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Food, Drug And Device Law Alert - FDA Describes Policy For Emerging Medical Device Signals In Final Guidance

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The Food and Drug Administration (FDA) recently issued a final guidance to describe its policy for notifying the public about medical device "emerging signals." For the purposes of the guidance, an "emerging signal" is "new information about a marketed medical device: 1) that supports a new causal association or a new aspect of a known association between a device and an adverse event or set of adverse events, and 2) for which the Agency has conducted an initial evaluation and determined that the information has the potential to impact patient management decisions and/or the known benefit-risk profile of the device."

According to the FDA, at the time a medical device is approved or cleared, it has a benefit-risk profile that healthcare providers, patients and consumers use to make treatment decisions. Once a medical device is on the market, new information, including unanticipated problems, may change the benefit-risk profile of a device. Timely communication of such new information may help healthcare providers, patients and consumers make informed treatment choices based on the most current available information. The guidance document proposes criteria, timeframes and follow-up for FDA communications for emerging signals.

Criteria

The guidance states that FDA considers many factors in the course of evaluating and communicating about medical device emerging signals. Differing somewhat from the draft version, the final guidance includes the following non-exclusive list of factors:

- Likelihood (probability) of the harmful event(s)
- Magnitude (severity), duration, and reversibility of the harmful event(s)
- Magnitude of the benefit (e.g., the degree to which a given condition, symptom or function is improved and whether the device provides life-sustaining or life-saving benefits)
- The quality of the data or information
- The strength of the evidence of a causal relationship between the use of a device and the adverse event
- Extent of patient exposure (e.g., how broadly is the device used, the duration of exposure, including whether the device is intended

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to be permanently implanted)

- Whether there is a disproportionate impact on vulnerable patient populations (e.g., children, pregnant women, elderly, cancer patients, chronically ill patients, at-home/unmonitored patients)
- Potential for preventing, identifying, monitoring or mitigating the risk
- Availability, risks, and benefits of alternative therapies
- Potential for patients to not receive treatments they should even in light of the new information
- Implications for similar or related devices (e.g., multiple models from multiple manufacturers)
- Anticipated time for completion of FDA's assessment of the available information and development of recommendations
- Accuracy and availability of information already in the public domain

The guidance advises FDA staff to consider strongly public communication about an emerging signal when all of the following statements apply:

- the information supports a new causal association, or a new aspect of a known association (e.g., increased rate or severity of event or reduced benefit), between a medical device and one or more adverse events or clinical outcomes
- the available evidence is of sufficient strength
- the information could have important clinical implications for patient management decisions and/or could it significantly alter the known benefit-risk profile of the device

Although the guidance states early on that "[i]nformation that is unconfirmed, unreliable, or lacks sufficient strength of evidence is not an emerging signal," device manufacturers may legitimately be concerned about what the FDA will consider "sufficient" strength of evidence to communicate new information about a device. The data needed to obtain approval or clearance for a device can be substantial. Hopefully, the FDA will not lightly disseminate negative new information based on anecdotes or other inadequate data. In this connection, it is worth noting that the draft version phrased the first statement above as "the information *represents* a new, *potentially* causal association…" and the second as "the available *information is reliable* and supported by sufficient strength of evidence" (emphasis added).

Timing

The guidance instructs FDA staff to conduct an initial assessment of the need to communicate about an emerging signal within 30 days of receiving the information.

Method of Communication

A template for communications on emerging signals that accompanied

the draft version of this guidance is missing from the final version. The guidance states: “In general, a public notification regarding an emerging signal for a medical device should include:

- a description of the device(s) to which the public notification applies
- a summary of the emerging signal, including the objective evidence on which the decision to issue a public notification is based
- information on the known benefits and risks of the device and its use

Follow-up

In cases where FDA staff decides not to communicate about an emerging signal, the draft guidance recommends the staff re-evaluate the decision within 30 days of receiving (more) new information.

Further, the draft guidance advises FDA staff to issue updates to the communication on the FDA website at least twice per year, or more often as necessary and appropriate, until either the FDA issues a more formal “Safety Communication” containing specific recommendations or until its evaluation of the signal is otherwise completed and the public is notified of its conclusions.

A copy of the final guidance can be found here.

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