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Client Alert

FDA & Life Sciences Practice Group

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FDA Releases Its Proposals to Strengthen the Medical Device Postmarket Surveillance System

On September 6, 2012, the United States Food and Drug Administration (FDA or "the Agency") made available for comment its report "Strengthening Our National System for Medical Device Postmarket Surveillance."[1] The report provides the Agency's proposals to strengthen the medical device postmarket surveillance system in the United States.

In July 2011, the Institute of Medicine (IOM) published a report entitled, "Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years." IOM's report recommended that FDA "develop and implement a comprehensive medical device postmarket surveillance strategy to collect, analyze, and act on medical device postmarket performance information." In its report, FDA proposes four specific actions to strengthen the medical device postmarket system:

- Establish a Unique Device Identification (UDI) system and promote its incorporation into electronic health information;
- Promote the development of national and international device registries for selected products;
- Modernize adverse event reporting and analysis; and
- Develop and use new methods for evidence generation and synthesis and appraisal.

FDA's current medical device postmarketing surveillance system relies on: reporting of possible device-associated serious injuries, deaths, and malfunctions (Medical Device Reporting); an enhanced surveillance of approximately 280 hospitals nationwide to better understand and report device use and adverse outcomes (Medical Product Safety Network); post-approval and postmarket surveillance studies for selected devices ordered by FDA; discretionary studies; and other tools to track, restrict, ban, and/or recall medical devices from the market.

The Agency believes its proposed actions for strengthening the medical device postmarket surveillance system "would augment, not replace," its current mechanisms for postmarket surveillance.

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Establishing a UDI System

On July 10, 2012, FDA issued a proposed rule for establishing a UDI system for medical devices.[2] The UDI is an alpha-numeric code that consists of two parts: (1) a device identifier specific to a device model, and (2) a production identifier (*e.g.*, name of manufacturer, lot or batch number, serial number, expiration date, and/or date of manufacture). In its report, the Agency states that it intends the UDI system to enhance its current postmarket surveillance by "providing a standard and unambiguous way to document device use in [electronic health records], clinical information systems, and claims data sources." FDA believes that the UDI system will allow FDA and the industry to more accurately report, review, and analyze adverse events reports because critical device specific information will be available and can be included in the adverse event reports. In addition, the report states that the UDI system will allow for a more precise identification of a device, will allow specific information to be obtained about a device, and will improve the ability to trace a device.

Facilitating the Creation of National and International Device Registries

Although FDA acknowledges that it is "neither practical nor feasible to have registries that address every medical device problem or issue," the Agency believes that targeted registries in key product areas can "enhance public health and be cost-effective for industry, health care providers and payers." These "product areas of high importance" can be determined by the "large public health need, patient exposure, uncertain long-term or real-word device performance, or societal cost." While it is not seeking to centralize or regulate the registries, FDA proposes to continue to help facilitate the creation and maintenance of medical device registries. FDA intends to hold public workshops to discuss how medical device registries could be useful for medical device surveillance and assessment of benefits and risks.[3]

Modernizing Adverse Event Reporting

Because of the limitations of spontaneous reporting of postmarket medical device adverse events, FDA acknowledges that modernizing adverse event reporting and analysis is a "key requirement of a comprehensive medical device postmarket surveillance system." In its report, the Agency discusses several activities to improve and modernize adverse event reporting, including:

- The use of automated adverse event reporting systems (*e.g.*, software capable of exporting real-time adverse event reports with UDI information from hospital incident reporting systems to FDA) to automatically detect and report adverse events related to specific devices to improve the number and quality of the adverse event reports and more regularly alert FDA;
- Increasing the use of electronic reporting of medical device adverse events to enhance the timeliness, quality, and efficiency of reporting and surveillance;
- Developing and implementing a mobile application for reporting medical device adverse events to increase the submission of voluntary adverse event reports;
- Developing a new adverse reporting system (FDA Adverse Event Reporting System (FAERS)) to replace the Manufacturer and User Facility Device Experience (MAUDE) database as MAUDE is exceeding its design capacity and cannot take advantage of modern analytical capabilities; and

- Examining the use of automated, computerized statistical methods to focus on identifying patterns of association and more rapidly identify safety signals.

Developing New Methods for Evidence Generation, Synthesis and Appraisal

FDA believes that new methods for evidence generation, synthesis, and appraisal "will improve the efficiency and quality of decision-making by identifying new and better ways to leverage existing data sources by providing more timely information about the benefits and risks of marketed products, and by translating data into knowledge to help better inform regulatory and clinical decisions." In its report the Agency includes several approaches it is exploring to generate, synthesize, and interpret postmarketing information, including:

- The use of quantitative decision analysis to better quantify the benefits and risks of a medical device;
- Combining medical device performance and clinical outcome data from diverse sources to provide a comprehensive, up-to-date benefit-risk profile for a device and developing data standards to promote the efficient sharing of information;
- The use of automated signal detection software to promptly identify safety signals, *e.g.*, the Data Extraction and Longitudinal Time Analysis applied to cardiovascular device registries to detect safety signals for approved cardiovascular devices; and
- Establishing a process for timely evaluation and management of safety signals.

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Please contact us if you have questions regarding the potential implications of FDA's proposed actions for strengthening the postmarket surveillance of medical devices or if you would like assistance in developing comments. FDA is requesting comments by October 9, 2012.

[1] FDA, "Strengthening Our National System for Medical Device Postmarket Surveillance," September 2012, *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM301924.pdf.
[2] 77 Fed. Reg. 40736 (July 10, 2012).
[3] *See* http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm300724.htm.