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

Guiding Principles for Virtual Breakout Sessions to Discuss Hypothetical Scenario

October 6, 2021

1. Participation in the breakout session is completely voluntary.

2. Participants in the breakout session cannot ask questions of one another but can comment on the questions or prompts included in the scenario and on comments provided by other participants. FDA moderators and notetakers will interrupt you if you question one another. This restriction is a requirement of the Federal Advisory Committee Act.

3. FDA moderators will guide the discussion but will not be providing comments or feedback on the scenario. They will also not be acting in their role as FDA staff members but solely as moderators to ensure that your voice is captured.

4. Participants in the breakout session should mute their phone if they are not speaking.

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PEAC MEDICAL DEVICE RECALL SCENARIO

Please note that this is a hypothetical scenario and is not describing a real device or patient situation. We ask that you imagine yourself in the scenario below as you answer the questions.

Seven years ago, you had Pulsaaar, a device manufactured by Best Medical Company, surgically implanted in your body to help your heart work better. After recovering from the surgery, you noticed an overall improvement in your quality of life.

Today, you see a news headline that Best Medical Company issued an urgent medical device recall of certain lot numbers of the Pulsaaar device.

1. **How would you feel hearing the news of the recall?**

2. **What information do you most want to know?**

3. **What other questions do you have about this recall? Where would you go for more information?**

You decide to speak with your health care provider. She informs you that in some cases, the recalled device malfunctions. If that happens, you could have serious complications, including sudden death. There are two options for patients using Pulsaaar. This includes either: Option A) keeping the device implanted while monitoring closely for signs that your device is having problems, or Option B) removing it and replacing it with an alternative device, which would require another surgical procedure.

In your discussion, you talk about the pros and cons of each option. This includes risks from the recalled device and risks from a repeat surgery, and cost. Your health care provider informs you the alternative devices on the market might be safer than Pulsaaar, but the risk of a repeat surgery is very high in your case.

4. **If your doctor recommended:**

    a. **option A (keeping the device while monitoring closely for problems), how likely are you to follow this advice? Why or why not?**

    b. **option B (removing your device and replacing it with an alternative), how likely are you to follow this advice? Why or why not?**

5. **If you aren't currently having negative effects or signs of problems from the recalled device, what would make you want to remove the device and replace it with the alternative?**

Let's say you did not speak with your health care provider.

6. **What would you do to find out if this recall impacts you? What approach would you take, and where you would go for more information?**

7. **After going through this recall experience, what would you like to see the FDA and industry change, to make it easier to:**

   a. **get the information you need about recalls and safety issues for devices you use?**

   b. **quickly determine if the recall or safety notification affects your specific device?**

   c. **make decisions (independently or in consultation with your healthcare provider) about the best course of action for you in response to the recall?**