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New FDA Guidance on Medical Devices

Client Advisories

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December 20, 2016 — On December 14, 2016, the Food and Drug Administration issued a Guidance for Industry and Food and Drug Administration Staff regarding emerging signals associated with medical devices. The Guidance describes the Center for Devices and Radiological Health's (CDRH) policy for notifying the public about emerging signals that may arise after a medical device is placed on the market.

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, and (2) for which FDA has conducted an initial evaluation and determined that the information has the potential to impact patient management decisions or the benefit-risk profile of the device. Information that is unconfirmed, unreliable or lacks sufficient strength does not constitute an emerging signal.

Medical devices are thoroughly studied and tested before they are placed on the market, but no amount of testing can approximate real-world conditions. After a device is marketed, unanticipated adverse events, new product-to-product interactions, and other changes to the device's benefit-risk profile may be reported. These reports need to be evaluated to determine whether they are real and causally related to the device — i.e., whether they represent a potential safety concern with the device or its use.

If the new information is deemed to be a signal, CDRH convenes an in-house team of subject matter and regulatory experts. The team gathers relevant information from multiple sources; interacts with the medical device company to the extent it is feasible to do so; and may engage external experts, as appropriate. In the first phase of its work, CDRH attempts to better understand the potential risk and whether there may be a causal relationship between the potential risk and the use of the device. CDRH also attempts to assess the scope of the risk — i.e., whether the risk is limited to a particular model or manufacturer or may have a broader impact across a device type.

CDRH considers numerous factors in deciding whether to alert the public about an emerging signal, including:

- the likelihood or probability of harmful events;
- the magnitude, severity, duration and reversibility of harmful events;
- the magnitude of the benefit, including any 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 the device and the adverse event;
- the extent of patient exposure;
- whether there is a disproportionate impact on vulnerable patient populations;
- the potential for preventing, identifying, monitoring or mitigating the risk;
- the availability of alternative therapies;
- the potential for patients to not receive treatments that they should receive;
- the implications for similar or related devices;
- the anticipated time for completion of FDA's assessment of the available information and development of recommendations; and
- the accuracy and availability of information already in the public domain.

As can be seen from this list of factors, whether to notify the public about an emerging signal requires careful consideration. There is an obvious desire to provide health care providers and patients with up-to-date information, but a false or inconclusive warning may unnecessarily alarm doctors and patients, discouraging them from using beneficial devices or pursing appropriate treatment. There is also a concern that early notifications may lead to increased litigation. FDA's decision to alert the public about an emerging signal does not mean that FDA has found a causal relationship between the device and an adverse event. But this may not matter to plaintiffs' lawyers looking to file cases, and juries may not distinguish between an emerging signal and a definitive causal relationship.

FDA's decision to issue notifications to the public before reaching final conclusions represents a departure from CDRH's current practice, whereby information about emerging signals is not released until an investigation is complete. Early publication of safety information before it can be fully vetted is subject to misinterpretation by the public, can cause reputational harm to the manufacturers of approved devices, and can lead to unfounded lawsuits. To avoid discouraging health care providers and patients from using beneficial devices, FDA should carefully evaluate emerging signals and reach firm conclusions and recommendations before issuing warnings to the public.

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