunity to be here this morning. Thank you.

[Slide 59]

MR. WATSON: Thank you.

Speaker number 15, please unmute yourself, turn on your camera, and introduce yourself.

(No response.)

MR. WATSON: Okay.

[Slide 60]

Speaker number 16, please proceed to the podium, speaker number 18, please proceed to the next speaker chair.

MS. SHIELDS: Hello. My name is Richelle Shields. Thank you so much for having me here today to talk to you. I really appreciate it. Our son, Chase, was 3 and a half when he got sick from a glass of juice. My mom had given him a glass of juice as a treat. It was labeled as a food health drink. It was wonderful, and Chase loved it, so he drank this juice, and a week later, we left for a trip to the ocean, and our kids were super excited. We have 4 kids, and they were super excited to go to the beach, see Keiko the whale, and play on the beach. My husband flies hot air balloons, so he was going to take them up. They were going to be

around all their friends, and we were just going to have a wonderful vacation.

Well, in the middle of the night, Chase started to throw up, he had diarrhea, and he ended up not even being able to hold down a glass of water. He was so, so sick. That morning, we decided we had to drive back to our hometown of Bellingham, Washington and get him to the hospital or to a doctor. So as we're packing up our children, they are devastated. They don't understand why they don't get to see the whales, they don't get to go in a balloon, and they don't get to spend time with their friends.

They were surely really, really sad, but they were really sad that their little brother was so sick, so they understood that we needed to leave, but it's a 4-hour trip, so we got there and then left, basically, really early in the morning. So they were just really, really devastated, and we were worried about Chase.

So we got home, and my husband called the doctor, Chase's pediatrician, and said, "Well,

Chase maybe has the flu. We think Chase has the flu, maybe some simple bacteria." And the doctor said, "You need to bring Chase in." So we brought him in to the doctor's office, and the doctor said, "You know, let's run some tests." So he took some blood and sent it to the lab. We were fortunate because we had a friend who was working in the lab that day and said, "You know, I'm going to run this. I'm going to go ahead and run this and make sure it's not *E. coli* 15787." And he ran the test, and sure enough it came back as *E. coli*.

So they admitted Chase to the hospital, and we were with him when the doctor told us about hemolytic uremic syndrome. He said, "This is a multisystem disease that causes severe kidney failure." It can cause heart problems, seizures, bloody mucus. You would need transfusions. You had to have low platelets and low red and white blood cells, and some kids even die from this. So our doctor sat us down and said, "Chase has hemolytic uremic syndrome, and we can't treat him at your local hospital."

So here we have three other children, and we have to drive down to Seattle, which is a 2-hour drive for us, and we are like, "What do we do with our kids?" It's just devastating to know that we had to leave them and find a babysitter as Chase was put into an ambulance. He's tied down. He's screaming in pain. He is so scared but so lethargic that he just has severe headaches and is still vomiting and having diarrhea, and he's just terrified.

So we get into Children's Hospital, and right away Dr. Tarr [ph] meets us there, and he says, "We need to get a catheter to make sure he has some urine output." And they tried and tried, and the nurse said, "I can't get it in. He's too lethargic. There's just no way to get this catheter in." And the doctor said, "Don't worry about it; he's in acute kidney failure." So they admitted him into a room there, and they said, "He's going to need dialysis," so they put him into surgery, and he made it through, pulled through that surgery, and he was on dialysis every day, and

after 17 days of being in dialysis and us being in this hospital away from our children, they told us that 15 percent of children after 14 days need a kidney transplant, so we were very concerned and very worried.

Chase still had no urine output, and pretty soon he was just puffed up like a balloon ready to pop. If you just touched him, he bruised. He was just so, so sick. The doctor said, "He's not out of the woods. There's a chance he's not going to make it, and he will get worse if he gets better at all." And he just wasn't getting better, and one day during during dialysis, they couldn't even give him dialysis because his line had a blood clot in it, and they couldn't get heparin to work to unclog the clot, and he had a seizure, and we were just devastated. Here's our little guy in there, basically, near death. He was dying, and we were just really, really devastated. We went back to our room, and he was in the hospital for a month. They had to do a new line, and he was there for a month on dialysis.

Then one day, he just had a little bit of urine, and the next day he had more, and the next day more. They were able to pull the dialysis line out and he was able to come home, but he still has permanent kidney damage. He had to relearn everything because of the seizures. He was only 3 and a half in preschool, but he was at top of his class, and after he got back, he didn't know a number, he didn't know a letter, and he struggled with learning disabilities from that point on.

He got lots of help, and he's very smart, but it was just awful. We had to go into the hospital every day when we got home for him to have his blood pressure checked twice a day. They said, "No, you can't do it at home; this is too important. We really need you to do this at the hospital." So every day, we drove to the hospital twice a day to have his blood pressure checked. He still has to be checked today. He watches his blood pressure. He has permanent kidney damage, and he has to watch that. They said even as he got older, like as teenagers, they were saying he had a

high chance of a kidney transplant because of all the damage that had been done from the HUS.

Even now today, he's past teenage years, he's married, and he has a wife, and he has a lovely home that he's fixing up. And he's doing well, but he still runs a chance of needing a kidney transplant. They said by the time you're in your 40s or 50s, he may need one just because of what we put into our bodies. We don't always eat healthier, we don't always exercise, or we drink alcohol, or just things we do as adults that are different than what happens when we're children, so they said he always has to watch that.

So Scott and I, after we got home, we got involved with Stop, the alliance, and we really would hope that the FDA would have recalls a little quicker. We were able to talk, about five years ago, in Botheil to the FDA, and as we were telling our story, I passed out a picture of Chase in the hospital hooked up to all kinds of lines, and they had said to us -- afterwards, they came up, and some were crying. Some of FDA came up and said,

"We're going to keep this picture, and we're going to put it either up on our desk or up on our bulletin board, and it's going to remind us of what we're working for every single day."

So we really, really appreciated that, and we knew that they really meant it, that they were going to do their best. But we haven't seen as much change as we'd hoped to in the recall process, so I'm asking the FDA to make the recall process a top priority, to react quickly, so that lives will be saved. Thank you.

(Applause.)

MR. WATSON: Thank you very much.

[Slide 61]

Speaker number 17, please unmute yourself, turn on your camera, and introduce yourself.

MS. KINARD: Hi. My name is Madris Kinard, and I work for Device Events. Do you have my slides available?

[Slide 62]

Thank you.

So as I mentioned, I am the CEO of Device

Events. It's a company I started after working for the FDA. When I worked for the FDA, I was the Unique Device Identification Manager, which is the UDI -- it's kind of like a UPC for devices -- and I was the subject matter expert for medical device adverse event reporting. In the year 2000, if anybody remembers, there was a Firestone tire recall, and I was the manager for the network news outreach, so my role was to create a sense of urgency to be sure consumers knew they needed to have their tires replaced immediately.

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[Slide 63]

Two-thirds of medical device regulatory actions begin as an adverse event report. These include device recalls, warning letters, field safety notices, and they often take 2 months to 2 years to address. The vast majority of these recalls are manned or voluntary and often even coincide with the release of a newer version of the device. This allows users, meaning care providers and hospitals, to believe that the recall is not as

serious because it was not made mandatory by the FDA.

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[Slide 64]

Thank you.

So there is a difference between a recall and a commercial withdrawal, and I wanted to point those out today. Sometimes devices are removed from the market and there is no recall, and when that happens, hospitals only learn of a withdrawal when they seek to reorder a device, so hospitals use up the rest of the stock. If there's a recall, hospitals are notified and physicians are notified. With a commercial withdrawal, physicians often think a newer version means the device is improved. Physicians who have already paid for the devices continue to implant them.

Some patients are notified about recalls and most are not. There's no patient notification and limited funding available if an explant is needed after a commercial withdrawal. A good example of this would be the Essure device that was on the

market. That was a commercial withdrawal, and to this day there are now 56,500 hysterectomies because this device was not recalled and it was not pulled from the market early enough.

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[Slide 65]

When recalls are classified by the FDA and made public, they are assigned a device problem code, and most of these device problem codes are never updated by the manufacturer. So where this one says, "under investigation by the firm twice," that is the most frequently used device problem code by the manufacturers and that is not updated. There are recalls as far back as 2019 that still say "under investigation by the firm."

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[Slide 66]

So there are steps that the FDA can take now. We can learn from the challenges of the past to improve data collection. We can use electronic health records and claim systems to scan in the UDI of a device so that we know what is being used on

the patient. I'd like to request that the FDA not allow market withdrawals when the device needs to be recalled; provide the public with an easy way to scan or enter their UDI label to learn if their device is part of the recall; add features to the AccessGUDID database. This is the UDI system that the FDA already has and it does have the capabilities -- my Device Events software is built on the same platform, so I know the UDI system very well. It has the capability to include black box warnings, recall notices, instructions for use, and device materials such as alloys. Right now, we have a system in place that could be a very good publicly facing system for patients if they use it the way it can be used.

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[Slide 67]

The FDA needs to work with Congress to address inefficiencies. One of the ways that we're looking to do this is the Medical Device Recall Improvement Act, which was presented on the floor of the Senate and the House last week, and it will

require electronic communications between the FDA, hospitals, and patients when available, and it will mandate that providers contact patients in the event of a recall; ensure that when adverse event follow-up reports are submitted to the FDA, that the manufacturer received date or aware date cannot be changed to make the event seem more recent; and increase the number of FOIA staff to review and redact adverse event follow up reports, and they're currently five years behind; and finally, update the definition of a user facility to include physicians' offices. The practice of medicine has changed drastically in the last 10 years, and when there's an adverse event from surgery or elective procedure done in a physician's office, those physicians and health providers are not mandated to report to the FDA.

I really appreciate your time and letting me speak today. Thank you so much.

MR. WATSON: Thank you.

Speaker number 18, please proceed to the podium.

[Slide 68]

Speaker number 21, please proceed to the next speaker chair.

MS. DUDLEY-WELDON: Hi. I'm Monica Weldon. I'm the President and CEO of the SYNGAP1 Foundation, which is an ultra rare disease that causes brain development problems. Thank you for the opportunity to present potential considerations to help implement efficient policies and frameworks for food and drug recalls. The initiatives are aimed to enhancing regulatory processes, including the effectiveness of comprehensive recall distribution notifications and most importantly, prioritizing patient safety.

One key proposal is establishing a federated AI database system comprised of multiple networks specifically designed to aggregate pathways, disseminating information through multiple sources. A database such as this could potentially allow real-time drug recall tracking, incorporate mapping systems, and eliminate silos. It would make it significantly easier to identify specific target

products, in turn, potential and direct targeting of affected individuals in the event of a recall, thereby creating a robust infrastructure for monitoring healthcare technologies effectively and incorporating the concept of a federated AI-driven database as a new involving innovation, helping to streamline quantifiable data the drug and food industry can utilize for various outcomes.

Collaboration is also a vital component of these frameworks. It envisions manufacturers and distributors working together with healthcare providers, patient advocacy groups, and potentially other government agencies combining forces to share information. This collaborative approach would investigate recalls and ensure swift and effective responses to safety concerns, bringing effective collaboration with all stakeholders, creating new strategies, and identifying potential gaps in existing policies.

While the FDA primarily disseminates recall information to the public healthcare professionals and relevant industry stakeholders, insurance

companies are not directly involved in the standard process. Payers often work closely with healthcare providers and private sector client bases that have the potential to be informed of recalls through those channels.

By casting a broader net, collaborating with other government agencies that have existing digital framework who monitor drug and disease control at the federal and state levels, can serve additional communication channels. For example, the DEA, the Drug Enforcement Administration, is crucial in regulating controlled substances nationally.

This existing framework provides capable means and the ability to track controlled substance prescriptions as a potential conduit for information dissemination, reaching an additional level of opportunity to a broader population at the state level with the use of existing prescription drug monitoring programs that collect, and track, and monitor controlled substance prescriptions.

Other examples of an extra potential layer

is partnering with the CDC using diagnostic information from ICD 10 codes. Utilizing the data can be helpful in early identification for disease-specific conditions with existing standards of care, helping identify commonly used drugs and, in turn, notifying disease-specific organizations and patient organization networks. Information integrated into AI database can accurately track and monitor their specific disease populations.

In the U.S., a large percentage of households have access to the internet. According to the U.S. Census Bureau and American Community Survey, in 2020, approximately 89 percent of all households had a computer. Around 76 percent had a broadband internet subscription; however, 96 percent of all adults in the United States have a mobile phone. Like other automated systems that distribute information to consumers, a database would facilitate direct recall notifications, and pharmacies responsible for distributing these products.

For example, patients could opt in for

notifications through text or other digital means at the time of purchase, helping to consolidate pertinent contact information into a database, facilitating a systematic more efficient process. The system ensures consumers are notified in the event of a recall promptly.

Patient organizations can also be pivotal in disseminating recall information to their communities. As the FDA evolves into growing focus on patient centricity, collaborations are key with patient organizations and nonprofits. These relationships, growing the ability to effectively reach specific patient populations and community, directly affect potential drug recalls. Forging partnerships with influential patient member organizations like the National Organization of Rare Disorders, to extend recall outreach gaps into their networks, is a resource that could effectively reach underserved and smaller disease populations that use off-label and specialty drugs.

An additional benefit would be working with disease-specific groups that may create an adequate

opportunity, including recall education and patient-focused drug development meetings and listening sessions. Working with patient organizations and nonprofits enhance the ability to reach specific patient populations and communities, including underserved and rare disease populations.

In conclusion, these potential frameworks, enhancing the regulatory process, promoting transparency, and safeguarding patient safety through technology and collaboration, and for proactive strategies, these solutions seek to create a more efficient and more effective system for food and drug recalls, benefiting patients and healthcare providers, and thank you for your attention.

MR. WATSON: Thank you.

A note for our online presenters, if you are a presenter online, you must log into Zoom. If you only call in, we won't know who you are, so we can't promote you to a panelist. So again, if you're an online presenter, please log into Zoom.

[Slide 69]

Speaker number 19, please unmute yourself, and turn on your camera, and introduce yourself, please.

MR. RAPP: Just waiting for my slides here.

[Slide 70]

Thank you to FDA and to all of today's speakers and attendees. My name is Adam Rapp, and I'm outside counsel to Gluten Free Watchdog, which is an independent testing, informational, and advocacy organization devoted to the gluten-free community. We'd like to share today one of our recent experiences with FDA's Freedom of Information Act program and process, and some feedback on what we've learned that can help inform recalls.

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[Slide 71]

First, Gluten Free Watchdog is a private, subscriber-funded organization founded more than 10 years ago to advocate on behalf of the gluten-free community, primarily through testing, empirical and otherwise, of gluten-free claims made

on consumer food products.

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[Slide 72]

So we're here to talk about Gluten Free Watchdog's experience with The Salsa Texan, which is an independent food seller in the Dallas, Texas area. This entity had a small physical and online footprint, selling over the internet through its Facebook page and at local farmers markets in the Dallas area. It was advertising gluten-free coconut flour tortillas that some consumers had been raving about, but for those of us in the gluten-free community, we know that if a product sounds too good to be true, it probably is.

These coconut flour tortillas caused illness in a minor female, which was reported to Gluten Free Watchdog in October 2021. Third-party testing showed tens of thousands of parts per million of gluten, which is hundreds of times the FDA's acceptable level for gluten-free foods and on par with raw wheat flour.

After a series of FOIA requests beginning in

2021, Gluten Free Watchdog has sought to gain more insight on the recall process FDA implements for misbranded gluten-free foods, and we did so here in March 2022 for Salsa Texan shortly after this recall was announced, and based on what we learned, we have three suggestions today. First, improve turnaround time on these sorts of recalls; second, ensure that the target's responsibility to be truthful has some real teeth; and third, be consistent in how gluten-free misbranding is treated in the recall context.

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[Slide 73]

We have a timeline here, and as you'll see, there are some key time gaps that jump out. The first is a more than 4-month delay between the initial report and action by FDA, particularly where there is more information at the starting line than in other consumer product reports, and here we had third-party testing results. Consumers would benefit from a more robust and immediate response.

Second is the additional gap of time before the voluntary recall was expanded in scope. This expansion broadened the scope to all SALSA Texan and flour tortillas, given that the target had no labeling or lot codes according to FDA's records that we reviewed after the FOIA.

Third, and putting together what we know from the community with what we learned in the FOIA process, we've demonstrated delays between purchase dates and actual testing results, and this is important but frequently overlooked. We learned that these tortillas were very popular, and people from far away were placing bulk orders and freezing it for future use, so this should be considered in calculation of recall windows.

It's important to flag here that all of the testing that Gluten Free Watchdog conducted here was of products that were outside the recall window at the time they were tested. And the fourth is that it took some time to get responsive documents to us, and we want to emphasize that Gluten Free Watchdog and other groups like us have the

opportunity to work together with FDA per Erik Mettler's good suggestion this morning. The Gluten Free Watchdog could have done more had we known sooner, and we can help get the word out to the communities that matter most.

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[Slide 74]

What were the key issues and areas for improvement? Some figures here to wrap up; nearly 65,000 parts per million of gluten in the initial testing, and follow-up tests confirmed this and showed more. Paired with the consumer illness that accompanied the report, these data should flag the product as significantly out of compliance and warranting a robust response. This was a dangerous product, intentionally misbranded so it would be more attractive to an at-risk population, and it made a child sick.

More than 4 months between the initial contact and the voluntary recall is our second data point. We learned that the target of this investigation was stonewalling and in some cases

flatly lying to FDA investigators, and we only learned that from the FOIA request itself. Now, if FDA had a good-faith basis to believe that the target's representations couldn't be trusted, that's additional valuable information to consumers that can be made available sooner. And even if the endpoint of an investigation is a successful complete recall, a target's repeated misleading of FDA is significant, and we recommend that the FDA implement a process for evaluating and publicizing the truth or falsity of what targets are telling them in connection with recalled products.

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[Slide 75]

So to wrap it all up, we're of course grateful for FDA's critical role in ensuring consumer safety for all food products within its remit, but we urge FDA to broaden its information gathering so that parties beyond the target have a role in the process and can help FDA see the whole picture.

Finally, we caution FDA that pointing

consumers to the target itself for responsive information may not be the best practice in all situations. Direct outreach and leveraging outside organizations like Gluten Free Watchdog can help reach target audiences more effectively. Thank you very much for your time.

[Slide 76]

We look forward to continuing to partner with FDA.

MR. WATSON: Thank you.

Speaker number 20, please unmute yourself, turn on your camera, and introduce yourself.

[Slide 77]

MR. GUNASEKARAN: Hello. I'm Kert Gunasekaran, Director for the --

[Slide 78]

-- Science of Patient Input program at the Medical Device Innovation Consortium or MDIC in short. MDIC is a 501(c)(3) unique public-private partnership, advancing regulatory science of medical technologies for patient benefit. MDIC provides resources and leadership in

collaboratively developing solutions for regulatory, scientific, and health economic areas to remove barriers for patient access. I'm also a heart patient and more recently a device patient. I've also been in the device manufacturing sector for over a decade. Both my personal firsthand experiences and as a Director for the Science of Patient Input program at MDIC helped me prepare for this listening session, specifically to talk about medical devices.

First and foremost, I would like to wholeheartedly commend FDA for the continued focus on the recall processes, including conducting this listening session. Thank you. The low-hanging opportunity is for FDA to consider increasing adoption of its recall communication subscribers. This can include ongoing promotion on social media to encourage the general public to sign up; in fact, it can further recall awareness, as noted by several speakers, by maintaining social media pages and active accounts on such platforms as LinkedIn, Facebook, Instagram, X, and of course TikTok.

FDA can lead the industry by example here when it comes to both directly collecting patient input regarding recalls and communicating critical class 1 and class 2 recalls that impact public health in such platforms. This will allow patients to scan through very familiar platforms and interfaces on mobile devices and PCs for current and prior recalls.

Next, in rural areas, in addition to informing healthcare providers, unusual yet valuable allies for recall communication can stem from leveraging post offices, established fast-food chains, volunteer firefighters, and religious institutions in the area. Outreach efforts encouraging training on product recall communication in such entities can prove to be welcoming and valuable support in remote communities.

A recall communication actually formulates well before a recall; in fact, when there isn't a recall, but during actual use of the product with a patient. Product labeling must include UDI and

clear information to learn about products of interest directly from the manufacturer, and this digital destination conveyed through the label should also help patients learn about new or past recalls and the residual product risk information for comparison. This will help patients understand change in risk during a recall to help them have better conversations with physicians.

Such a digital destination or web page can also help enable patients to register themselves as an end user of the product directly with the manufacturer. For implanted devices, patient registration data must be enforced at healthcare facilities and with manufacturers within the time frame upon sale or use of a device. Currently, device information or web pages traced from labeling disclose only product benefits while excluding product risks, adverse effects information, and current and historical recall data. Any sample product label information for most manufacturers can be used to verify this large informational gap.

Next, reducing recall references. FDA can leverage well-studied statistical signal detection techniques and control charts enhanced by leveraging machine learning technologies to detect signals from the adverse event reports an FDA manufacturer and user facility device experience, i.e., MAUDE database, to help FDA proactively work with manufacturers to potentially prevent a recall. This especially is more viable in recurring recalls where signals are already evident.

Every recall communication by a device manufacturer to patients should be viewed and must contain two parts; first, when it was initiated or published, and second, when it is considered closed or terminated. The closure data must include clear timestamps, impacted models, UDI information, and present device options that patients may wish to revert to or benefit after the recall. You cannot leave patients hanging.

One last check and balance that can be critical for patients in hospitals is either as part of procedure prep activities and/or part of

informed consent processes and paperwork that is a checkbox that rules out pending recalls on to-be-used devices on patients. This will reinforce healthcare providers to check for recalls frequently and reassuring vulnerable patients. Thank you for listening.

MR. WATSON: Thank you.

Speaker number 21, please proceed to the podium, speaker number 26, please proceed to next speaker chair, and we're kind of on time now, so you may be either the --

[Slide 79]

-- last speaker before lunch or the first speaker after lunch, and speaker number 22 will be our next virtual speaker. Go ahead.

MS. McGILL: Good morning. My name is Julie McGill, and I'm the Vice President of Supply Chain Strategy and Insights at Trustwell. Today, I am speaking on behalf of AIM North America, and I'm the co-chair of their Food Supply Chain Work Group. AIM North America is a not-for-profit association, enabling the cooperation, development, and

standardization of automatic identification and data capture, which is also known as asset tracking or AIDC technologies.

Our membership represents resellers, system integrators, software developers, solution providers, manufacturers, and distributors of these automatic identification and mobility technologies in North America. We are a technology agnostic open resource for the FDA, and we thank you for the opportunity to speak today.

I would be remiss if we didn't take a second and recognize all of the very courageous speakers. I know some of you who are here today have never been in these meetings before, so we appreciate you sharing their stories. I'm going to get a little choked up. I have a very similar story. Unfortunately, my nephew who had *E. coli* did have to have a kidney transplant, and he has had a pancreas transplant, and no family should ever have to go through this.

The FDA provides a pivotal role in safeguarding public health and regulating the

safety and efficacy of medical devices, pharmaceuticals, food products, and other items that are on their list, and one crucial aspect of its mission is monitoring and initiating recalls when necessary.

Creating successful recall strategies is a challenge. Products may need to be pulled from many different training partners in many different locations, including warehouses; the back of a restaurant; off the shelves of a grocery store; out of a cabinet in a surgical theater; or a pharmacy. Reaching the end consumer to get items out of refrigerators, or pantries, or out of medicine cabinets is a huge concern. The sooner that we can identify these items, communicate the details, including instructions for removal or destruction, is critical, and once that is done, companies need to account for their actions and report back to local and federal agencies.

Modernizing our approaches to recalls will require modern technologies so we can connect the physical world and the digital system. To see real

change, we recognize the importance of standards, unique identification, data sharing, and interoperability. AIDC technologies enable automation, accuracy, and increased efficiencies for recall operations. Modernizing recalls will require data gathering from across our supply chains similar to what we have seen with the Drug Supply Chain Securities Act, Unique Device Identification, and the Food Safety Modernization Act, or FSMA, Section 204.

These regulations play a pivotal role in supply chain visibility and traceability by providing a framework of activities and define data attributes, and we encourage the FDA to take this into consideration as you begin working on recall modernization strategies. Industry stakeholders, solution providers, and industry groups are currently using terminologies such as "key data elements" and "critical tracking events" in their businesses and in their solutions today, so let's continue to build on that foundation.

AIDC technologies such as barcodes RFID,

IoT, and Ambient IOT have revolutionized supply chain visibility and traceability, and from that data, it has also revolutionized recall management in many, many ways. AIDC enables users to attach unique identifiers to products and allows for precise identification and isolation of affected items during a withdrawal or a recall. This not only reduces the scope, but it minimizes disruptions to supply chain and helps protect consumers from potentially harmful products.

These solutions streamline communication between stakeholders because they provide real-time data sharing with enhanced visibility, and users have better data to recall notifications and updates. Modernizing recall technologies allows us to put that data not only in our operations, but also out to consumer-facing platforms such as mobile apps, automated text messaging, and social media to notify consumers quickly and effectively.

So what is our current state? Although technologies have evolved, many industry partners have not automated their recall processes or

adopted tech-enabled solutions. Many rely on phone centers, customer lists, spreadsheets, and printed notifications. These approaches are slow, they're inefficient, which can be harmful or even life threatening to a consumer. In today's global economy, information is imperative to operate safe and effective supply chains. AIDC and tech-enabled recall solutions can capture, store, analyze, and share information when time is short and lives are at risk.

Safety and quality assurance is a fundamental responsibility of all food and pharma companies, and by utilizing these systems and solutions, we do have an opportunity to streamline our operations, enhance communications, and most of all, protect public health. It's time for the industry to evolve and embrace recall modernization. Thank you.

MR. WATSON: Thank you.

Speaker number 22, please unmute yourself, turn on your camera, and introduce yourself.

[Slide 80]

MS. LAPPIN: Hi. My name is Maria Lappin, and I am here to point out the facts.

Do we have my slides?

[Slide 81]

Thank you.

I'm here to point out the fact that unless the medical community is made to receive, understand, and respond to the information that you provide to them, then nothing is going to change, and we are all wasting our time here because some of us are dying due to our responses of implanted devices.

I am the founder of an education-only based cannabis company in the state of Michigan, which was developed throughout my health crisis, as I managed to survive a reaction to 5 titanium clips within my neck. I lost my career as a hairdresser in 2020, as I experienced my final back blowout, which now I know was a direct result and the response my body was in due to the clips, all based on the information that you, the FDA, has already researched, verified, and documented, that is shown

here, starting on slide 1, where you describe your executive summary in the Center for Devices and Radiological Health in the FDA, and its background, according to its mission statement in the FDA, is responsible for protecting the public health.

Slide 2.

[Slide 82]

The biological responses to metal implants that you released in September of 2019 states that other metals used, such as nickel and titanium and aluminum, are non-essential for human health, and when present at sufficiently high concentrations, can disturb normal biological function and result in cellular stress that may affect various tissues.

You go on to show the potential adverse effects of these metals once inside of us: pseudotumor formation; cancer concerns regarding cobalt and nickel; lymphoma; leukemia; prostate cancer; and melanoma; and its association to biological implants. And yet, the surgeon that placed my surgical clips specifically stated that metal doesn't cause any issues inside the body once

I found them 4 years after they were placed.

Slide 3, please.

[Slide 83]

Here we see mutations in other types of DNA damage and cancer potential that can be associated with biological implants. The corrosion of metallic implants may potentially increase the genotoxicity and carcinogenic risk. My surgeon was Dr. George Yu from Karmanos Cancer Institute in Detroit, Michigan, and as he is a head and neck surgical oncologist and a professor in the Departments of Otolaryngology Head and Neck Surgery at Wayne State University and Karmanos Cancer Center, if he would not listen to my concerns, then how can he relay the information back to you, the FDA, that there are reactions happening?

If your documentation states that you are responsible, how do you force him to allow you to uphold that statement? I would like to know exactly who's responsible for the 7 biopsies that I had on the tip of my nose, after the titanium clips were placed in my neck, because five of those

biopsies were in and after 2019, which leads me to my next slide 4 --

[Slide 84]

-- titled, The Statement from the FDA Commissioner and Director, released March 15th of 2019. Beginning at the bottom of page 4, it states that the symptoms some patients may experience include, but are not limited to, fatigue, rash, joint and muscle pain, and weakness. Although uncommon and varied, these symptoms may share common underlying immune inflammatory pathways and mimic well more established inflammatory conditions such as mine.

Please go on to slide 5.

[Slide 85]

The titanium clips were placed in 2013 on both sides of my face, as you see in the X-ray. I was not included in my healthcare plan, possibly because surgical clips fall under the standard of care and the medical community does not feel that their patients need to know everything that surgeons do to them once asleep, as my surgeon,

Dr. George Yu, stated. I bring this to your attention because not only is he a professor but a research educator, a chief medical Officer, a physician-in-chief, and the director of Clinical Affairs at the Karmanos Cancer Institute. I was not tested for metal allergies nor told about the clips deemed by you, the FDA, to be inert, but also to the nickel that is within the metal, as well as other alloys.

Again, you state that you're responsible for all biological implants. You also state that certain metals can bring forth negative health responses, yet you are not holding the medical community accountable for receiving the information that you developed and released. I had no help or support in my medical community in the state of Michigan, possibly because their continued response to my concerns were always discredited, and they had never heard, or been taught, or notified that there has been a discovery made by the FDA, who tends to regulate most things that we ingest, whether we know about it or not.

I found a surgeon in Massachusetts that graciously saved my life by removing the 5 titanium clips May 31, 2023, exactly 10 years and 1 day after they were placed, and since Doctor George Yu and the Karmanos Center in Detroit stated that they will not address my clips and to go elsewhere, as you can see in the letter on my presentation.

Slide 6, please.

[Slide 86]

Look at my nose. It is healed. The scar tissue has been reabsorbed and the lesion is gone from just removing the metal in my neck. Please take a look at what it cost me, and this is just over the past two years.

MR. WATSON: Maria, I'm going to have to ask you to wrap it up. Sorry.

MS. LAPPIN: Look at what it costs for the FDA to not communicate with the medical community and hold them accountable. Please connect your dots. You have all the information. You need to apply it. Thank you.

MR. WATSON: Thank you.

Would speaker number 23 please unmute yourself, turn on your camera, and introduce yourself?

[Slide 87]

MS. VALORAS: Hello. I am Danielle Valoras. I'm a physician assistant that has worked in the medical device field for over 20 years --

[Slide 88]

-- and currently working with patients that have significant reactions to implantable devices such as breast implants; orthopedic devices; dental implants; gallbladder clips; staples; et cetera. The FDA plays a pivotal role in safeguarding public health, but like any system, it has its challenges, particularly when it comes to the recall of medical devices. In the next five minutes, I will shed light on some of these issues and why it's crucial to address them.

Gap 1, ensuring safety of medical devices, this begins even before classifying a device into like class 2 or class 3. When we purchase a medical product, we expect it to be safe, reliable, and

tested; however, the current process often relies on older devices or predicate devices for approval without rigorous testing, and they lack long-term and real-time data to support their safety and biointeractions. This process can pose serious risks to patients. We believe that continuous testing and periodic reviews of the old testing methods and materials that are used, they're essential for the well-being of patients. Waiting decades to identify a device as ineffective or dangerous is unacceptable. The FDA should strive to ensure the highest safety standards for all medical devices and for all classes --

[Slide 89]

-- and this includes ongoing assessment of products and methods for manufacturing.

Gap 2, this is a big one. This is a big topic around data. We heard a lot about it today already. We need to improve the data collection, the reporting, the oversight, and the management. Underreporting adverse events is a significant issue, leading to incomplete data. The

manufacturer and user facility device experience, the MAUDE database system, can provide invaluable insights. This tool, though, is currently being underutilized, and as such, adverse events are underreported. We propose mandatory reporting of the adverse events by physicians and healthcare practitioners.

We also need flexibility to be able to report all problems, even the new ones that don't currently fit into the existing categories within this database. Terms like "breast implant illness" and other terms can't be bucketed accordingly. If we can't report them, we can't track them, and we don't have the real-time data. Then there's the gap of tracking devices. Some medical devices like breast implants lack the unique identifier. If we can't track them, we cannot obtain real-world numbers or even reach the patient that may have a recall implantable device.

Another gap with data collection is other registries. For example, breast implant registries, while seemingly useful, fall short in

addressing emerging health concerns. When a physician completes the input for a registry, they often believe that they have fulfilled their obligation to reporting to the FDA, and as such, that data remains unexamined by the FDA, hindering timely identification of issues. It is evident that we also need to do more than just collect the data. We must be able to utilize that data, enhance data collection, and reporting. It's obvious that there must be accountability along the way as well. If we want prompt action, we must be able to access all data, even for the less severe issues, and as such, we should adopt user-friendly software tools like Device Events. A tool like this can help analyze complex data more effectively.

Gap 3. Gap's an FDA classification.

[Slide 90]

If we don't have real-world numbers, as mentioned above, how can the FDA make informed decisions to guide the recall? How can the FDA discern the probability of the adverse events or

the probability of safety? Clarity in the recall thresholds can help prevent tragedies caused by delayed responses to emerging issues.

Gap 4, gaps in the recall strategy development. Currently, there are key differences between an FDA-initiated recall and a manufacturer voluntary recall.

[Slide 89]

At the end of the day, we need to see ample proper and unbiased notification to hospitals, physicians, and patients with clear communication of the plans.

In conclusion, the issues within the FDA recall process are critical concerns, and addressing these issues require a collaborative effort between regulatory bodies, healthcare professionals, and manufacturers, and of course the public. We must prioritize safety by ensuring rigorous safety, rigorous testing of medical devices, improving postmarket oversight, clarifying recall thresholds, and enhancing recall strategies. Only by addressing these issues can we create a

safer, more reliable healthcare ecosystem --

[Slide 96]

-- that keeps pace with emerging healthcare concerns and ultimately save lives. Thank you for your attention.

MR. WATSON: Thank you.

Speaker number 24, please unmute yourself, turn on your camera, and introduce yourself.

[Slide 98]

MS. BASSONI: Hello, everybody. Can you hear me? Yes.

My name is Carolyn Bassoni. I am the Regulatory Affair Director of Cosmed.

So next.

[Slide 99]

Cosmed is a French professional association created in 2000, with more than 1,000 members, mainly small and medium-sized cosmetic companies.

You can move to the next.

[Slide 100]

Cosmed is deeply engaged in the European development of the regulatory framework, especially

through our representation as SMEunited, acting as a direct stakeholder in the cosmetic working group of the European Commission. As cosmetics are part of ADA regulated products, we are glad to share today our European experience on recall.

Next.

[Slide 101]

The European recall system is Safety Gate, and it's a process which is known under the Rapex name. They've existed since 20 years, and this tool enables the rapid exchange of information on dangerous products between the 30 network countries from the European market and the European Commission. This search system allows to circulate quickly among the national authorities and measures taken and contributes to ensure product safety in the European Union. The system is capable of dealing with a massive number of alerts, more than 2,000 in 2022, and around 4,000 follow-up actions successfully.

Next.

[Slide 102]

The criteria, how does it work? Here, we have three steps. First, the companies report dangerous products on an online platform called Business Gateway, and then market surveillance authorities review if record criteria are met, and if confirmed, they publish a set of information, product identification, level and nature of the risk of the product, and the measure taken to eliminate the risk. And finally, each alert is followed up by the other competent authorities with concrete action and communication along the supply chain and up to the consumer level to allow, if needed, the withdrawal or the recall of the product.

Next.

[Slide 103]

On top of this recall system are some complementary tools for the support of overall efficiency. In 2021, the Commission launched an e-surveillance tool to allow the detection of online offers of dangerous products signaled in the Safety Gate system. You see here it's a great

analytical program. In the first 6 months, around 600,000 websites were scrutinized to ensure the actual enforcement up to the provider level with withdrawal or ordering of those products. This is key in helping to harmonize action and this addressed the challenges of monitoring the online sales of dangerous products.

Another key question is the management of dangerous products at the international level, and here are two angles for which the cooperation between the country is critical, first, at custom level, controlling and stopping unsafe products. So here, sharing of information between countries is a key level [indiscernible]; and secondly and more long term, coordinating standardization efforts and awareness on the safety requirements. Cooperation exchanges have already started and have shown positive results.

Next.

[Slide 104]

As an illustration, you can see here various initiatives of cooperation at international level

with the same willingness to ensure consumer safety. For the sake of time, I'm not presenting it today.

Next.

[Slide 105]

Just an illustration of the daily alerts from the Safety Gate system, precisely finds a product incriminated, the nature of the risk, the presence here of the noncompliant ingredients in the cosmetic product, and [indiscernible] and the media, they can share the marketing ban.

Next.

[Slide 106]

Here's another illustration with the extent of the alert and follow-up action in 2022 for non-food products, where you can see that every country is actively engaged in this process with the success of the cooperation principle across Europe, and showing that alerts are followed by concrete follow-up action to support consumer safety.

Next.

[Slide 107]

As key takeaways from the European Safety Gate system, it has proven to be efficient and relies mainly on the rapid exchange of information under dangerous products at two levels, first between the 30-member states through a common Safety Gate tool, and then managing the follow-up action through the supply chain, and help to the consumer, alerting them through various communication channels. Another key reason for success is a common regulatory framework in the European economic area and the further development of international agreements and customs cooperation to guarantee protection for all consumers.

So we want to thank again the FDA for the opportunity to contribute to this consideration today, and we hope the European experience could serve as an inspiration.

MR. WATSON: Thank you.

Virtual Speaker number 25 will be our last speaker before lunch. Please unmute yourself, turn on your camera, and introduce yourself.

[Slide 108]

MR. SOEHNER: Good morning. Good afternoon. My name is Christian Soehner.

[Slide 109]

I'm calling you from Berlin, Germany. We've seen a lot of really individual stories. I remember the one of Maria, speaker number 22, and what can happen if, really, trace and track is not guaranteed on medical devices. I worked for 15 years in the medical device industry, so it started from very small, kind of a trauma plate, going all the way up to complete reconstruction.

Why is it so important to modernize recalls? I faced in this time a [indiscernible], and I know what it means, even with my mother's situation having the tense hip surgery and what it means to have fully safe and secure trace and track.

Can you go, please, to the next slide?

[Slide 110]

I'd like to take you on a little journey to see why is it not just in a paper, why isn't it just required and forced, and I really appreciate

this from the FDA. To have a unique device identification, it really has to be very sure that anything used in a patient during a surgery can be traced and tracked. I know the regulatory says only for medical devices intended to be used more than once, so it means every search arrangement has to bear a unique device identification; implants do not. I don't know why this decision came, but in the end, I see it more and more, and I think it's smart, hospitals having to prove a trace and track on a medical device.

It's really so important, and you see this is the whole process. We make this laser mark machines for the medical device industry, and you see this is the whole process, as it should be, safe and secure, starting the software, and not just marking anything under medical device; everything is controlled by a camera. So anytime even your auditor comes or the FDA auditor comes and wants to see a trace and track, who marked which part at what time makes secure that what is on the part is also what is described on the label

outside of the packaging.

If you go to the next slide, please --

[Slide 111]

-- this shows a real case in the hospital. Many hospitals have loaners from the medical device industry to test the product. Sometimes they're out of stock and sometimes they have not enough budget to buy the loaners. You see different steps here. It starts from the left to right, and you see the loaner's not just being brought to the hospital being used; it's being scanned in the receiving department. It's being scanned in the department of surgery, like CMF, neurosurgical, and so on. It will be scanned just before being used in the patient's body and scanned from the sterilized nurse or assistant before being brought into the body.

In this case, you see the whole set. Everything is really traced and tracked. Everything has a name on it, but it has to be really genuine and authentic, so this should be really a unique code, not any code. It should be a

unique code, and then after this, it can be reprocessed. It will be reprocessed, and it will be seen, and you have maybe 100 cycles, 200 cycles, and 1,000 cycles.

But what do you do if there occurs a bacteria and mirrors a situation in a hospital? You can really go to your networking hospital and see which patient is really threatened by this situation. This makes it really sure to really mark it durable and readable, because if you mark it and it's fading out -- so let's say if a knife is still sharp, you can use it, but in the end, it's not a medical device anymore because there is nothing shown on it and nobody can read it with the phone. You don't need a special reader for it; you just can read it by any scanner or a scan app.

So you cannot understand and see if this is a device being used in other patient's body, so that's why we're really concerned. We clean it. We do testings, 500 [indiscernible] cycles before we ever had this in the market, so this helps for you, not our customers, for the patients, and in

this case, my mom, too, to have, really, something that's been really traced and tracked.

That's mainly it. If you go to the last slide --

[Slide 112]

-- I'll give you some final words. Whenever you are involved, regulatory-wise, we are not forced to mark implants because it's a single-use product, but whatever you can, you can have at least a serial number. Maybe you do not have the whole product identification, but the serial number helps so much, even to count for the hospitals how often it has been used. Maybe it's still in a good function, but maybe it should not be used because there's a risk of getting it not really clean in the end.

So those are my final words. We are really focused on this and proud to support any medical device in the industry here, and to give patients more security and modernize in the end the recalls. Thank you very much for the FDA.

MR. WATSON: Thank you.

Speaker number 26 will be our first speaker after lunch. Please return in time to begin promptly at 1:00 p.m. Eastern. Thank you.

(Whereupon, at 12:04 p.m., a lunch recess was taken.)

A F T E R N O O N S E S S I O N

(1:01 p.m.)

Speakers

MR. WATSON: Welcome back.

Just a note for anybody who may be taking the metro from here to National, apparently there has been a disruption in service, so if you've got a flight that you've been planning to take, you may want to go on and just check and see where that stands at the moment. We don't want to miss any flights.

Alright. Any other announcements? I heard there was one other announcement that we couldn't remember.

(No audible response.)

MR. WATSON: Okay. That being said, we will go ahead and get started.

[Slide 114]

Speaker number 26, please proceed to the podium, and speaker number 33, please proceed to the next speaker chair. Thank you.

MR. SHIELDS: Hi, everyone. Thank you for

allowing me to address you today. My name is Scott Shields. My son, Chase, was infected by *E. coli* 15787 at the age of 3 years old from drinking a popular juice brand that was promoted as a health product. Unfortunately, the result of that was he developed hemolytic uremic syndrome, HUS, and he was very close to death. His hands and feet were swollen up like a balloon. His kidneys had completely stopped functioning. He gained 11 pounds of water weight. His blood pressure was so high that they warned us he could stroke or have an aneurysm. His platelets were critically low and he needed several transfusions.

He developed a heart murmur and he had severe pain and excruciating headaches. That's the part he really remembers today. He spent a month in the hospital and weeks on dialysis, and months of follow-up after that, and he still has lasting effects from the infection.

Shortly after Chase's foodborne illness, my wife, Richelle, and I joined the group called Safe Tables Our Priority, or STOP, which the group that

exists today is Stop Foodborne Illness. We've worked with that organization and with legislators, and senators, and the FDA to promote a culture of food safety and try to get changes made to make improvements. We've pushed for legislation. We've presented to and worked with the FDA multiple times to promote change.

Over the past couple of years, we've worked with the STOP Alliance, with food producers, and suppliers, and distributors, and with the FDA to push for a modernized recall process at the FDA. It's discouraging, though, that over the past couple of decades, meeting with the FDA and large groups many times, and having them tell us what an impact it is to hear Chase's story and the stories of other families, that we've really seen not a lot of change over those two decades. We've seen really very little progress, I think.

In the 21st century in America, we shouldn't have to wonder if our food supply is safe. We should have policies and procedures in place to initiate recalls quickly and efficiently to prevent

larger and ongoing outbreaks, other foodborne illnesses, and death. As an example, when Chase was infected -- and mind you, this was a long time ago, but when he was infected, he was one of the first known cases from that particular outbreak. The company that produced the product knew that their plant was contaminated, but of even more concern, the government knew that the plant was contaminated. They noted lack of proper sanitizing procedures; poor employee hygiene; and the plant accepting decayed fruit from their suppliers. They even had a note stating, "black scum growing on the machinery at the plant," but the facility and the government failed to take quick action.

Had a robust recall process been in place back then, it could have prevented over 70 very serious infections, many more less medically serious ones, and at least one death just from that outbreak. And while Chase was deathly ill, and he still has high blood pressure and compromised kidneys, he and we are among the lucky ones, because he's alive. He's 30 years old, lives a

very active and productive life with his wife Ruby.

The Stop Foodborne Illness and their alliance are pushing for changes to the recall process. These leaders in the food industry and distribution are pushing for an action plan to be implemented by the FDA and other federal agencies, and the larger food industry, to improve recall execution and consumer communications to protect the public health. Even though Chase's incident was a long time ago, had it been today, there still wouldn't have been a recall. It would take some months or longer to initiate a recall and decide what category the recall is going to be. How many people are going to die from that? It needs to happen faster.

The CDC estimates that 48 million people a year get sick from foodborne illness, 1 in 6 people every year; 128,000 people are hospitalized and 3,000 people die each year from foodborne illness. So how many foodborne illnesses, hospitalizations, and deaths will it take in order to make change to the recall process? What if it was your child, or

husband, or wife, or parent? Are you actively doing what it takes to make changes today and willing to push forward changes to your recall process that will prevent illness and save lives?

I do want to thank the FDA for this opportunity and for the work you do because I know you do good work. You just need to push forward with this recall process, and thank you for this platform to discuss the critical need for modernized recall. Thank you.

(Applause.)

MR. WATSON: Thank you.

Speaker number 27, please unmute yourself, turn on your camera, and introduce yourself.

(No response.)

[Slide 116]

AV TECH: We're going to move on to presenter 28 because 27 is not on yet.

MR. WATSON: Speaker number 28, please.

MS. DAGA: Yes. Thank you so much --

[Slide 117]

-- for giving me the opportunity to speak

today. Like many other speakers, I have a lot to share, and I have a lot to offer for this partnership. I appreciate FDA's initiative to take this critical step in modernizing recall, so I will turn up my speed to 10x and get started.

Next slide, please.

[Slide 118]

I'm Shweta Daga. I am an Executive Regulatory and Quality Leader with over 15 years of experience within the regulated industry. I come from a pharmaceutical and medical device background, with extensive regulatory experience. I'm here to talk about recall strategies for device software functions and how the current infrastructure does not cover that in totality.

Next slide, please.

[Slide 119]

I think within the device software function, the challenges we face are slightly different with the actual physical product, where the current framework of medical device reporting, as well as recall, is structured towards physical device. The

strategies used for effective software functions are very different from the ones that would be effective for hardware. Because of the current framework focused towards the physical devices, many software functions of medical device reporting, as well as recall, get underreported.

Just to take an example of the difference in strategies, we use the exact same framework for software functions as well, but the immediate correction, containment, and corrective actions could be very different for a software and they could happen a lot faster. So unlike the regular challenge, where removing the product from the field has to be fast, software can do that. It's the latter part, the communication and the rapid response, that is not caught up to that agility and speed.

Next, please.

[Slide 120]

Comprehensive communication is another area where the current recall framework, again, is very, very focused on the physical devices. For

software, we need a little bit more elaborated comprehensive communication. We need more than one channel to reach every user, possible user, knowing that softwares can have many different users in many different areas. So we need press releases, social media, websites, all those in the framework of the comprehensive communication.

Patient education, that's another critical part in a software-based communication, where there should be a mandatory framework where a material can be directed towards a patient in that language that they can understand. There are instructions. I know it sounds very clear here, but unlike a physical product where you can ask the user, throw your software and get a new one, that approach doesn't work here, so we do require a step-by-step guidance on how a patient or a healthcare provider can respond to that recall.

And lastly, interactive platforms and a recall hotline, they sound like very obvious options, but for software recalls, we need real-time updates. We need to be able to make sure

that, as a consumer or as healthcare providers, they are constantly made up to date of the critical updates being made.

Next, please.

[Slide 121]

Similar to the communication, reaching underserved communities become even critical for software. Again, there could be many, many different users out there, so it's critical that the recall program is structured in a way that it could have emphasis on cultural sensitivity, especially in the communication material. We tend to ignore the individuals with disabilities in the process of recall just because of the way the framework is set up, so it's critical to update the recall in a way that they could be always part of it.

The last three buckets, partnership with the local community organizations, telehealth outreach, and mobile clinics, they are becoming critical and critical for reaching the underserved community and should be part of the recall framework.

Next, please.

[Slide 122]

So I'll summarize, it's perfect timing to modernize recall and include device software function in the recall framework. We do have CFR 7, 810, and 806 that covers medical device broadly, but now that we know that strategies are so different and softwares are being underreported, both under MDR as well as the recall program, it's critical timing -- looking at the exponential rise of these softwares that do treat and diagnose critical diseases today -- to have enough guidance, both for industry as well as these regulations to emphasize further. Thank you so much for your attention today.

[Slide 123]

MR. WATSON: Thank you.

Speaker number 30, please unmute yourself, turn on your camera, and introduce yourself.

MS. DUCKETT: Thank you. Good afternoon. My name is Jeanne Duckett, and I work for Avery Dennison. My primary focus is on enabling the

interoperable food supply chain. I want to thank the FDA for this opportunity to speak about harmonizing recalls across product silos. I, too, am a foodborne illness survivor. I contracted giardia when I was pregnant with my daughter, who was born early and in distress. She is fine today.

Avery Dennison supports the FDA's focus on technology-driven food safety modernization, including for food recall. Among the challenges to achieving actionable and reliable food supply chain information is the absence of a common language, missing data points, and the lack of a universal data management and data exchange protocol. This 204 final rule addresses aligning on the critical tracking events along the supply chain, along with the creation of a sortable spreadsheet, but these address only part of the gap.

Avery Dennison recognizes that this recall workshop is conducted across multiple product silos and is a watershed moment in the movement towards the interoperable digital supply chain, which crosses both digital and organizational silos. In

2021, I led a discussion group for the International Association for Fresh Produce. The need to cross organizational data silos became clear to me when an employee of a big box retail grocery produce department said, "Why don't we just do what pharma's doing for solving the same problem?"

Looking at the DSCSA Section 583(2) of the Food, Drug, and Cosmetic Act, it specifically states that systems and processes necessary to promptly respond for a product in the event of recall shall be required. This section, among others, led the FDA to conduct pilots to test key sections of that rule.

Findings from the 2020 pilot noted that processes are highly manual and fragmented, using various disparate systems, which can increase the response time and the number of patients impacted by the recall. The exchange of standardized critical tracking events and key data elements, enabled by serialization of products, quickly identified the location of recall products,

eliminating unnecessary communication, while improving supply chain efficiencies. This aligned with the pilot conducted by IFT, Improving Product Tracing in Food. Their 2012 final report reported similar findings on manual processes and lack of standardization, which continue to plague the food supply chain today.

Avery Dennison calls on the FDA to continue bridging data and organizational silos by building on two key points from the 2019 FDA Blueprint for the New Era of Smarter Food Safety, Pillar 2, Recall Modernization. The first two points from the blueprint include harmonizing how the FDA and USDA communicate recall information to consumers and explore the ability to create and incentivize widespread use of standards to prevent the sale of recall product at point of sale.

To achieve these initiatives, the FDA can collaborate with existing industry initiatives. In 2027, there will be a sunrise date for 2D symbols across point of sale which can leverage web-enabled barcodes. The FDA, working with industry on this

initiative, can be an effective method to address consumer communication and registered lockdown. ISO is preparing to publish global standard ISO 18975, web-enabled barcodes, which encompasses GS1 digital link, as well as other international standardization work.

Another key point from the blueprint is connectivity of data from the Reportable Food Registry. The FDA has reported that CORE, Coordinated Outbreak Response and Evaluation, will ingest [indiscernible] the electronics sortable spreadsheets applied for FSMA 2O4 and convert the data into a supply chain visibility data standard called EPCIS, Electronic Product Code Information Services.

This standard is intended to promote data interoperability within the FDA. While it's not a requirement for industry to utilize the GS1 EPCIS standard, one can imagine the future where the FDA will enable accepting EPCIS events directly from compliance suppliers to speed outbreak processing and coordinate responses. Currently, the DSCSA

leverages the GS1 EPCIS standard to meet regulatory requirements outlined above.

Finally, I'd like to call on the FDA to partner with the industry to initiate a mere set of pilots for FSMA 2O4 that align with the FDA accomplishments in the DSCSA pilots. Thank you for your attention today, and Avery Dennison looks forward to partnering with the FDA, the global standards organization, and industry partners to move recall readiness forward. We truly believe that zero is achievable. Let's move the needle on food recalls. Thank you.

MR. WATSON: Thank you.

Speaker number 31, please unmute yourself, turn on your camera, and introduce yourself.

[Slide 124]

MS. BAUDIN: Hi. Good afternoon. Can you hear me?

MR. WATSON: Yes.

MS. BAUDIN: Wonderful. Thank you.

I'm Donielle Baudin. I've been in the medical device industry for over 23 years. I am

currently serving as Director of Quality of a medical device manufacturer. I do truly appreciate the opportunity to participate in this open forum for modernizing recalls and especially being able to hear directly from some consumers and the impacts that products have had on them.

From an industry perspective, there's a lack of clarity on what thresholds and criteria would constitute the need for a recall, specifically when you're dealing with a non-violative product, so one that is meeting all the requirements that we have designed, and manufactured, and been approved for, but may still cause an adverse event in the field. When looking at guidance documents related to recalls and whether it's a recall or an enhancement, you can improve a device that is non-violative for safety reasons, yet when you look at it from a consumer perspective, it would appear to be in conflict with ensuring the safety of our public.

As a medical device manufacturer, we do strive for highest levels of safety and performance

on the devices, but that is still balanced with the clinical benefit when considering the risk levels of the device and the potential occurrence of a significant adverse event, and the lack of clarity on the requirements of when to initiate, or thresholds for initiation, especially around voluntary recalls, is leading to delays in the industry.

Additionally, the recall process itself lacks transparency from both industry and to the consumers as to the status of the recall. The speaker earlier today had indicated that most recall statuses have the root cause listed as under investigation by the firm. I want to take a brief moment and share a professional experience related specifically to that.

Several years ago, I was in a firm that initiated a recall. We had provided root cause at the time of the initiation of the recall. Within 6 months, we had 100 percent effectivity in reaching all consignees and device recovery. We at that time requested closure and were to understand

that there's a 90-day target for closing recalls. After 6 months waiting for closure, we were visited by an investigator at the FDA for a site audit related to the recall. The audit resulted in zero findings of noncompliance.

It has now been over two years since the initiation, one and a half years since the closure, one year post the audit, yet the status on the FDA website still lists it as open, unclassified, and the cause is under investigation; yet all of this information had been provided to the FDA and the information provided to the auditor. So from an industry standpoint, it gives the impression that we are not following through on our actions.

Some opportunities for improvements could include clear thresholds for initiation, improved communication between the FDA and the industry as to the status, and perhaps assigned cues, dashboards, and database updates that are timely. It's difficult to track closure requests, so perhaps they could be done on a risk-based event as well, perhaps on the efficacy of consigning

notifications, recurrence by the company -- not just by the device, but companies with multiple recalls -- and results of directed audits or use of third-party consultants would be helpful. Thank you for the opportunity to speak.

MR. WATSON: Thank you.

Speaker number 33, please proceed to the podium --

[Slide 126]

-- and speaker number 35, please proceed to the next speaker chair. Speaker number 46 will be our next virtual speaker.

[Slide 127]

MR. LEISTIKO: Hello, and thank you to the FDA for putting this event together. We're glad to be a part of it.

Next slide, please.

[Slide 128]

I'm Justin Leistiko. I'm the Manager for Rx Recall Solutions at Inmar. With our recall offerings, we work in Rx and CPG spaces, with 16 domains, including pharma products, food, and

more. Sixty percent of all the U.S. hospitals are using our one recall service for alerts and 85 percent of all Rx returns come through our facilities at some point or another. I myself have been involved in executing Rx recalls for over 10 years. It is with that lens of experience that I want to come to you to explain some of the pain points that we've seen in exercising those recall processes, and hopefully come up with some solutions to help modernize them.

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[Slide 129]

One of the recurring themes that we find in executing recall events is that unless organizations are performing them regularly, they just don't know how exactly to best execute that. That's why we strongly encourage using mock recalls as a means to exercise their SOPs. That coupled with clear workflows and checklists/templates to follow, allow for a more complete event to be conducted. That said, all the checklists that we have don't amount to much if it's not what the FDA

is actually looking for during an event, and we'll talk about that a little bit.

Next slide, please.

[Slide 130]

Delays in notification put all of us behind. The traditional methods of printing and shipping the recall notices take time. Once we're given final approval, most events go out the following day. Even with overnight shipping, that still puts an extra 2 to 3 days before somebody gets that notice in their hands, then we're actually counting on them opening it and actioning it, and depending on the depth, it has multiple channels to get down through. All this time, the recall product could still be moving down the supply chain instead of being quarantined.

We suggest pivoting to more digital communication channels in conjunction with the physical mailings. Emails with read receipts and alert systems could all help cut down on that timeline from approval to delivery, but also assist when changes need to be executed, like a change to

the depth of the recall or corrections of lot numbers.

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[Slide 131]

Recall alerts do not always reach all the way down, particularly in the underserved communities. Small rural areas, differently abled, or unhoused populations can be difficult to engage with our current methods. Utilizing social media, partnering with community outreach organizations, or having a national alert system for safety recalls could help broaden that audience. Also, how the message is presented could be updated to better gain attention. Most of it is very heavily text-based today, so using visual aids like pictures of the products, where and how to find if your product is impacted, and even potentially creating a universal recall icon for quick recognition.

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[Slide 132]

I hit on this earlier, but there's a lot of

room for interpretation with today's guidance, and that causes a lot of variation between manufacturers and their recall strategies. By standardizing requirements, we could help cut down on that, and we could use some reporting templates that are posted to an FDA website and there wouldn't be any guesswork on what needs to be presented and how it needs to be presented. Taking it further, having a more robust recall portal where firms could have the opportunity to upload event documents, see their status, and see real-time feedback could help provide some faster interaction as far as executing those events.

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[Slide 133]

There are a lot of manual touch points today to log and report back data. Between consumers, service providers, manufacturers, and the agency, it's a lot of hands touching that data. Using a recall solution that's established could help cut down some of those through targeted notifications, inventory matching, ability to respond through a

central location, and even leveraging an interoperable network with serialized data to conduct a more precise event.

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[Slide 134]

Finally, on how to speed up closures, having clear targets set up front for what a successful event looks like is important. We know we want to shoot for a hundred percent but, realistically, that's just not the typical outcome. So knowing where the benchmarks are would be very helpful and allow firms to close an event prior to the physical destruction. This step often takes a very long time to get through and can sometimes lead to months, if not years, of extending that event.

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[Slide 135]

So in closing, I just want to say that we would all benefit from a more streamlined process. Although our primary client base is the manufacturers, we all benefit, from the consumer, to the agency, to the manufacturer, and to the

service providers, if we can get this under control. Thank you.

[Slide 136]

MR. WATSON: Thank you.

Speaker number 35, please proceed to the podium, speaker number 37, please proceed to the next speaker chair.

[Slide 137]

MS. MATTHEWS: Good afternoon. My name is Stephanie Matthews. I'm a Senior Director at Johnson & Johnson for Med Type Devices. I'm very pleased to be here. Thank you to the FDA, to the consumers, the patients, the advocacy groups, and industry for putting this on today.

Next.

[Slide 138]

Next.

[Slide 139]

We at Johnson & Johnson are very grateful for this opportunity to talk with the agency today. We'd like to share some ideas on how to modernize, how industry and manufacturers work and partner

together to serve our patients. The first topic I'd like to discuss is just recall strategies. We've had a lot of topics go through this today, so I want to thank all of the ideas and information back on industry. We have a robust removal and correction process, including points of interaction with the agency to confirm our strategies. We've always appreciated the agency's feedback and support to confirm our strategy.

One item we'd like to augment these abilities and allow us to better collaborate and inform our own process is for FDA to be transparent with its health hazard evaluations and the thought process behind its classification decisions. Providing these items to firms at the time of removal or correction when it's classified can give us these insights into the agency's thinking and considerations for our products. Likewise, the agency should consider including an assessment as to whether existing conditions such as current clinical practices and labeling could mitigate a clinical situation that would expose humans and

that would allow them not to be exposed to a health hazard situation.

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[Slide 140]

Moving on, we applaud the CDRH's reorganization that it's clear that the collaboration and focus on the entire device lifecycle is providing the center with a more holistic view on devices it regulates and the medical industry as a whole; however, we have seen a few gaps in knowledge sharing across departments that could be bridged in order to create efficiency so that both the agency and firms can act more decisively and efficiently together.

One way that efficiencies could be gained is if firms knew when they would receive a comprehensive response from the FDA on its recall strategy and communications. Likewise, resources could be better focused on executing removal or correction if the center coordinates its request to firms that we speak in one voice together.

In a recent instance, the team started to

respond to a request for information from the recall coordinator and had to pause immediately to respond to a different, but slightly different, information topic presented from a different format in a tighter timeline from ORA. The recall coordinator and ORA were not aware of each other's questions, and it resulted in some duplicative efforts that would have been better served on recall operations.

Let's continue to leverage the 806 process as a centralized mechanism to collect and distribute information on the different departments of the agency, which would not only create better inefficiencies together while executing these removals and corrections, but also create some efficiencies for the agency when considering whether an inspection is needed to verify recall effectiveness.

Next.

[Slide 141]

Finally, precise timely and targeted public warnings are critical to conducting an effective

recall; however, public warnings are currently a blunt tool we have an opportunity to sharpen together. The purpose of a public warning, according to the CFRs, is to alert the public that a product being recalled presents a serious health hazard. It is critical that the language used by both firms and the agency is clear and transparent to lay people as a type of recall and the risk the product poses to the public.

For example, the agency could consider using more specific language, such as terms as "correction" and "removal" in the public communications of these items rather than the more general term, "recall." This has been particularly a source of confusion, both in the public and the medical community, and has led to devices not available to patients because hospitals return product that is not subject to removal. We ask that the agency consider providing firms with the opportunity to review public warning communication so feedback from firms could help to ensure clarity and accuracy in our messaging.

Lastly, in conclusion, thank you for holding this meeting, allowing opportunities for both agency, together --

[Slide 142]

-- learning for the firms and at Johnson & Johnson so we can share our experiences and recommendations together and continue to promote consistency and transparency as we work together to modernize recalls. Thank you.

MR. WATSON: Thank you.

[Slide 143]

Speaker number 37, please proceed to the podium, speaker number 39, please proceed to the next speaker chair.

[Slide 144]

MR. TROSIN: Good afternoon. My name is David Trosin. I'm the Senior Managing Director of our Global Certification Programs at NSF International, a global health and safety organization. My specific focus for the last two decades have been in the areas of safety and compliance for products such as dietary

supplements, cosmetics, and personal care items, over-the-counter drugs, and medical devices. It's our hope that the FDA designs a recall strategy that places the consumer at the center and as a focal point of each stage of the recall process. Every step should be designed to serve a consumer, as the safety of the consumer is the reason for the process to exist.

We would love to see the FDA start with the consumer accountability deliverables --

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[Slide 145]

-- if FDA would start with the consumer actionable deliverables and work backward from those when designating industry and FDA inputs to inform the system. On the reporting side, it must be user friendly, easy to report, with a quick breakdown to the consumer relevant component.

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[Slide 146]

These deliverables should include new classes of recall that better convey the risk to

consumers and recall strategies that are more meaningful to the individual rather than to a business, and successful leveraging of a platform that reaches all communities. Subsequent notifications for the same recall should be adequately descriptive to tell the consumer if they are receiving new info on an existing recall, or expanding, or if it's a new recall with the same category. Consider a silent option with auto unsilence if new relevant info comes to light.

Current classes of recall are not intuitive as to what is urgent and require immediate action on the part of the consumer, such as contaminated injectables or allergens contamination, and what is not so urgent like a lack of appropriate GMP with no identified contamination. We suggest the FDA consider switching to language and imagery that conveys the health threat level to the consumer more directly. Color coding such as red for high such as death, et cetera, and some universal iconography, where immediate action should be taken, for example, would be better to convey to

all consumers regardless of background, the level of urgency, and risk. General GMP issues such as packaging issues, yellow and so forth, I'm sure you're all really familiar with colors, so you probably don't need me to walk through that for you.

Delivery platforms need to be included and better use of social media. FDA should look into the feasibility of over-the-top internet streaming advertising for people who do not pay for cable television or who do not watch other forms of news. Online platforms need to be cell-phone friendly and an app should be considered, and if possible, minimal data entry required with autofill features that hasten the sign-in [indiscernible] process to encourage greater research.

We'd love to see the FDA complete the final guidelines on posting recalls to a point of sale. Most consumers will return to the same retail location again and again, and this is by far the most targeted means to inform affected consumers. To reach all affected consumers, recall information

should be available where appropriate, printed in the foremost common spoken language besides English and U.S., being Spanish, Chinese, Tagalog, and Vietnamese. I wasn't familiar with Tagalog as being fourth, so that was something that was impressive in the research.

When an individual signs up to receive recall information, categories should be tailored to the individual needs of a consumer instead of a broad technical category. For example, allergens are currently categorized together. Most consumers have specific allergens and need to be warned about. Some consumers may not want to receive all recalls or prefer to receive specific classes. To create an effective system, the consumer must come first.

Finally, I'll say it's difficult to get below the surface in in 3 to 5 minutes; however, there are a number of organizations committed to public health, including NSF; organizations like the Global Retailer and Manufacturer Alliance and other associations; reputable retailers, and

brands, and manufacturers who seek to partner with the FDA to share data, knowledge, and technical expertise.

I encourage the FDA to open these external partnerships to help make enforcement and recalls more efficient, effective, and welcome further in-depth conversation. Thank you very much for this forum. It was a great pleasure to be here and have the time to address you all.

[Slide 147]

MR. WATSON: Thank you.

Speaker number 39, please proceed to the podium --

[Slide 148]

-- speaker number 41, please proceed to the next speaker chair.

[Slide 149]

MR. HANCOCK: Thank you for convening this listening session on recall modernization and for the agency's ongoing work in this important area. From the comments today, my admiration grows for the scope of the responsibility that you bear and

the way that you do it, and I am also thankful that you're wanting to get better and having this listening session.

My name is Roger Hancock. I'm President of Recall InfoLink, a firm that processes thousands of recalls each year for our clients to their customers, both B to B and B to C. Prior to that, I led the food safety and quality functions for Albertsons, a nationwide retailer, where we did hundreds of recalls a year from suppliers to our warehouses, our retail stores, and our consumers. I'm here today because I have lived, breathed, and managed product recalls, and I believe that now is the time to modernize the recall process in the U.S. for the good of the consumer to protect public health.

To that end, I've teamed up with a small but growing working group of recall professionals, representing manufacturers, wholesalers, and retailers. Together, we have developed a model for improving the way recalls are processed across the supply chain and we were pleased recently to

present this model and discuss it with Erik and others at the FDA. The model identifies three key elements that are important for improving the way recalls are managed across the supply chain, for the benefit of everybody in the supply chain, but most importantly, to protect the health of the consumer. Here are three insights.

First, recalls need to happen as a coordinated supply chain action rather than individual company activities. The company approach results in gaps in the flow of information, the timeliness of information and notification that produces delays and produces confusion, and delays that result in increased exposure to the public of compromised products in the food supply.

We believe this needs to be a whole new paradigm in the way recalls are thought about and processed. We call this paradigm a recall-ready community. It goes beyond telling individual companies to be recall ready and it adopts a community approach to conducting recalls.

Second, today we're in an information age, a digital age, and when it comes to recalls, we lag behind in that respect. Recalls, effective recalls, require the sharing of standardized data from machine to machine so the data flows quickly and efficiently so that actions can be taken. This cannot happen without standardized data. There's been mention before about GS1 standards and sharing data. That absolutely has to be part of the recall process, and the FDA knows this, and the FDA is working on this through the RFR connectivity project that they're trying to connect RFR to recall systems, and we commend that work. That kind of information sharing needs to go even further to company-to-company information, sharing companies, and regulatory information sharing, et cetera. In the digital age, modernized recalls must be communicated using standardized data.

Third, today mock recalls are conducted by FDA regulated manufacturers across the country; however, those mock recalls really are simply traceability exercises which are insufficient.

Mock recalls done today do not prepare manufacturers, or anyone else in the supply chain, to effectively recall a product quickly and efficiently. But part of this new paradigm of recall management is to transition from mock recalls to recall simulations, where all the steps of preparing the product attribute data, the instructions, the disposition directions, et cetera, are provided and communicated across the supply chain.

The only way for a supply chain to be ready to process unlikely, unexpected recalls and protect people is to practice each step of the process ahead of time. That's why we need to shift, as I said, from mock recalls to recall simulations, to practice, to set expectations between companies, to teach, to train, to identify gaps that can be closed ahead of time, and ultimately to sleep better at night. Together, these changes will enable us to protect the consumer with better product recalls.

I've submitted the model as part of written

comments to the FDA. We ask the FDA to support and promote the concept of a recall-ready community that conducts recalls as a coordinated supply chain action, that shares standardized data, and that practices with recall simulations annually to protect the public's health. Thank you.

MR. WATSON: Thank you.

[Slide 150]

Speaker number 41, please proceed to the podium, speaker number 43, please proceed to the next speaker chair.

[Slide 151]

MR. PRINCE: Thank you.

Thank you for this opportunity to come before the group to speak about recall modernization at FDA. I did my first food product recall in 1968, and since then have done several thousand of product recalls. And even in my later years these days as a retiree, I review and write recall programs for multiple companies around the country.

First slide, please.

[Slide 152]

Today my comments are going to be focused on consumer communication of food product recalls involving food allergens. Since about 1990, I have been working with the allergen community and understanding their needs and challenges on a daily basis, and making sure that the food that they eat or feed to their children is safe and wholesome.

Next slide, please.

[Slide 153]

When we focus on recalls involving allergens, they occur in many different ways in providing this particular information. As we see on this particular slide, there are hundreds of product recalls that happen, and about 70 percent of them can be identified with either a microbiological problem or a food allergy situation. So that means there's about 500 to 700 product recalls that occur related to allergens each year, so you figure out how many you may have per day.

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[Slide 154]

The most common allergen that triggers food recalls these days and the last five years has been milk or a milk derivative. This is widely used in the food manufacturing process around the world in the way of different derivatives of milk. And you can see that each allergen has its own little niche, and we need to be looking at those niches and thinking about how many people fall in those categories, and how we can better communicate to them on those particular issues.

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[Slide 155]

I have to compliment FDA on their RSS feed about pulling out the allergen recalls and putting them online for individuals to identify, then you take a look at the RSV feeds that would go into some software and think about is this a friendly way to deliver the information. Even to the pro who has done thousands of recalls, it's even difficult for me to sort some of this out. We need to do a lot of quality to address the

inconsistencies in the way this particular information is presented.

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[Slide 156]

When I think about recalls, I think about putting them in boxes, and we think about the number of people that may be affected and how we can ease that particular plane in communicating this very important vital information to this particular segment of the population. Think about if you were allergic to a given item about the risk you'd think about on every bite that you would take and is this particular product safe. We know that the size of the food business and the size of the number of ingredients going in various products, and the importance of this.

I'm recommending that we put all the allergens in the recall outboxes that are most appropriate for that particular one so those individuals that do have a allergy to a given item can select and get those delivered to their little computer they have in their hand. As we heard

earlier today, 96 percent of the population has one of these, a device that was announced in June 2007 and readily available and a way to circulate this particular information.

So next slide, please.

[Slide 157]

It's very important that it be in a subscription service where you sign up and put the responsibility on the particular user so that they have to sign up to get this information.

Next slide, please.

[Slide 158]

So it is available. The recall information given allergy is available at a minute's notice before somebody takes their next bite and ends up with a life-threatening situation. Thank you for this opportunity to share with the FDA on this particular procedure.

MR. WATSON: Thank you.

[Slide 159]

Speaker number 43, please proceed to the podium, speaker number 44, please proceed to the

next speaker chair.

MR. OYSTER: Hello and good afternoon. My name is Josh Oyster. I'm a Partner in the FDA regulatory practice group at the law firm of Ropes & Gray, based in Washington, DC. I want to quickly thank FDA for the opportunity to speak on this important topic today. As an attorney focused on FDA regulatory matters, a substantial portion of my practice involves counseling medical products manufacturers and other FDA regulated entities on recall-related considerations, and it's through this lens that I provide my comments today.

I want to focus on ways that FDA can improve how it requests information from recalling firms to provide clear expectations to industry and to enable recalls to be initiated more efficiently. Generally speaking, FDA regulated entities are not legally required to report recalls to FDA. The one big exception to this is the requirement under the Part 806 regulations for medical device manufacturers to report certain corrections and removals to FDA.

Nevertheless, FDA has long requested that firms recalling FDA regulated products immediately notify FDA of a recall. This is reflected in FDA's nonbinding guidelines in 21 CFR Part 7, as well as the more recent 2020 guidance for industry entitled, Product Recalls, Including Corrections and Removals, where FDA urge firms to contact FDA as soon as a recall decision is made and, quote, "if feasible, before any public notice or customer communications are issued."

The 2020 guidance includes a detailed set of recommended information that firms should submit to FDA about a recall, but the guidance is clear that information should be submitted as it becomes available rather than waiting until everything is ready. In my experience counseling clients, there's a disconnect between this concept from the 2020 guidance and the ways in which FDA recall coordinators in practice request information from recalling firms.

When a firm contacts an FDA recall coordinator about a potential recall, the

coordinator, in my experience, will typically send one or more recall information forms to the firm to complete within particular time frames. For example, for a food recall, I've seen FDA ask for the completion of what's called an Attachment A, as well as an Attachment B, within particular time frames. In the drug context, I've also seen FDA request that, quote/unquote, "Attachment B be completed," but it's a different Attachment B from the one used in the food context. Then then in the device context, FDA has in the past asked for completion of what's called a Device Correction/Removal Report Model for Industry.

The suggestion to use these forms can be challenging for industry and adds complexity to the initiation of a recall for several reasons. First, to my knowledge, none of these forms are actually publicly available on FDA's website or otherwise. That means that a firm that isn't used to conducting recalls will typically be seeing the form for the first time when they receive it from the recall coordinator, and although the

Attachments A and B forms sent to firms appear to be loosely based on Attachments A and B to Chapter 7 of FDA's Regulatory Procedures Manual, those attachments in the manual are framed as internal documents that FDA completes for its own intraagency communications rather than forms that a recalling firm would complete.

Second, the forms I'm aware of are not squarely aligned with the recommendations from the 2020 guidance in that, in certain respects, they request more information than what's described in that 2020 guidance. And third, although the 2020 guidance has that recommendation that firms submit information as it becomes available, certain forms I mentioned include statements that appear to contradict this recommendation or might be interpreted that way.

For example, one attachment, quote/unquote, "Attachment B" form I've seen, states in all caps and bolded text at the beginning, "DO NOT MODIFY OR DELETE ANY QUESTIONS OR PART THEREFORE. ANSWER EACH QUESTION AS IS." These instructions have the

potential to create confusion by suggesting that firms need to fully complete all of the detailed information requests that FDA has before they will be able to get FDA feedback regarding a proposed recall strategy. These concerns are particularly important to take into account because they have the potential to delay the initiation of product recalls.

In closing, I offer a couple of recommendations for FDA to consider going forward. First, if FDA recall coordinators are going to use model forms or templates, make sure those documents are publicly available for industry to review and comment upon. Also make sure that the documents align with FDA's recommendations in the 2020 guidance.

Second, FDA should consider revising its 2020 guidance and any model/template recall information forms to clarify the criticality of different categories of information that may be requested about a recall.

Specifically, FDA should differentiate

between, A, information that is legally required to be reported to FDA within a given time frame, for example, under Part 806 of the device regs; B, information about a proposed recall that is essential for FDA to be able to evaluate a firm's proposed recall strategy and to comment on a proposed customer communication or press release, and that should in turn be provided to FDA in advance of recall initiation in cases where a firm is trying to get FDA's advanced feedback. And then the last category, information that does not meet this prior criterion that I just described, and, therefore, need not be provided in advance of recall initiation and could be provided later.

Thank you very much for your attention to these important issues. I appreciate the opportunity.

MR. WATSON: Thank you.

[Slide 160]

Speaker number 44, please proceed to the podium, speaker number 45, please proceed to the next speaker chair.

MR. ROTHSTEIN: Hi. Good afternoon. My name is Jared Rothstein. I'm the Director of Regulatory Affairs at the Consumer Brands Association. Consumer Brands represents the consumer packaged goods industry, including the nation's leading food, beverage, household, and personal care product brands.

The safety of consumers is a priority shared by the CPG industry at FDA. We are united in our efforts to protect public health by preventing consumer illnesses and injuries, ensuring that products are properly labeled and preventing the entry of unsafe or mislabeled products into the marketplace. Our members are committed to execute on recalls when necessary to protect public health. The CPG industry effectively and efficiently executes on recalls today. Communications can be disseminated rapidly and products blocked from sale and retrieved immediately from the marketplace.

We appreciate FDA's willingness to engage with industry on recall modernization, a key element of the agency's Human Foods Program

redesign and its planned structural governance and leadership reforms of that program. We believe that procedural and policy reforms are critical to ensure FDA's recall system can effectively protect American consumers, ensure the resiliency and sustainability of the food supply, and keep industry viable. The agency's current approach could be improved to better meet those needs.

We ask that FDA provide clarity about the reorganization of the Humans Food Program and how recalls will be handled within the planned offices at CFSAN and in the field. We believe the agency should work towards centralizing its recall functions within a single centralized team of dedicated recall coordinators to allow for a faster and more efficient action in urgent public health situations.

Relatedly, FDA should leverage technology to enhance recalls, including through building predictive models that can improve the speed and efficiency of recall classifications. FDA should also better facilitate coordination and consistency

across its field districts and headquarters on recalls, standardized recall reporting forms and processes, and reduce geographic silos for recalls that cross multiple divisions.

FDA also needs to advance its work with USDA FSIS to develop best practices and align on common recall management policies and procedures. Agencies currently use different models of which viable parts of each can be shared and implemented jointly. We believe that recalls between the agencies need to be consistent to ensure timely identification, classification, and communication of recall notices across federal jurisdictions.

Consumer Brands also believe that FDA should advance a modernized recall communication system that can effectively reach consumers. For example, the agency should work with industry to encourage adoption of voluntary digital disclosure communications such as text, e-mail, and social media, and the use of digital labels like SmartLabel to quickly distribute notices of recall products to consumers. Similarly, FDA should work

with industry on communication strategies for recalled products sold directly to consumers via e-commerce.

In addition, FDA should also explore opportunities to use new technologies to effectively target communications where appropriate, such as when only a certain product is being recalled or a product distributed in only one state. FDA should also work to make the product recall information it collects and publishes online more easily accessible.

Ultimately, agencies should be setting the end goal and expectations for recall notices, identifying the relevant tools, templates and tested approaches that the agency believes produce desired consumer behaviors and letting companies leverage the most relevant and modern communications for their specific recall situation.

Consumer Brands also recommends that FDA identify actionable steps to enhance visibility of class 1 recalls to consumers, particularly when a recall product presents a serious concern to health

and safety. Presently, FDA increasingly relies upon press releases for all recall notices, requesting their issuance in most class 2 situations. The present situation reduces the impact of the press release communication and diminishes the effectiveness of the public notice to consumers.

We appreciate FDA's recall modernization efforts and look forward to further collaboration with the agency. It would benefit stakeholders to gain a better understanding of what the intentions of the agency are with respect to recalls, its next steps and potential actions, and how it plans to make use of the feedback provided by stakeholders here today, as well as with the open comment period. We encourage the agency to continue a transparent and collaborative approach to modernizing recalls, including through additional recall workshops on specific regulator product categories. Thank you.

MR. WATSON: Thank you.

[Slide 161]

Speaker number 45, please proceed to the podium, speaker number 51, please proceed to the next speaker chair.

MS. GARREN: Good afternoon. I'm Donna Garren, Executive Vice President of Science and Policy for the American Frozen Food Institute or AFI. I also want to thank Erik and others at FDA for hosting this event and appreciate and thank you for the opportunity to speak today about recall modernization.

AFI represents publicly-traded and family-owned companies who help produce frozen foods and beverages for today's food service and retail marketplace. Our members are committed to implementing strong food safety programs that take a preventive focus. We want to ensure that the frozen foods are safe and properly labeled when they enter commerce every day; but when necessary, AFI members are willing to effectively and efficiently perform a recall to remove product from the marketplace and disseminate information rapidly and block product from the marketplace for further

sale.

In light of our commitment to food safety, we have thoughts about how best to modernize the recall process to better protect public health. We will provide written comments to FDA on several of the specific topics addressed in today's public meeting, but for the time being believe that we can effectively group our comments and recommendations under two topics.

The first is how to make the recall administrative process more efficient in order to ensure that recalls are executed as quickly as possible. The second is how to ensure that recall communications and other public warnings reach consumers and enable them to take prompt and appropriate action, basically empowering the consumers.

With respect to how to make recall administrative processes more efficient, we believe that to effectively modernize recalls, there should be greater consistency and transparency. For example, AFI recommends small changes such as

greater consolidation of FDA's recall resources so that they are available to industry in one place and preferably in one document, a recall handbook, for example. AFI recommends that FDA provide greater transparency regarding the recall process internally at the agency; who makes the decisions; which decisions are made; when and which subject matter experts are going to be involved; what factors are considered; and what the process is for industry to have a dialogue with the agency personnel.

We'd like to see greater consistency and transparency regarding recall classification. Recall classification can affect whether a public warning is appropriate, as well as the depth and strategy for the recall. Therefore, consistent and predictable classification will help industry develop a recall strategy that aligns with FDA's expectations and improve recall efficiency.

We also recommend that FDA undertake efforts to standardize and centralize the recall process. Currently, recalls are primarily handled at the

division level, and there are differences between divisions, including how recall coordinators approach recalls. And even the information they request with respect to Attachments A and B, it seems to us there is an opportunity to modernize the process and create a portal with a standardized set of information that industry would submit as part of the recall process. We also recommend that the nationwide recalls that may cross different divisions, one recall coordinator should take the lead. Quite simply, it is not an efficient use of resources for multiple recall coordinators to be following up with the recalling firm and conducting effectiveness checks.

With respect to the way to improve recall communications and other public warnings, earlier this month, we hosted a food safety forum titled, Narrowing the Gap Between Mitigating Food Safety Hazards and Communicating Public Health Risks, where we gathered food safety and public health stakeholders to discuss strategies for risk communication. To this end, we appreciate and

underscore the need for effective outreach to consumers with recall information. As such, we encourage FDA to think beyond the press release and to explore emerging technological solutions that may be able to reach consumers directly, particularly for things like direct-to-consumer sales over the internet or when a limited amount of product is distributed in a limited area.

AFI would also recommend and would like you to consider that we are concerned that consumers hear about recalls too frequently, and therefore may not be able to respond. We encourage FDA to take a risk-based approach to recall modernization -- and in both turns, when a press release is necessary and when the press release conveys -- so that consumers will be more likely to take appropriate action.

Finally, we ask FDA to share additional information on how it intends to approach human health and human food recalls in light of a reorganization taking place within the Human Foods Program at the agency. Reorganization presents a

key opportunity to think of how best to modernize the recall process to ensure that recalls are effective and efficient. Thank you for this opportunity today to present AFI's viewpoints about recall modernization. Thank you.

MR. WATSON: Thank you.

[Slide 162]

Speaker number 46, please unmute your mic, turn on your camera, and introduce yourself.

MS. WAGNER: Thanks. Good afternoon. I am Roberta Wagner, Lead for Regulatory and Scientific Affairs at the International Dairy Foods Association. IDFA represents companies that make most of the dairy products and ingredients marketed and sold in the United States and around the world. We appreciate the opportunity to provide oral testimony on FDA's recall modernization today.

IDFA agrees that FDA's recall authorities, policies, and procedures are antiquated and they're in need of modernization. More specifically, IDFA believes recall regulations, policies, and procedures should reflect current industry and

agency best practices; that consumer messaging when recalled should be grounded in science-based research; that FDA should encourage and support the use of the many available modes of communication delivery for consumer recall messages; that modernization needs to also address the recall of products sold through digital platforms; and importantly, that any updates need to protect commercial confidential business information and the personal information of consumers. Additionally, we have specific recommendations for FDA that I will cover in brief.

The large majority of food recalls are voluntary. Food companies act with urgency to remove adulterated and misbranded products from the marketplace to protect public health and often fully execute voluntary recalls before FDA has cleared industry press releases or classified the recall. That's because, relative to FDA recall classifications specifically, it can take the agency weeks to make these decisions, not to mention there are inconsistencies in how light

recalls are classified within FDA and across federal agencies.

We urge FDA to dedicate staff to its recall operations to perform health hazard evaluations and classify recalls to ensure more consistent and timelier decision making. Moreover, FDA should consider consolidating recall staff from both ORA and CFSAN under the new Human Foods Program to ensure those in the field managing food recalls are in lock-step with the program's policy makers, experts, and compliance officers.

With that said, IDFA encourages FDA to be bold and consider establishing a regulatory oversight framework for voluntary food recalls that looks quite different from what exists today. First, we recommend FDA update its policies so that food companies are responsible for independently handling voluntary recalls, including the scoping, classification, and communication of the recall. In follow-up to voluntary recalls, food companies will continue to be expected to reassess their food safety program, take appropriate corrective

actions, but also report these actions to FDA.

Second, we recommend FDA focus its oversight on retrospective reviews of a company's voluntary recall activities during routine inspections. Given the development of recall plans and management of recalls typically occur centrally in medium and large companies, these retrospective reviews could be carried out, in part, as remote regulatory assessments or as part of a two-tier inspection approach.

Third, we recommend FDA create a tool for industry to classify its own voluntary recalls that is also able to flag unique and novel recall situations that would require FDA engagement. If such change is not possible, we recommend FDA adopt a recall committee process akin to USDA's Food Safety and Inspection Service, which has proven to be quite efficient and effective. More generally, we urge FDA and USDA to harmonize federal recall processes and communications so that facilities that make both FDA and USDA regulated products can more easily navigate the federal recall process.

The number of class 1 food recalls and the major reasons for these recalls have remained relatively static over the years despite the passing of FSMA. IDFA encourages the agency to adopt a prevention-oriented approach to tackle these persistent issues. We would like to see FDA work with industry to capture the contributing factors for the major categories of class 1 food recalls, use this information to identify the top 2 to 5 factors per category, and subsequently develop and communicate prevention strategies similar to what the agency is doing for repeat outbreak situations.

In closing, we recommend the agency hold a public meeting specific to voluntary food recalls, which present their own unique challenges distinct from medical product recalls. Thank you for the opportunity to provide oral comments today.

MR. WATSON: Thank you.

[Slide 163]

Speaker number 48, please unmute yourself, turn on your camera, and introduce yourself.

MS. MOHAMEDSHAH: Good afternoon. I'm Farida Mohamedshah, Lead for Scientific and Regulatory Affairs at the National Confectioners Association or NCA. The National Confectioners Association appreciates the opportunity to provide comments to the agency regarding its recall modernization efforts. NCA is the leading trade organization for the U.S. confectionery industry. NCA strongly supports food safety and the importance of examining current practices to ensure public health and a safe food supply.

Our comments today will focus on increasing consistency, predictability, and transparency in the recall process. Our comments address three components of the recall process where we think modernization is needed: recall initiation, recall execution, and recall communication. With respect to the recall initiation process, we encourage FDA to look for ways to modernize the process by bringing about greater consistency, standardization, and transparency.

First, NCA and its members would like the

agency to consider strategies to enhance transparency, consistency, and predictability regarding recall classification. Giving industry greater insight into FDA's classification reasoning would better allow industry to more reliably align its recall strategies with agency expectations. The most successful recalls are the result of partnership between the recalling firms and FDA, which is best achieved when both parties have a common understanding of the goals and the steps needed to achieve it.

Second, we encourage FDA to look for ways to modernize the process by which the agency collects information from recalling firms through greater standardization. We believe there are opportunities, for example, to modernize the current process, where recall coordinators e-mail forms to be filled out, which often differ across field offices. This can slow down the recall initiation process. With a standardized form, companies with multiple sites operating under the Preventive Controls Rule would be able to adapt

their written recall plan to respond to a uniform list of FDA questions regardless of location. Additionally, this information should be made available on FDA's website for download.

We also encourage FDA to look for ways to modernize the recall execution process. For example, FDA should consider updating its modern recall consignee communication and effectiveness materials to reflect current technologies and communication methods such as e-mail. Recall communication to consignees are no longer sent by postal mail. Further, the district-by-district approach makes FDA's oversight of multistate recalls cumbersome to FDA and industry alike. The agency should consider appointing a primary recall coordinator tasked with managing the entire recall in such situations.

As for recall communications, we believe there are additional opportunities for modernization and greater consistency and transparency. Specifically, we encourage the agency to be more transparent in the criteria for

when a press release is appropriate and beneficial. With greater consistency and transparency, industry can be prepared to issue a press release at the outset of recall when appropriate and necessary. At the same time, we encourage FDA to explore additional means to reach consumers and modernize recall communication. In particular, there are likely opportunities to make recall communications more risk based and reach consumers more effectively.

As another example, the evolving e-commerce retail environment is not addressed in the agency's current guidance. The agency should consider establishing guidelines for recall communications and effectiveness check situations, where there are direct sales to consumers and the recalling firm can contact all consumers of a product directly via e-mail, phone, and/or mail.

Thank you again for the opportunity to provide these comments. NCA will be providing additional comments to the docket on this topic and looks forward to providing input on ways to

modernize food recalls.

MR. WATSON: Thank you.

[Slide 164]

Speaker number 49, please unmute yourself, turn on your camera and introduce yourself, and then we're going to take a 25-minute break.

DR. ALINOVI: Good afternoon. I'm Catherine Alinovi, Executive Director of Next Generation Pet Food Manufacturers Association. I want to thank you for this opportunity not only to speak but also listen to the wide diversity of speakers. You certainly have quite the challenge at FDA to address all of our concerns.

At NextGen PFMA, the health and safety of our product's consumers is always key in all of our manufacturers' procedures. We believe that the recall system is a useful tool to notify the public of demonstrated food safety issues or violations of federal regulations; however, we also believe that the recall process is currently being used by the FDA to drive compliance with non-binding agency policies, which are not based on regulations;

specifically, 21 CFR, Chapter 1, Part 7, Subpart C, Section 7.41, which is the Health Hazard Evaluation and Recall Classification section.

In particular, we recommend the following. Recalls should be reserved for those instances in which there is either a clear violation of federal law or a demonstrated public health concern. Recalls should not be based merely on noncompliance with non-binding agency policy established in lieu of required rulemaking procedures. In a number of cases, FDA has directed manufacturers to issue voluntary recalls or face the threat of public warnings due to noncompliance with non-binding recommendations made in guidance documents, in this particular case at CPG 690.800, regarding salmonella in food for animals.

Furthermore, these recommendations have not been subjected to federally mandated rulemaking procedures. We do not believe it appropriate for a federal agency to utilize such methods against manufacturers as a means of enabling it to bypass well-established and lawful processes for

addressing regulatory issues.

Next, the current recall process does not distinguish between the various levels of recalls that have been established. In the case of salmonella in pet food, FDA has never conducted a risk analysis, as mandated by 21 CFR 17(c) [sic], Section 741, to determine whether a serious adverse health consequence or death to humans or animals exists in each instance for each species of intended consumer despite legal requirement prior to classifying the recall. Instead, in all cases, FDA classifies the risk as class 1.

Thirdly, the purpose of any communication regarding a recall, whether issued by the manufacturer or by FDA, should effectively communicate with the affected consumers while minimizing unnecessary reputational harm to any of the parties involved. We encourage the use of other communication systems rather than relying only on press releases. Furthermore, the language of any such notice should reflect the demonstrated risk of the specific instance to the intended

consumer. Statements made to the public should match the actual risk, otherwise credibility of the agency is undermined and public confidence in the recall process is diminished.

We encourage the FDA to reevaluate the recall system to develop rulemaking procedures in lieu of using policy to drive recalls, update the level system to reflect all scenarios in the marketplace, and continue to allow alternative communication methods and language to protect the public. Thank you for the opportunity to contribute to this very important topic.

MR. WATSON: Thank you.

We'll go ahead and take a break now. Let's return and be in our seats ready for the next speaker to start at 2:50 Eastern.

(Whereupon, at 2:22 p.m., a recess was taken, and the meeting resumed at 2:52 p.m.)

MR. WATSON: If you could please make your way to your seats, and speaker number 51, if you would proceed, and 55 is already in the next speaker seat, so we're good to go.

[Slide 166]

MS. KHAN: Good afternoon, everyone, and thank you to the FDA for having us out here and allowing all of us to bash you at everything you're doing wrong --

(Laughter.)

-- but we do think you're doing things great. However, my name is Sharmeen Khan, and I am the Founder of OpsSmart Global, a traceability software company, and I will be commenting on increasing efficiency and effectiveness of recall information exchange and ensuring effective recalls as they apply to FSMA Rule 204, which establishes additional recordkeeping for food on the food traceability list. The goal of the rule is, of course, to increase transparency through additional traceability records. This is done by asking facilities to maintain documentation in whatever format they're choosing to use.

I completely understand the FDA's flexibility in allowing companies to use paper, pencil, laptops, notes, whatever they're using;

however, then when it comes to a recall, the FDA is requiring an electronic sortable spreadsheet that must be provided within 24 hours of the request or within some reasonable time to which the FDA has agreed. To me, both of those are kind of an opposing end of that spectrum. I understand that you can't exactly tell people you must follow Microsoft Word or follow this one software or that software; however, to expect to receive electronic sortable spreadsheets in the case of the recall is not realistic.

As the conversation today has gone on, there has been comments of disconnect, information or the lack of information sharing, children getting sick, the lack of timely communication, and then when I start reading about why that isn't happening, often you come across comments that it's a matter of PII; that you cannot request -- or personal information cannot be shared amongst different silos of information.

I don't think that should be a hindrance to our sharing information, especially when it comes

to foodborne illness. Any of us who shop on Costco, or Instacart, or anything, they all know what we're buying, where we're buying, and when we're buying it. And when it comes to a food recall, I think there should be a certain amount of urgency to get that information by customer service cards, or loyalty cards, or other methods so that information can come to me, and you, and all the other parents who are feeding our children or grandparents to make sure that the food is pulled off the shelf, out of refrigerators, and returned. So what I'm asking the FDA is to create a better system so that the information can be shared and effectively recalled. That's it. Thank you.

MR. WATSON: Thank you. Speaker number 53, please unmute your phone, turn on your camera, and introduce yourself.

[Slide 168]

MS. REED: Good afternoon. I appreciate the opportunity to speak today. My name is Terrie Reed. I'm Chief Strategy Officer at Symmetric Health Solutions, a data enhancement firm that's

supporting over 800 hospitals to adopt unique device identifiers, or UDIs, in their healthcare IT system. My experience includes my role as a former FDA Associate Director of Informatics, with responsibility for the initiation of the UDI program.

For over a decade, I, along with countless others, have advanced to increase the efficiency and effectiveness of recall information exchange, specifically focusing on leveraging the availability of scannable UDIs, that when scanned can be tied to standard attributes like model description, implant status, latex, and MRI safety information for the over 4 million device records in FDA's public database called AccessGUDID.

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[Slide 169]

My motivation is selfish. I have a clavicle implant, and I have friends and family members with implanted devices. We've heard today from patients suffering from adverse events associated with implantable devices. Everyone who plans to have an

implant procedure and those with an existing implantable device have a right to easy and timely access to the latest recall information.

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[Slide 170]

Consumers in other sectors are being directly notified about product recalls via their mobile phones, emails, and other means. This is a screenshot of my neighbor's cell phone taken back in 2018. It shows Pepperidge Farm Goldfish crackers she purchased at our local Walmart were recalled on July 23, 2018, and she was notified on July 25th. The same easy access to recall information is rarely available to patients with implants. Why? Well, there are several factors.

Fundamentally, we are not capturing the identity of an implant and tying it to the patient that received the device. Likewise, the FDA is not capturing, storing, and providing access to recall information about these medical devices, using structured data as the basis for enabling innovative access found in other sectors. Progress

is being made to link patients to their devices in care settings.

In early September, we calculated that our company alone has helped health systems automatically match over 5 million of their collective hospital devices to the device identifier portion of UDI in FDA's database.

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[Slide 171]

And we're not alone in our efforts. Multiple organizations are notified by the Office of National Coordinator Health IT, ONC, and the Center for Medicare and Medicaid Services, CMS, regulatory requirements to capture UDIs as part of implant procedures documented in electronic health records and downloadable to patients. This slide highlights the steps and data specified in those regulations. ONC and CMS regulations support linking a patient to the UDI via their health record.

FDA can be part of this linkage by improving the way it provides standard recall information

about a specific device through more effective use of structured data and FDA systems, including the more consistent use of UDI.

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[Slide 172]

If FDA improved the submission, storage, and access to device recall information, as outlined in the recently proposed Medical Device Recall Improvement Act, there would be a direct positive impact on recall processes for all parties involved, the manufacturer initiating the recall, the hospital managing the recall, and the patient whose implant or other devices used for their care has been recalled. The proposed Act calls for a form to be used for recall submissions. I believe that form should identify every specific data element to be submitted electronically to FDA for every device recall, including those that identify the device.

Specific to UDI, FDA should up their recall system to eliminate the field identified as Code, C-O-D-E, where UDI and other identifiers are stored

as unstructured descriptive text, and to replace that with all necessary, well-defined identity elements, similar to what is done for EMDR and the UDI database. The submitted data should be made available as soon as possible in the open FDA APIs and be downloadable. Every attempt should be made to make the data available within 1 to 2 days as we saw in the cracker recall example to allow innovative and timely access to information via mobile apps and other tools.

Hundreds of thousands of patients have received implants since the time of my implant procedure. Today, it's difficult to believe that I or any other patient should have to proactively track recalls associated with our implants or have any doubt that the healthcare system has an efficient recall process. We should receive texts or emails as we do with other product recalls, and in the case of implants, these should be targeted to us based upon the recording of the implanted device in our EHR. We're happy to partner with any other organizations seeking to identify innovative

ways to use UDI to improve the recall process. Thank you for allowing me to share these opinions publicly in this forum.

MR. WATSON: Thank you.

Speaker number 54, please unmute yourself, turn on your camera, and introduce yourself.

[Slide 173]

MR. CHEN: Good afternoon. First and foremost, thank you to the FDA for this opportunity.

[Slide 174]

You're the number one health authority in the world. Thank you for helping us navigate the pandemic. Today is all about modernizing recalls using data in Six Sigma to improve it. When you really think about it, recalls are a strategic national interest. We protect public health, we have food security, we have strategic stockpiles of drugs and countermeasures, and we have to preserve GDP.

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[Slide 175]

We believe recalls can be solved by stacking tools, ranging from Six Sigma, supply chain management, quality and regulatory, and so on, but today we have AI, ML, and Cloud computing.

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[Slide 176]

So we've taken all the topics of today's conference, ran it through ChatGPT to map out the various streams, and 100 percent verified that it's valid, and we created a platform to analyze FDA's data.

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[Slide 177]

So based on this, we suggest process mapping end to end. So from start to finish, you have the risk trigger, you analyze it from a health and hazard evaluation perspective, and you basically look at all the existing data to the past, to predicted future, and optimize your mitigations.

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[Slide 178]

So what are we seeing holistically when you

cross-cut across the centers? There's, on average, 7,000 recalls per year. That means there are 70,000-plus data points you can trend. And when you drill down by category, you can see there's wide variation based on risk and hazards.

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[Slide 179]

Based on this variation, it's important to streamline and standardize the data and harmonize it across centers. For example, the USDA FSIS actually catalogs each hazard with each recall, so when we can retrospectively analyze this, this gives us a better starting point.

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[Slide 180]

Therefore, when we process-map this, it's important to establish KPIs, benchmarks, and expectations, and this may vary across industries, as well as product categories. For example, infant formula may vary from drugs and over-the-counter pharmaceuticals. So our ask and recommendation is for FDA to use the gold mine of data they already

have to retrospectively trend it on a date basis and then establish statistics for this. For example, there's a class 3, and we call it 5 years to terminate, and I think we can all agree it should be shorter than the presidential term.

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[Slide 181]

This is real-world evidence. We have a class 2 recall. They posted it, they took it off after one month, but the reality is, it's still open today, so how do we measure, control, and analyze this for improving recalls across the board?

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[Slide 182]

In conclusion, when the customer wins, we all win. We are seeking public-private partnerships to improve recalls across the board for all industries. We're currently an open beta. We encourage you to take a look at our website. Thank you.

MR. WATSON: Thank you.

[Slide 183]

Speaker number 55, please proceed to the podium, speaker number 57, please proceed to the next speaker chair.

MR. GENDEL: Good afternoon, everybody. My name is speaker 55 --

(Laughter.)

-- also known as Steve Gendel. I'm here today as an independent food safety consultant, but my remarks are going to be based on a 25-year career in CFSAN, where I was involved in doing recall trend analysis in several projects but also worked on the risk control review team that reviewed all the submissions that come into the reportable food registry and followed the processes that were followed afterwards on recalls. I do promise, though, I'm not going to be giving away any internal secrets.

(Laughter.)

I want to address the subject which has not come up yet today, which is the the bullet point, in the request when this meeting was announced, for

information about strategies for reducing recall recurrence in similar situations. I think this is a really important area. I would say that it's ripe for modernization, except I don't know that it exist yet, so I'm not sure how you would modernize something new.

The most impactful opportunities in this area come from recognizing that each recall is a near-miss situation, a near-miss incident, that could have resulted in an outbreak or other widespread significant health impact. In fact, each recall is essentially a failure of the food safety system. As such, there's much to be learned from doing a thorough root cause analysis for every recall and importantly sharing the results of that analysis; and by thorough root cause analysis, I mean going beyond excuses like a temporary breakdown of a process or an employee error, which are meaningless fillers that are found in many recall notices.

Without sharing information on these recall root causes, the lessons learned from one control

failure will be hidden from others who could benefit from that knowledge, including FDA inspectors and private auditors. When one facility has learned something, others should be able to learn how to improve their systems without needing to have them risk harming consumers. There are other government agencies responsible for protecting the public, who view each incident, regardless of the immediate consequences, as an opportunity to learn and improve. The FDA and the food industry should do the same. Only when everyone in the food system can learn from real-world data will it be possible to take preventive approaches to improve food safety.

One specific example of an opportunity for sharing in communications comes from FDA recall classifications, which have been discussed here several other times. There are very few, if any, in the industry, or the public, who understand how the agency decides whether a recall should be class 2 instead of class 1, or why information on class 2 and class 3 recalls is not in the same

web page as the information on class 1 recalls. We also had a discussion earlier from Gale about how hard it is, even for people who know what they're doing, to get the information out of FDA's system.

To the extent that the agency is committed to transparency, one simple first step to, quote, "reducing recall recurrence in similar situations," would be for the agency to post the health hazard evaluations for each of its recalls. Though I recognize the agency will feel obligated to redact some of the information in an HHE, that burden has not stopped the agency from posting warning letters. There is no reason why HHEs can't be considered to be as important as a warning letter, and that using a few resources now to do that redaction and get things posted would greatly reduce the need to use many more resources later to clean up problems that have been caused and have caused recalls.

Finally, I think it's important in this context for FDA to think about changing its thought process to becoming not a gatekeeper but a

facilitator of information exchange, and it should be a role model in the world where transparency is key to ensuring information quality and utility. Thank you.

MR. WATSON: Thank you.

[Slide 184]

Speaker number 56, please unmute your phone, turn on your camera, and introduce yourself.

MR. CHANDRA: Hello, everyone. Thanks for this opportunity. I hope I'm on live right here. I just can't tell.

Could the host please confirm?

AV TECH: Your audio is connected, and you do not have a camera on.

MR. CHANDRA: Okay. Thank you. It looks like my camera is glitchy.

Thank you for this opportunity. Good afternoon, everybody. First of all, this is such an amazing opportunity to bring opinions out to this forum, which is public, and eventually make the difference to the safety of Americans and this great nation to food safety. So a bit about me;

I'm a mission-driven technology founder based in California, and over the past four years, my company has built various innovative software products for social good, and all those impactful social good products my team has built is called Food Recalls & Alerts. I know some of you may have heard about it, and many have not heard about it, but today it's got over 20,000 happy users in America on the platform. In fact, what we're going to do is we're going to modernize the food recalls on the list for Americans so they stay safe from foodborne illnesses and threats.

Today I'm here to talk about a recent wave of comments. We've actually asked our users to comment on this initiative, food recall modernization, and what they want to see in particular. And boy, they actually did comment. In fact 80 people, users on our platform, have written to the FDA over the last two weeks, which is mind-blowing, and staggering, and of course great, because they feel strongly about recall modernization. You can see their posted comments

on regulations.gov today.

A single theme that popped out is what I want to talk about, which is about need for FDA to double-down on our mobile app for food recalls. I'm in fact going to quote the users comments to kind of support these arguments here.

Why should FDA double down on our recalls app? Here is what users have said, "Because consumers like the convenience of a real-time alert system on the go, not emails, not walls of text."

Here's one particular consumer that said, "We desperately need a mobile phone app in the U.S. to notify us, the consumers, of recalls as soon as possible. The food recalls app is extremely helpful."

Another one says, "Every citizen of this country deserves the right to know what is going on with their food. Food recalls have saved thousands of people from illness, and even death. Not everybody has time to watch the news 24/7 about the recalls, so it's important they get the recall alerts in live time." Here's another customer that

basically says, "I was so sick of the emails and still wanted a way to see it a long time ago [indiscernible], and the app is exactly what I needed."

Adding more codes, another thing that popped up is consumers today want modern tools to get and share recall information. Sharing is the key here. Here's what a particular user has said. "Food recalls app is basically a life-saving device, so easy to use, shared to social media platforms and friends, family, and my own personal online accounts. As soon as an app notification, I am on it to see if I have that product."

Another one says, "People need an app like this because many don't use Facebook. I don't think social media is the right way anyway, so it's important you get the notifications on time so you can share them with others."

Another theme that popped up was they want easier ways to basically get alerted for life-saving information. For instance, just yesterday there was an alert about cantaloupe

recall, and this is what a consumer has to say. "Yesterday, there was a cantaloupe recall which included my state. I haven't bought any cantaloupe recently but my parents did, and turns out it was recalled, and I'm so glad this app helped me alert to it."

If you recall the Jif peanut butter recall about a year ago, another consumer says, "I was already one-fourth of the way through the Jif peanut butter recall, but when I received the notification from this app, I was notified on the app several days before I even saw it on the news."

So as you can see, apps such as this are really making a difference to consumers. Here's another one, where they've actually said governments to take action on this. "This app has helped me ensure I did not purchase contaminated food. On two occasions, I actually had unopened contaminated food in my freezer. Thank goodness I was made aware in real time."

Here's another one, and she says -- a mother of two -- "As a mother of a child who was allergic

to so many foods, I know the importance of reading labels. We didn't have an app like this when my children were growing up, and I'm so grateful we have it now, and it should be supported by our government as a critical health tool."

So in summary, to me, it's very clear Americans are on high alert when it comes to food safety, now more than ever. I really urge the FDA to fast track the development of the food recalls app to ensure the safety of all Americans. Thank you for the time.

MR. WATSON: Thank you.

[Slide 185]

Speaker number 57, please proceed to the podium, speaker number 59, please proceed to the next speaker chair.

MS. JONES: Hello. My name is Katy Jones. I am the Chief Customer Officer at Trustwell, and on behalf of Trustwell, thank you to the FDA for the opportunity to speak today. The FDA plays a pivotal role in safeguarding public health, and the modernization of recall processes is a critical

step in ensuring the safety and well-being of consumers across the nation.

Our food travels through a complex network of producers, distributors, and retailers, involving countless transactions and handoffs. With its intricate web of food distribution, it becomes increasingly challenging to identify and isolate unsafe products when issues arise. Modernizing recall technology is pivotal -- pivotal -- in streamlining this process, allowing us to respond quickly and efficiently to protect consumers.

In this age of rapid technological advancement, our means of communication have evolved dramatically; however, our current recall system, as has been pointed out multiple times today, relies heavily on traditional methods such as press releases and paper notices. These outdated approaches can result in significant delays in reaching consumers who need to be informed about potentially dangerous products. By modernizing recall technology, we can harness the

power of digital platforms, social media, texting, QR codes, mobile apps, APIs to connect to supply chain systems to disseminate this critical information rapidly and efficiently. This would help notify consumers, distributors, and retailers alike much more effectively, ensuring that tainted products are removed from the market swiftly.

In addition to enhancing communication, modernizing recall technology can also be augmented by improvements to traceability within the food supply chain. Enhanced traceability, supported by the upcoming FSMA 2O4 requirements, means that we can pinpoint the source of contamination with precision and minimize the extent of recalls. This level of traceability not only aids in faster recalls but also minimizes unnecessary food waste by pinpointing the affected products with accuracy.

As part of FSMA 204, the FDA has standardized the terms and definitions for the data exchanged during a trace-back event. Much of that same data is needed for recalls, and we urge the FDA to take that into consideration as you move

forward with any regulations or guidelines for recall management. Furthermore, modernizing recall technology is not just about reacting to these issues. It's also about prevention. By employing data analytics and artificial intelligence, backed by strong nutritional analysis and quality management systems, we can proactively identify potential risks in the food supply chain. This enables us to take preventive measures before a recall becomes necessary. The shift towards predictive analytics can save lives and protect public health.

At our company, Trustwell, the leading provider of nutrition analysis, supply chain traceability, and recall management software, we offer our customers the ability to proactively monitor for issues that may result in a recall while also acting swiftly when one does occur. For the retailers, manufacturers, and food service operators that we work with every single day, they're leveraging our software to reduce the time needed to execute a recall or a stock withdrawal,

by sometimes over 70 percent. We've seen recall reactions and the resolution of recalls go from taking days to resolve, down to just a matter of hours.

Lastly, I speak today not just as an advocate for food technology, but as a mom. Undeclared allergens make up the largest percentage of U.S. recalls, and they have over the last 18 months, making up 47 percent of all recalls in 2022 and 63 percent of all recalls in 2023 so far. And for my son, who suffers from a life-threatening tree nut allergy, the speed in which food companies are able to communicate and fully resolve a recall due to an undeclared allergen is paramount. It could literally save his life.

Modernizing recall technology in the U.S. food supply chain is not merely a suggestion, it is an absolute imperative. Our world is evolving rapidly and our systems must evolve with it. Ensuring the safety and security of our food is a fundamental responsibility that we all share in this room today, and modernizing recall technology

is one of those key pieces to doing that and fulfilling that obligation. By doing so, we can protect public health, we can address food waste, and we can reduce the risk for the millions of people like my son who struggle with food allergies. It's time for us to come together as an industry and prioritize the modernization of food recall technology and systems. Thank you so much.

MR. WATSON: Thank you.

Speaker number 58, please unmute your phone, turn on your camera, and introduce yourself.

[Slide 186]

MS. WALL: Good afternoon, and thank you for this opportunity to provide comment on recall modernization. My name is Gretchen Wall, and I'm the Director of Food Safety and Quality at International Fresh Produce Association, which is a trade association that represents companies from every segment of the global fresh produce supply chain.

With a continuing obesity epidemic and concurrent urge for consumers to incorporate more

fresh fruits and vegetables into their diet, the safety of fresh produce and the ability to protect consumers if a public health hazard is identified has really been magnified over the last decade, and the ability to expeditiously recall contaminated or potentially hazardous produce from commerce is absolutely critical to protecting public health and maintaining consumer confidence in the food supply at the same time.

So our comments today really reflect opportunities that our membership and our Food Safety Council have identified for modernization of the recall process and guidance, and I will say after having listened to many of the comments today, it's been really reaffirming to hear so many colleagues working in the food industry, that many of our comments align with the same challenges and the same opportunities that our members have encountered.

For our first comment, I was really pleased this morning to hear how well we're aligned with the first speaker, Steve Mandernach from AFDO, and

the ability to carry out a recall must be done as quickly as possible to limit the exposure to consumers; yet, there have been a number of barriers to achieving expeditious recalls within the produce industry. One of those is just the timeliness of communication and how it is critically important to produce companies. This really includes and focuses on classification of recall type, and that will help determine whether a press release is required or not.

Without this timely communication of recall class by FDA, several member companies noted that they weren't able to make communication decisions, with some members noting that confirmation of recall class actually wasn't communicated by the recall coordinator until greater than 36 hours after initial notification to FDA, and in most cases, the members had to move forward even without this classification confirmation due to this delay in communication from FDA. Further guidance is also warranted for industry members to understand how FDA classifies their recalls. This could

include providing a list of scenarios and examples to both industry members and recall districts based on prior classifications to help increase the classification time and improve on that timely communication release.

Our second theme is around recall preparation and planning, and I especially appreciated the comments that Roger Hancock shared earlier today about developing recall communities and moving from mock recalls to recall simulations. I will say that one of IFPA's most requested training and learning experiences are both the public and private recall simulations that we organize for produce and food industry members, and as future guidance is issued to help modernize recalls, an emphasis really should be placed on practice for those recall situations, which include members through the entire company, not just the food safety and communication teams, and ideally involve other supply chain partners in activities such as with realistic simulations.

We routinely hear, after hosting these

simulations, about how valuable these experiences are in identifying weaknesses within a company's recall plan, their program, and their team, and to support these efforts, guidance should include recall plan templates and other preparation exercises which engage both internal and external communication teams.

Our third general theme is around calibration and consistency. In general, there are multiple rules, guidance documents, and now traceability requirements spanning three different agencies. Any work on modernizing recalls should have a focus on building synergy with the FDA, USDA, and Consumer Product Safety Commission, and between the agencies, both food and non-food should be aligned with their similar scopes and expectations.

Standardization of information collected and conveyed during a recall process should also be pursued. For those who are working with multiple suppliers, such as in produce distribution, receiving consistent and standardized information

regarding supplier recalls could help streamline the process and allow for a more effective communication of those food safety risks. Additionally, all field offices must be held accountable for consistency across their regions and districts on that recall initiation, information collection, and follow-up inspections.

Finally, we recommend that FDA and other agencies transparently share root causes of recalls and those issues which tend to occur with a high rate of frequency. This would allow our industry members to continuously evaluate their own operations and implement practices to prevent future recalls with the same cause; so thank you for your time today and for the work that FDA is doing to listen to members of the industry, advocacy groups, and consumers to further protect public health and modernize the recall process. Thanks.

MR. WATSON: Thank you.

[Slide 187]

Unless I'm mistaken and have misunderstood

some messages, this is our last scheduled speaker, number 59. If you were scheduled to speak and were not in the room for some reason, please come to the front; and this is only if you were scheduled to speak and did not.

Please proceed.

[Slide 188]

MS. BADOUR: Alright, the last speaker of the day. We started with AFDO; we're ending with AFDO. My name is Jessica Badour. Good afternoon, and thank you for the opportunity. I work for the Association of Food and Drug Officials, but I'm going to take a step back in time and speak to you from my experiences with the Georgia Department of Agriculture, where I was the regulatory recall coordinator for about nine years, as well as my involvement with the Partnership for Food Protection.

If you are unfamiliar with what the PFP is, it is a group of dedicated public health professionals from federal, state, local, tribal, and territorial government agencies with roles in

food protection.

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[Slide 189]

So back in 2020, I had the opportunity to conduct a recall shadowing experience -- that was what we called it -- between FDA's Human and Animal Feed East 3 -- AKA what I call the Atlanta district office -- and the Georgia Department of Agriculture's Food Safety Division, and we set a meeting for the recall coordinators, myself, as well as the federal district recall coordinator, Emma Nesbit. And what did we do? We just talked.

We talked to each other about how we were conducting recalls from the federal versus the state perspective. We reviewed our processes, we discussed scenarios, and then she started calling me and saying, "Hey. I've got a recall event here in Georgia. Would you like to hop on the call with" so and so firm? So we started conducting joint industry calls, and she was the lead, but she always gave me the opportunity to ask questions and to provide feedback, and then after the calls, I

was able to ask her additional questions. So much was understood through those and we had a unified front as we were contacting the food industry, rather than them having to conduct multiple inquiries from multiple regulatory agencies.

We also case studied past Georgia recall audit checks, or RACs, and we compared notes. We discussed the goal and the intent from our individual agency perspectives, which I found are not always the same. Let me explain.

Next slide.

[Slide 190]

So Georgia Department of Agriculture would conduct recall audit checks occasionally -- we fall into that sometimes category -- and we were conducting these to truly spot check in the marketplace to see if we were finding recall products on the store shelves. Using a form, the 3177 form, to determine if a recall is effective or ineffective becomes meaningless if the product is still in the marketplace. Even if the firm has done what they were supposed to do, if that product

is still in the marketplace and the state inspectors are out finding it in those small convenience stores and those mom and pop retailers, we know that this is a gap.

So we talked about how we would address these things that were outside of formal distribution channels, and it left us with more questions than answers. If it's not technically ineffective, how should a regulator document that on the form that we were filling out? How could the regulator educate that retailer so that they understood the risks that they were taking by falling outside of formal distribution? So they weren't getting any formal notification. And when do you tell the recalling firm that they might need to do more, based on existing product in the marketplace?

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[Slide 191]

So the Partnership for Food Protection took this concept -- I was very excited to see -- and they added it to their strategic plan, their

current plan, to expand and replicate this in more jurisdictions, and a work group called the Surveillance Response and Post-Response Work Group worked really hard for a couple years on this project. They renamed it the Recall Integration Partnership Project -- they had to get a new acronym, so it became the RIPP -- and it was, by all accounts, pretty successful.

Agencies that participated at the state and federal level had an increased knowledge of each other's roles and responsibilities. They got to better know their points of contact within the agencies and they addressed gaps in recall coverage and areas to increase collaboration.

On the next slide --

[Slide 192]

-- I want to show you one of the results, and that is the Human and Animal Feed West 1's flow of information sharing during recalls, internal.

Can you all see anything that's on here?

(No audible response.)

Does it look simple? It doesn't look that

simple, but if you advance, this included how recalls might result, and if you advance again, I wanted to highlight the communication between the state regulatory agencies and the state liaisons, and the emergency response coordinator. Now, those have dotted lines so they're not always engaging together. And over on the side, you have the compliance branch with the district recall coordinator and the compliance officers, and I urge FDA to consider how we can make this particular area more circular and less branched out.

Next slide.

[Slide 193]

Additional recommendations are really just to continue to create a culture where you have recall coordinators talking to each other so they feel comfortable going together and doing things together. Some of these initiatives under the project replication tool are currently being done, from what I understand, which is fantastic. So those need to continue, and we need to make sure that recall coordinators don't operate in silos but

instead talk to each other as they talk to industry. Thank you.

Adjournment

MR. WATSON: Well, thank you everyone for joining us today. This concludes today's listening session. As mentioned earlier, a replay of the listening session will be available, but it will not be on FDA's YouTube channel, but it will be on our website. A transcript of the listening session will be posted on the website at fda.gov also, as soon as possible following the event.

We have, as mentioned earlier, also established a public docket for the listening session that can be accessed on regulations.gov, and we encourage participants to submit written comments to the public docket by October 27, 2023, when the comment period will end. Thank you all and have a great rest of your day.

(Whereupon, at 3:32 p.m., the meeting was adjourned.)