FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Summary of the Patient Engagement Advisory Committee
October 6, 2021

Introduction:

The Patient Engagement Advisory Committee to the Food and Drug Administration (FDA) met October 6, 2021, to discuss and make recommendations on the topic ''Medical Device Recall Communication.'' Once a medical device is available in the U.S. marketplace and in widespread use, unforeseen problems can sometimes lead to a recall. When a device is defective or potentially harmful, recalling that product—removing it from the market or correcting the problem—is the most effective means for protecting the public. A company may recall a device after discovering a problem on its own, or after FDA raises concerns. In rare cases, FDA may require a company to recall a device. When a device is recalled, FDA reviews the company's strategy for resolving the problem by assessing the relative degree of risk associated with the product and making sure the strategy effectively resolves the problem with the device. FDA provides transparency and communicates information when the public needs to be alerted to a serious hazard, as well as once the recall has been appropriately resolved.

The recommendations provided by the committee addressed factors FDA and industry should consider to effectively communicate medical device recall information to patients and the public, including but not limited to content, format, methods used to disseminate the message, and timing of communication. The committee also considered concerns patients have about changes to their device in response to a recall and ways patient perspectives could be incorporated in FDA and industry benefit-risk decision making, as well as the health care provider and patient decision-making process related to a recalled medical device, including implanted devices.

Presentations:

Jeffrey Shuren, M.D., J.D., Director, Center for Devices & Radiological Health (CDRH), FDA, welcomed the Committee and public and provided opening remarks.

Erin Keith, Associate Director, Compliance & Quality, Office of Product Evaluation & Quality (OPEQ), CDRH, FDA, presented an Overview on Medical Device Recalls.

Angela Calman, Director, Office of Communication & Education (OCE), CDRH, FDA, presented on Medical Device Recall Communications.

Ommeed Shahrokh, Director, Regulatory Compliance, Stryker, presented an Industry Perspective on Medical Device Recalls.

Elizabeth Eisenberg, MSN, RN, CVAHP, Director, Scripps Health, presented a Health Care Provider's Perspective on Medical Device Recalls.

Kimberly Platt, Breast Implant Patient, presented a Patient's Perspective on Medical Device Recalls.

Open Public Hearing:

Thirteen open public hearing speakers presented and provided comments. Speakers included patients and representatives of patient advocacy groups, health research and health care professional organizations, and industry.

Virtual Breakout Session:

During the Virtual Breakout Session, the audience was asked to discuss amongst their breakout group a theoretical scenario about Medical Device Recalls.

Virtual Breakout Summations:

Concluding the Virtual Breakout Session, FDA representatives presented comments to the Committee and the public generated by the Virtual Breakout participants. The comments from the breakout rooms' participants revolved around feelings of concern and the need to receive more information when hearing news of an urgent medical device recall that may potentially impact them. They also expressed a level of puzzlement. For example, they wondered if they received the model of the device that was recalled and whether their doctor had provided them with any information about the device that would help them recognize whether they have the recalled device. There was also concern voiced about how they would know if they were affected by the recall, especially if they no longer had connection to the surgeon or facility where they received the implanted the device.

The information the virtual breakout participants most wanted to know was the details of the risks of the recalled device, whether their device was affected, how they may have been impacted by the recalled device, their options and relative risks associated with them, as well as the actions they need to take to ensure their safety. They also wanted to know what the word "recall" means, why the device was being recalled, how urgently they should act, how long the device was anticipated to last, and what is currently unknown (e.g. evolving knowledge about the risks associated with the recalled device). Other questions revolved around whether their health care provider knows about the recall, and how many people have been hurt or died. The participants indicated that some of the sources they would use to receive additional information about the recalled device included Google, FDA's website and databases and the Manufacturer's website. Participants also

recommended that recall information should be consolidated at a single FDA site or one central outlet.

In terms of the decision to remove the recalled device or not, the participants felt they needed more information than provided in the scenario before they could make an informed decision. They wanted to know about the risks of alternatives, likelihood of sudden death, the unknowns about the recalled device, and if the doctor is making a general recommendation or one based on the specific patient's case. Participants also wanted to know who would pay for getting the device removed and replaced. If the participants were not having any negative effects or signs of problems, before making a decision as to whether to remove a device and replace it with the alternative they would want to know whether the risks of the device were high or low. Participants indicated that to get more information and find out if the recall impacts them, they would get the opinion of another provider, do as much online research as possible, including patient chat rooms, and go straight to the manufacturer. Participants recommended that FDA should provide more clear recall information. Participants wanted more access to credible registries, to receive a card for each implanted device, and to receive multi-culturally targeted recall communications directly and promptly for any recalled implanted device.

FDA Questions and Committee Discussion:

The Committee discussed approaches FDA and industry should consider as it pertains to Medical Device Recall Communication.

FDA and medical device industry share responsibility for informing the public about medical device risks. Manufacturers are responsible for ensuring their direct customers receive information about recalls. 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.

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.

The Committee generally agreed that nomenclature matters and terms like "safety" are important because they are clear and heighten attention. The most important information to clearly convey to patients and caregivers about medical device recalls are the safety concerns, the urgency of the issue, and information to help identify affected patients. Patients also want to know about alternative options and associated risks. The Committee also discussed uncertainty and the evolving knowledge related to recalls. Many patients may want to hear about unknowns regarding

safety risks (e.g. severity, likelihood, and factors associated with higher risk). The Committee recommends adopting a classification system that explains the level of uncertainty in the risk estimates associated with a medical device recall. The Committee also suggested that FDA has a role in patient education and should better understand what patients think when they hear the term "recall." Communications surrounding a medical device recall should make it clear to patients when the device being recalled poses a safety concern.

The Committee recommended that FDA develop a framework that manufacturers follow when issuing communication about a medical device recall, including working with patient groups and health care providers. The Committee highlighted that recall communication must be "simple, understandable, and actionable" for patients. The Committee recommended using social science and data-driven personas that represent the affected population. The Committee also suggested including affected patients and/or patient advocacy organizations to inform communication about a recalled device and how best to convey the information to patients. The Committee recommended FDA and Industry use a variety of platforms to communicate recalled information to patients, including radio, television, and social media. The Committee also emphasized the importance of including outlets that reach underserved patient populations.

The Committee underscored the importance of communicating directly with patients about recalled devices, particularly with implanted recalled devices. The Committee focused on challenges patients face figuring out whether a recall affects them, particularly with implanted devices, if they don't know which specific device they have, or if they no longer have a connection to the implanting provider or facility. The Committee suggested that encouraging vendors of Electronic Health Records (EHRs) to include the medical device Unique Device Identifier (UDI) may help identify specific impacted patients. The Committee suggested other ways to help patients know whether a recall affects them, including reporting UDI information in various digital records of patient health information accessible to patients, patients requesting UDI and/or other pertinent device information directly from their physicians, and external registries that could potentially be used to directly notify patients with implanted devices about a medical device recall.

The Committee suggested other types of devices that may warrant special communication approaches, such as devices used at home, including external equipment, or those that involve mobile applications or telemedicine. Mobile applications may help inform and activate patients about recalls and provide patients with the information that they need. The Committee generally recommended that manufacturers should consider this early during device design and development, and build in mechanisms or proposed approaches for identifying and communicating with patients in the event of a recall. The Committee recommended FDA evaluate this during the medical device authorization process.

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.

The Committee recommended that the FDA's communications on recalls be clear that there is a safety risk, while acknowledging that risk tolerance varies from patient to patient. The Committee recommended the FDA and industry consider existing data driven approaches, including patient preference information on how patients evaluate the benefit/risk trade-offs associated with recalls, generating personas, and other approaches to incorporate patient voices on benefit-risk related to medical device recalls.

The Committee recommended that the FDA play a role in promoting shared decision-making in the context of medical device recalls, in order to support individualized discussion of benefits and risks between patients and providers. To assist health care providers, the Committee recommended sharing a prioritization scheme based on comorbidities and other considerations that can help inform how they counsel their patients to make the best decision for the individual. While the Committee indicates that manufacturers and health care providers have a responsibility to communicate medical device recall information to patients, they made it clear that FDA also has a role as a regulatory authority.

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, the Committee generally recommended using different terms for lower risk recalls, to differentiate them from higher risk recalls. The Committee also recommended factors the FDA should consider as "triggers" to identify which lower-risk recalls to prioritize for patient-focused communication, including likelihood of risk, the level of impact it will have on the patient's life, and whether there is information about the actions that should be taken. Under life-critical circumstances, the Committee recommended the FDA consider issuing a patient-focused communication to raise awareness about a recall before the FDA's assessment of the recall is completed.

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, health care providers, or patients to raise awareness about a particular safety issue.

The Committee recommended the FDA leverage broader stakeholders lists, such as the Office of Personnel Management's (OPM) Combined Federal Campaign (CFC) list, to disseminate FDA's communication for certain medical device recalls. The Committee generally suggested patients want to receive information about medical device recalls in a variety of ways. This includes social media platforms which focus on visual content (i.e., Pinterest, Instagram) which could use pictures of affected devices. To reach wider audiences, including racially and ethnically diverse populations, the Committee pointed to COVID-19 pandemic practices by the government as well as prior experiences by health agencies, and recommended including radio, television, local media outlets,

partnering with medical societies and patient groups, as well as regional health agencies, tribal councils, and local/regional health professional networks who know a particular community.

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

The Committee recommended FDA consider using a color-coded tiered approach that would make it easier for patients to quickly understand the level of urgency and risk associated with a particular device recall. The color coding should be based on "common sense" approaches used in other public alert systems. Descriptions should clarify the level of urgency associated with the different colors. Social science methods should be used to test alternative approaches, and the system should be concise and clear. The Committee also recommended that FDA considers using other terminology besides "recall", in certain cases, for example with lower risk recalls, which reflect a different level of urgency. The Committee discussed potentially harmonizing with international terminology (e.g., field alerts).

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