U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Patient Engagement Advisory Committee (PEAC) Meeting
Hilton Washington DC North/Gaithersburg

Audience Discussion Scenario

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Instructions: The theoretical scenario below is an example of a postmarket safety dilemma that many device companies and FDA have encountered. Every table will not be discussing every question; therefore, your active participation and thoughtful comments are necessary. We encourage active and free discussion as you participate in this exercise. Your comments will be aggregated with all the comments generated by your table and will be discussed by the PEAC members.

Scenario: You are employed by a medical device company that manufactures Device C. In your position, you are responsible for conducting postmarket surveillance on Device C (that is, evaluating potential safety concerns for the marketed device). Device C, designed to cure lung cancer, has completely changed how physicians treat this disease and has exponentially increased survival rates for lung cancer patients.

You received an email from one of your field technicians that Device C may be causing strokes in patients by causing an irregular heart rhythm like atrial fibrillation. You are asked to determine whether there is a real safety problem. You have already talked with healthcare professionals and have searched the peer-reviewed medical literature but are still unsure if there is truly a safety concern. You have also exhausted all the set processes that your company usually has you follow when there are potential safety concerns with their marketed medical devices. Your boss does not want to pull Device C from the market (for example, issue a voluntary recall) unless there is evidence of a true safety concern; however, your boss is concerned about possible lawsuits and patient deaths if Device C is associated with strokes. You would like to explore the issue a bit more before making your recommendation. You are interested in researching patient sites for more information.

Q1: Which patient-driven or patient-focused sites would you visit to collect more evidence about this possible safety concern?

Q2: What are the challenges with using these sources of data to inform your decision?

Q3: What additional information would you need to feel more comfortable deciding whether to remove or keep Device C on the US market?

Your review of those sites reveals that there may be a safety concern with Device C. You receive a call from the FDA who has also received several reports in the MedWatch database about strokes occurring

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with the use of Device C, and heard a few providers presenting on it at an annual meeting of oncologists. The FDA decides to order a postmarket surveillance study (that is, a 522 study) to better understand the nature, severity, or frequency of this suspected problem reported in the adverse event reports. Both the FDA and your company discuss the design of the postmarket surveillance study to collect more data to evaluate the safety of Device C. Your company's safety team suggests that you do a randomized, controlled clinical trial to evaluate the safety.

Q4: How could you use the internet to find patients with the condition to participate in your clinical trial? What are the challenges with using this approach to identify patients?

The FDA encourages your company to consider another study design format instead of a randomized controlled clinical trial.

Q5: Would you consider using a different study format such as a patient-driven registry to evaluate whether there is a true safety concern? Why or why not?

Your company has identified a multistate lung cancer registry owned by state Departments of Health that collects information on Device C as well as tracks the survival rate of patients and any data on hospitalizations and emergency room visits (since acute stroke patients are often hospitalized). There is also a patient-driven lung cancer registry that collects information about the quality of life of lung cancer patients and saves all information collected by their activity trackers which includes, continuous heart rate, sleep pattern, and number of steps.

Q6: What information would you want to see collected in the registries?

Q7: Would you use one or both registries to help evaluate the safety concern or would you devise your own clinical trial? Please discuss why or why not for each of the registry approaches.

Q8: How would you use the registries to evaluate the safety concern of interest? What concerns would you have with using the activity trackers to monitor the irregular heart rhythm? Are there patient behaviors that could impact the reliability and validity of the activity trackers? Are there characteristics of the activity tracker that may limit its usefulness?

To increase transparency to the FDA's stakeholders, including consumers, physicians, and industry, the FDA posts information about your postmarket surveillance study on the FDA's 522 webpage (see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm for an example of what is typically posted). You and the FDA also agree that a safety message needs to be communicated to patients revealing the results of your company's 522 study.

Q9: What factors, if anything, would you consider when planning the wording and dissemination plan for the safety message to ensure it is understandable and available to your audience?

Q10: The FDA and your company determine that the safety message should be for general awareness or public notification of an emerging postmarket safety signal.

a. *Based on your market research (findings from audience poll), which media platform(s) would you use to communicate the problem to patients? To healthcare providers?*
b. *How should the FDA disseminate the communication messages to patients? To healthcare providers?*

c. *Who else should be involved in disseminating the communication message to the public? How should they disseminate it to the patients? To healthcare providers?*

Q11: The FDA and your company determine that the safety signal should lead to the voluntary recall of the device.

a. *Based on your market research (findings from audience poll), which media platform(s) would you use to communicate the problem to patients? To healthcare providers?*
b. *How should the FDA disseminate the communication messages to patients? To healthcare providers?*
c. *Who else should be involved in disseminating the communication message to the public? How should they disseminate it to the patients? To healthcare providers?*

Q12. The FDA and your company determine that the safety signal should lead to a restriction of the product in certain patient subgroups.

a. *Based on your market research (findings from audience poll), which media platform(s) would you use to communicate the problem to patients? To healthcare providers?*
b. *How should the FDA disseminate the communication messages to patients? To healthcare providers?*
c. *Who else should be involved in disseminating the communication message to the public? How should they disseminate it to the patients? To healthcare providers?*