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

U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Patient Engagement Advisory Committee (PEAC) Meeting
Virtual

FDA DISCUSSION QUESTIONS

OCTOBER 6, 2021

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?

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."

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 health care providers should have available to aid their individualized discussion of benefits and risks with patients?

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 a 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?

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 email, 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 health care providers, healthcare facilities, the internet or other wireless technologies; or

e. availability and findability of information (including by search engines and mobile device viewing).

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

   a. Are there other terminologies or approaches (e.g. color-coded alert levels) the FDA should consider to convey the degree of risk associated with a specific recalled device?

   b. What other terminology besides "recall" should the FDA consider using, in certain cases, for example with lower risk recalls?