SUMMARY MINUTES

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

PATIENT ENGAGEMENT ADVISORY COMMITTEE

October 6, 2021

Via Video Conference

Attendees:

Chairperson

Paul T. Conway
American Association of Kidney Patients
Patient Advocacy

Voting Members

Cynthia L. Chauhan, M.S.W.
Patient Advocacy

Bennet R. Dunlap, M.S.
Health Communication Consultant
Diabetes Patient Advocacy

Necie L. Edwards
Health Care Advocate/Pain Management

Amye L. Leong, M.B.A.
Healthy Motivation
Patient Engagement in Care & Translational Research

Monica Parker, M.D.
Emory Alzheimer's Disease Research Center
Emory University

Rita Roy, M.D.
National Spine Health Foundation

Temporary Non-Voting Members

Samprit Banerjee, Ph.D.
Weill Medical College
Cornell University

Shelby D. Reed, Ph.D., R.Ph.
Duke Clinical Research Institute

Ruth M. Parker, M.D.
Emory University School of Medicine

Industry Representative

Jijo James, M.D., M.P.H.

Johnson & Johnson
Consumer Representative

Rachel Brummert, M.S.
American Society of Pharmacovigilance

Food and Drug Administration

Kathryn Capanna, B.S.E, Deputy Division Director
Division of All Hazards Response, Science & Strategic Partnerships, Office of Strategic Partnerships Technology Innovation

Erin Keith, M.S., Associate Director
Compliance and Quality, Office of Product Evaluation and Quality

Letise Williams, Designated Federal Officer

CALL TO ORDER

Panel Chairperson Paul T. Conway called the meeting to order at 10:00 a.m. He noted the presence of a quorum and affirmed that the Committee members had received training in FDA device law and regulations. He read the purpose of the Patient Engagement Advisory Committee into the record and highlighted outcomes of its recommendations to date. He announced that the Committee would be discussing and making recommendations on medical device recalls.

He then asked the Committee members and the FDA staff to introduce themselves.

CONFLICT OF INTEREST STATEMENT
TEMPORARY NON-VOTING MEMBER STATUS STATEMENT
GENERAL ANNOUNCEMENTS

Letise Williams, Designated Federal Officer, reported that a conflict of interest waiver had been issued to Dr. Shelby Reed. She announced that Dr. Jijo James would be serving as the Industry Representative and that Dr. Ruth Parker had been appointed as a temporary non-voting member.

She then made general announcements regarding speaker identification, transcripts, and breakout session procedures, and introduced Lauren-Jei McCarthy as the FDA press contact.

WELCOME AND OPENING REMARKS

Jeffrey Shuren, M.D., J.D., highlighted the progress and accomplishments of work being done at CDRH with respect to patient science and engagement, and outcomes from previous panel meetings. He apprised the Committee of recent events, workshops, and endeavors in the areas of patient-generated health data, cybersecurity, and artificial intelligence.

PRESENTATIONS

Medical Device Recalls: An Overview

Erin Keith, M.S., reviewed the definition and purpose of recalls, key stakeholder activities, and major steps in the recall process. She clarified what manufacturers' and FDA's responsibilities are during a recall, identified common causes that can lead to disqualification of products from the market, and discussed the benefits of the Unique Device Identification system.

Medical Device Recall Communications

Angela Calman, M.P.A., gave an overview of the Agency's communication process and specified what communication can and cannot do. She described how a patient-centric approach can aid in overcoming challenges to the exchange of information and looked at best practices in recall communications, including social science and content development.

Industry Perspective - Stryker Medical Device Recall Process

Ommeed Shahrokh provided insight and gave hypothetical examples of the execution of product recall with an emphasis on the importance of product field assessment, postmarket surveillance, and effectiveness monitoring. He discussed main factors that determine whether recalls will be initiated, reviewed the components of hazard and harm identification, and outlined steps that are taken when a recall is issued.

Healthcare Provider Perspective - ScrippsHealth

Elizabeth Eisenberg, M.S.N., RN, CVAHP, looked at the role that clinically integrated supply chains play in supporting expeditious, systematic responses to device recalls. She shared examples of steps taken within the ScrippsHealth network to resolve two current recalls, and highlighted critical achievements by key stakeholders in addressing these issues.

Patient Perspective

Kimberly Platt recounted how she became a patient advocate after being diagnosed with anaplastic large cell lymphoma from textured breast implants. She stated that she has learned that manufacturers have very little knowledge about who has their implants, that oftentimes patients do not know the types of implants that they have, and that her viewpoint on what should and should not be restricted by HIPAA laws has changed.

Open Committee Discussion

Rachel Brummert, M.S., Consumer Representative, asked how Stryker would notify her, as a patient, about a recall. **Mr. Shahrokh** explained that the company's ERP traceability goes through its end users which are usually hospitals or surgeons.

Ms. Platt expounded on her concerns about limitations posed by HIPAA at the request of **Cynthia L. Chauhan, M.S.W.** She pointed out that privacy laws limit the amount of information that hospitals can give to manufacturers, which can be a deterrent to real-time notification of recalls.

Ms. Keith provided further clarity on product liability at the request of **Ruth M. Parker, M.D.** She explained that manufacturers are required to contact their customers, which could be hospitals, caregivers, or retail outlets, who then become involved in helping with the recall process.

BREAKOUT SESSION

A virtual breakout session for discussion of scenario questions was held from 12:00 to 12:55 p.m.

BREAKOUT SESSION SUMMATIONS

Breakout Room Number 1:

Allen Chen, Ph.D., recapped his group's discussion of the question, "How would you feel learning about the news of the recall?" He noted that the overall impression was one of concern and of wanting to know more.

Questions generated by the discussion include:

- What are the issues?
- Am I affected?
- How do I know if I'm affected if my surgeon isn't here anymore?

Breakout Room Number 2:

Donna Engleman recounted that the group was interested in details about risk, lot numbers, how they may be impacted by the recall, and the steps that would need to be taken to ensure their safety.

The group also indicated that they would want to know if their devices were affected, what the word recall means, the reason for the recall, and if there are similar devices that they might need to know about.

Breakout Room Number 3:

James Walker recapped his group's discussion of the question, "What other questions do you have about this recall and where would you go for more information?"

Issues generated by the discussion include:

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

The group also discussed additional sources of information such as Google, FDA's websites and databases, and manufacturers' websites.

Members of the group further indicated that it would be preferable to have one global specific source of accurate information.

Breakout Room Number 4:

Kemba Ford related that the members of her group discussed whether they would keep the device while monitoring closely for problems or if they would have it removed and replaced with an alternative device.

The group members determined that they would want more information on the

following points before making a decision on either option:

- the alternative device,
- likelihood of sudden death,
- recommendations,
- unknowns,
- adverse events, and
- warning signs.

Breakout Room Number 5:

Indira Konduri related that her group's discussion focused on why a patient would want to have the recalled device replaced with an alternative if they are not having negative effects or signs of problems.

The group felt that more would need to be known about the risks of the device and the benefits of having a second surgery. Most members agreed that they would opt for a replacement if the risk is high.

Other topics and recommendations generated from the discussion include:

- Development of communications specific to consumers and consumer education.
- The speed in which information should be provided.
- Concern about healthcare providers who are so busy that they push for replacements.
- Making information available to an extensive audience that is culturally targeted and in different languages.

Breakout Room Number 6:

Katelyn Bittleman recapped her group's discussion of the questions, "How would you find out if this recall affects you? What approach would you take and where would you go for more information?"

She noted that the discussion focused on trust, trusted sources, and the importance of those sources. Members of the group also indicated that they would get second opinions if they cannot trust their original healthcare providers, that they would do as much online research as possible, and that they would seek information from manufacturers on specific lots and affected devices.

Breakout Room Number 7:

Ms. Bittleman also summarized the discussion from Group 7, which focused on the question, "After going through this recall experience, what would you like to see FDA and industry change to make it easier to (1) get the information you need about recalls and safety issues for devices you use; (2) quickly determine if the recall or safety notification affects your specific device; and (3) make decisions about the best course of action for you in response of your recall?"

The discussion centered on trust, credible sources of data, and more access to and transparency of information. This includes having more access to credible registries, better implementation of the UDI system, device recalls patterned after those in the auto industry, and medical device ID cards.

Additional insights:

The moderators shared supplementary observations gleaned from the discussions.

- Group 1 expressed interest in knowing the time allotment before a decision would have to be made, consolidation of FDA's datasets, and information on possible injuries or deaths.
- Group 2 expressed interest in knowing how detectable a problem might be if the recommendation is to monitor the device, what the costs would be, and if there would be coverage for replacement if that was the recommendation.
- Group 4 expressed interest in knowing what the manufacturer and FDA may not know, and whether or not a device is permanent or would eventually have to be replaced.

OPEN PUBLIC HEARING

Peter Pitts, president of the Center for Medicine in the Public Interest, observed that the traditional role of the patient voice may not result in the most meaningful engagement. He stated that anecdotes must be combined with a more dispassionate scientific understanding of regulatory paradigms in order to have the right kind of impact, and that the patient voice can and must evolve into a tool to influence regulatory decision making.

Rich Kucera, CEO, Symmetric Health Solutions, spoke of the complexities and dependencies that exist in health care. He suggested a structured and programmatic recall process with fields for UDIs or barcodes to properly and automatically identify medical devices so that patients can be alerted to potentially life-threatening issues promptly and efficiently.

Terrie Reed, Director, Partner Relationships, Symmetric Health Solutions, called for improvements in the recall notification process by requiring the inclusion of accurate device identification information in health records, the use of UDIs by manufacturers, and communication of recall information to patients in a timely manner.

Maria Gmitro, president and co-founder of Breast Implant Safety Alliance, made the following recommendations:

- Use text messages, e-mail, and social media to convey recall information.
- Update MedWatch.
- Use language that the average patient will understand.
- Make UDI adoption mandatory.
- Ban the sale of recalled medical devices.

- Increase funding for postmarket surveillance, and examine adverse event reports more often.
- Impose strict consequences for noncompliance.

Madris Kinard, M.B.A., CEO, Device Events, Member, Patient Safety Action Network, remarked that the voluntary nature of recalls effectively depreciates FDA's reputation for protecting patients. She stated that recalls should be mandated and done in a more timely fashion, that commercial withdrawals should not be allowed, and that postmarket surveillance staffing should be increased to keep pace with the number of devices on the market.

BettyAnn Connors told the Committee that one injection of Sculptra has caused osteoporosis in her arms, facial deformity, and severe fatigue as well as various other chronic symptoms. She related that her physician did not believe her when she told her that it felt like the product was migrating, that doctors now seem to shy away from her since lab reports have proven her right, and that test results have been removed from her medical records. She asserted that doctors are not reporting adverse events, and that vendors and manufacturers do not respond when voluntary reports are made to the MAUDE database.

Gretchen Riccardi shared her observations and experience related to Boston Scientific's S-ICD Class I recalls and advisories. She related that patients are kept from directly accessing data from their own implants because the company's remote monitoring framework operates outside of HIPAA privacy law. She further stated that patients get no feedback and have no idea if their devices are functioning or not. She asserted that medical device manufacturers should be regulated and that patients should be given direct access to their data.

Gregory Greco, D.O., F.A.C.S., spoke on behalf of the American Society of Plastic Surgeons. He discussed how medical specialty societies are key components in recall communication strategies, noting that many of them can provide robust clinical data through their own registries; that they are uniquely positioned to partner with industry to ensure the availability of clear and accurate information; that they can provide direct support to patients and serve as a bridge between the patient community and physicians; and that they can serve as unbiased, authoritative subject matter experts in dealing with the media.

Laura Mauri, M.D., M.Sc., spoke on behalf of Medtronic. She informed the Committee that the company is investing in and developing a more comprehensive systematic approach to receiving patient input, that it recognizes that patients are important determinants about their own experiences and outcomes, and that it wants to do everything it can to support patient care and decision making.

Karuna Jaggar made the following recommendations on behalf of the Breast Implant Working Group:

- FDA should play a leading role in announcing medical device recalls and safety notifications.

- It should give the same level of outreach and public engagement to recalls as it does to new device approvals.
- It should develop standards for Class I recall announcements that include all medical options including risks and potential benefits.

Diana Zuckerman, Ph.D., President, National Center for Health Research, stated that UDI numbers are frequently not included in medical records and are not being put directly on implants even though that was the intent when the law and regulations were established. She pointed out that there is usually not enough good data to determine what is known and not known about risks, that inadequate answers to questions and efforts to reduce fears by being overly reassuring can be construed as a cover-up, and that there is a big question surrounding who will be considered as an unbiased source of information. She further noted that FDA's explanations tend to be technical and hard to understand, and that its database is not user friendly and is difficult to utilize by those who are inexperienced.

Carol Small, a BIA-ALCL Stage 4 survivor, stated that there is no reason for any doctor to not know about this disease. She related that many women with serious symptoms are reporting on social media that they were never advised by their physicians of the dangers of their implants. She emphasized that somebody other than social media should be telling patients that they need to find out about the risks before getting an implant and that they need to know what the symptoms are post-implant.

Jamee Cook made the following recommendations on behalf of ALCL in Women with Breast Implants:

- improved postmarket safety measures, including electronic surveillance options;
- increased effort to get recall information out to the public;
- ongoing involvement between FDA and patient support groups;
- increased staffing efforts to accommodate public requests for documentation;
- accountability for companies who do not follow approval guidelines and do not properly track or inform consumers; and
- mandated device registries that can track and contact patients when there are issues.

Open Committee Discussion

Monica Parker, M.D., commented that breast implant associated cancers were apparently not being tracked on the National Breast Implant Registry. **Dr. Greco** replied that the recall highlighted how difficult these issues are to track and that this is why the NBIR was developed. He described the simplicity of entering implant data into the registry, noting that paper tracking is no longer needed and that patients will also be able to use it to self-report. **Dr. Zuckerman** explained that that kind of information was not available on the registry at first but is now being added, that many women who get breast implants are not using surgeons who are members of the ASPS, and that there will still be a multitude of patients who are not going to be in the registry.

Ms. Chauhan remarked that a comment made by Mr. Pitts about anecdotes not being

data seemed somewhat dismissive of patient input. **Mr. Pitts** clarified that he did not mean it that way, but wanted to emphasize that the only way to prevent the patient voice from being dismissed by regulators and physicians is to enhance its value by making it more technically accurate and more in line with regulatory terminology.

In response to questions posed by **Ms. Brummert** and **Amye L. Leong, M.B.A.**, **Dr. Mauri** explained that Medtronic shares information with patients either directly or through physicians, depending on the type of device. She further explained that the company provides an 800 number for patients to use, that it puts information on its websites, and that it considers other mechanisms that may be effective.

COMMITTEE DISCUSSION OF FDA QUESTIONS

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

a. What information do you think is most important to clearly convey to patients and caregivers about medical device recalls? Consider the following:

   i. details about the issue with the recalled device and which devices are affected;
   ii. possible actions you could consider taking to mitigate risks, including the use of alternative devices;
   iii. risks and benefits associated with continued use of recalled devices versus switching to alternatives, if available;
   iv. level of urgency to take action;
   v. describing what the FDA does not yet know, and the level of uncertainty about the information provided; or
   vi. any other information (please specify).

b. How can the FDA and industry clearly convey the most important information patients want to know about recalls?
c. Is it important to consider different information needs for patients who currently use a device versus patients considering use of one?

Dr. Monica Parker suggested verbal and written safety report updates from providers.

Ms. Chauhan stated that she believes the most important elements are level of urgency, details about an issue, and risks and benefits. She recommended prompt conveyance of this information to patients.

Jijo James, M.D., M.P.H., Industry Representative, suggested a better understanding of terminology that is more easily comprehensible to the intended audience.

Necie L. Edwards indicated that she would want to know when an issue was first discovered and the number of people who are affected by it, and that she has concerns about what should be done if patients find that their implanting physicians have relocated or are no longer in business.

Samprit Banerjee, Ph.D., affirmed that robust data is needed to determine levels of urgency and timelines. He also suggested a classification system for degrees of uncertainty with respect to safety issues.

Ms. Brummert stated that patients need to receive information directly from FDA. She advised the Agency to work closely with patient advocacy groups.

Shelby D. Reed, Ph.D., R.Ph., concurred with the idea of having a classification system for levels of uncertainty.

Dr. Ruth Parker emphasized that it should be clear to everyone that recalls are an issue of safety, that devices need to be included on medication lists, and that it is crucial for individuals to know if recalls relate to them.

Rita Roy, M.D., suggested that external registries could play a role in helping to directly notify patients who are affected by recalls.

Chairperson Conway summarized the Committee's response:

- Terminology has great significance.
- Sense of urgency is the most important information to convey to patients.
- The opportunity exists for FDA to become a better partner with stakeholders.
- Concerns were expressed regarding what an individual should do if they find out their physician is no longer available.
- Ascertain whether methods from other industries could be modeled or replicated.
- Patients with chronic conditions and multiple devices need information specific to their circumstances.
- Quality of life information is particularly important to patients.

Commander Olele read Question 2: Communicating recall information to patients with implanted devices (such as a defibrillator or deep brain stimulator) is particularly complex. The choice patients often face is whether to remove and replace the device or continue using the faulty recalled device. Each patient, in consultation with their physician, must weigh the risk of surgery or other procedure to remove and replace the device compared to the risk of continuing to use the recalled device. These can be difficult decisions as neither option is without risk.

a. What recommendations do you have for the FDA and industry in communicating recall information to patients facing these kinds of decisions?
b. What other types of devices do you think may warrant special communication approaches? Consider for example, devices that are worn, devices used at home without supervision of a healthcare professional, or other devices that patients "depend on."

Ms. Chauhan recommended direct communication with patients instead of relying on physicians who may or may not choose to recognize a recall.

Dr. Monica Parker mentioned the cost of device removal and replacement and asked who would be covering it.

Dr. Banerjee agreed that patients should be notified directly. He also suggested that the use of personas might be an effective method of communication.

Ms. Edwards proposed an easily accessible nationwide reporting system and government-issued guide.

Dr. James suggested a joint effort between industry, FDA, and patient groups to figure out better ways of conveying information.

Chairperson Conway summarized the Committee's response:

- There is a need for more communication.
- Communications should be simple, understandable, and ready to be put into action.
- There are concerns regarding who will cover the costs of additional surgical procedures and what the role of FDA is in this process.

He also suggested that manufacturers should be expected to address the need for special communications as part of the approval process.

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

a. What additional methods do you think the FDA and industry should consider to incorporate patient perspectives on these factors into benefit-risk decision making around recalls?
b. What additional information do you think healthcare providers should have available to aid their individualized discussion of benefits and risks with patients?

Dr. Ruth Parker highlighted the importance of clarity on safety issues.

Dr. Roy stated that manufacturers should be responsible for the conveyance of safety information to patients.

Mandatory adverse event reporting was suggested by **Ms. Brummert.**

The following recommendations were put forth by **Bennet R. Dunlap, M.S., Ms. Leong,** and **Ms. Edwards**:

- Communication protocols should be considered as part of the premarket approval process.
- FDA should work with industry in developing a framework for shared decision making and should have more control over the supply chain process.

Dr. Banerjee suggested the inclusion of additional data on patient-reported outcomes.

Chairperson Conway summarized the Committee's response:

- Recall communications and protocol should be part of the preapproval process.
- More clarity is needed, as well as a greater understanding of safety issues and risk tolerance.
- Other topics discussed include the use of artificial intelligence, responsibility of providers to communicate risk, supply chain issues, and FDA's regulatory authority.

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

a. What information do you think patients want to see in communications about lower-risk recalls? What factors should the FDA consider as "triggers" to identify which lower-risk recalls to prioritize for patient-focused communication?
b. Under what circumstances, if any, do you think the FDA should consider issuing a patient-focused communication to raise awareness about a recall before the FDA's assessment of the recall is completed?

Mr. Dunlap stated that communications before completion of recall assessment should be done if it is a life-critical situation such as a Class III device with serious problems.

Dr. James endorsed having a better understanding of what terminology should be used. He cautioned that not knowing what actions to take would be detrimental.

Dr. Banerjee emphasized the importance of communicating the likelihood of hazards and classifying the uncertainty about risk.

Dr. Roy underscored the value of relying on advocacy groups to aid in getting communications out to patients.

Ms. Leong stated that preliminary dialogue between patients and physicians should include discussions about recall awareness.

Chairperson Conway summarized the Committee's response:

- It is essential to be clear in understanding and communicating the likelihood and/or certainty of risk and its impact. This will precipitate what patients need to know and what they will need to do.

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

recalls. Please consider:

a. how you believe patients want to receive information about medical device recalls;
b. existing channels through which information is conveyed (such as e-mail, web posting, and social media), as well as new ones;
c. additional approaches for reaching "must-reach" audiences, including partnering with other organizations or groups;
d. additional approaches for reaching harder-to-reach populations, including those in rural or other areas with limited access to healthcare providers, healthcare facilities, the Internet or other wireless technologies; or
e. availability and find-ability of information (including by search engines and mobile device viewing).

Ms. Edwards opined that patients would like to receive information regarding medical device recalls in a variety of ways. She suggested newsletters, neighborhood networking services, and online community venues.

Dr. Monica Parker reasserted that medical societies and advocacy groups in partnership with larger media organizations are better at getting the messages out.

Chairperson Conway summarized the Committee's response:

- Partnerships and collaborations with patient support groups provide exceptional opportunities for networking.
- Tribal councils, specialty newsletters and publications, area agencies on aging, and local health agencies could also be potential avenues of communication.
- There are multiple platforms such as Pinterest and Instagram that could also be utilized, and there are many patient and professional organizations that have expressed the desire to work with FDA on these issues.

Commander Olele read Question 6: This question focuses on medical device recall terminology. The FDA assigns recalls as classification (I, II, or III) to indicate the relative degree of risk associated with use of or exposure to a recalled product. Class I recalls mean there is a reasonable probability that use of the recalled product will cause serious adverse health consequences or death. A medical device recall is considered Class II when use of a recalled product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote. Class III means use of the recalled product is not likely to cause adverse health consequences.

a. Are there other terminologies or approaches (e.g. color-coded alert levels) the FDA should consider to convey the degree of risk associated with a specific recalled device?
b. What other terminology besides "recall" should the FDA consider using, in certain cases, for example, with lower-risk recalls?

Mr. Dunlap pointed out that the inverted use of Roman numerals for device

classification and recall classification is confusing. He suggested looking at the kinds of terminology that other regulatory bodies use in these circumstances.

Dr. Monica Parker, Ms. Chauhan, and **Ms. Leong** encouraged the use of a color-coded system.

Dr. Ruth Parker recommended education about uncertainty, as well as accessible, up-to-date, data-driven evidence about risk.

Dr. James suggested further social sciences research, observing what other international regulatory bodies are doing, and using proper terminology for different types of medical devices.

Chairperson Conway summarized the Committee's response:

- Color coding is recommended along with clarification of need, expedience, and seriousness.
- Explore alternatives that are based on social sciences.
- There are various types of devices, and some may need different terminology and assessment.
- Phraseology should be clear and concise, and it may be helpful to consider what other entities are doing in that context.

CLOSING REMARKS AND ADJOURNMENT

Kathryn Capanna, BSE, recognized the Committee's fifth year. She and **Ms. Keith** thanked the members for their service on behalf of FDA.

Chairperson Conway thanked all of the participants. He underscored the complexities of this issue and the importance of understanding multiple means of communications and how they are sequenced.

He then adjourned the meeting at 5:24 p.m.

I certify that I attended this meeting on October 6, 2021 and that these minutes accurately reflect what transpired.

Letise W. Williams -S
Digitally signed by Letise W. Williams -S
Date: 2021.12.17 12:37:14 -05'00'

Letise Williams
Designated Federal Officer

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

Paul T. Conway 12/26/2021
Chairperson

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