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FDA Unveils New System to Track Medical Devices

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FDA's New Plan

The Food and Drug Administration ("FDA") recently proposed a new system to track medical device malfunctions, increase patient safety and streamline product recall.[1] On July 3, 2012, the FDA released its plan to label high-risk medical devices with tracking numbers, known as Unique Device Identifiers ("UDIs").[2] A UDI is a unique numeric or alphanumeric code, which operates "as a key to certain basic identifying information about a device, such as the name of the manufacturer, type of device, expiration date and batch or lot number."[3] This information will be available to the public on the FDA database.

According to the FDA, "the proposed rule reflects the considerable input the FDA received from the medical device industry, the clinical community, patients, consumers, and industry experts. To minimize industry costs and expedite implementation, the proposed system builds upon current standards and systems already in use by some companies."[4] FDA Commissioner, Dr. Margaret A. Hamburg, stated that the "safety of medical devices is a top priority for the FDA, Congress, industry and patients."[5] Commissioner Hamburg further declared that the "unique identification system will enhance the flow of information about medical devices, especially adverse events and, as a result, will advance [the FDA's] ability to improve patient safety."[6] The UDIs will enable the FDA to access data maintained by government agencies, insurers and hospitals to determine which devices have a high degree of failure.[7] Such product information will also be accessible to patients, doctors, industry regulators and consumer advocates.[8]

Prior to the proposed UDI regulation, the FDA did not have a comprehensive plan to monitor medical device malfunctions. Currently, the FDA's monitoring system relies heavily on ad hoc reporting from doctors or manufacturing companies. As a result, it is unclear which devices have safety issues and whether any safety issues affect a single batch of devices or an entire model of devices. Until now the FDA was not able to reliably link a device with the trend of patients' or practitioners' experience with that device. For instance, al-

[1] Lavine, Greg, *FDA Planning Identification System to Track Medical Devices*, Am. J. Health-Syst Pharm, Vol. 66 (March 15, 2009).

[2] *See* (6 MELR 442, 7/11/12) and http://www.gpo.gov/fdsys/pkg/FR-2012-07-10/pdf/2012-16621.pdf.

[3] U.S. Food and Drug Administration, News and Events, *FDA Proposes Unique Device Identification System for Medical Devices*, *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm310505.htm (last visited August 26, 2012).

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[4] *Id.*

[5] Walsh, James, *FDA Lays Out New System to Track Medical Devices*, *available at* http://postbulletin.com/news/stories/display.php?id=1501658 (July 5, 2012).

[6] *Id.*

[7] Burton, Thomas M., The Wall Street Journal Online, *FDA Unveils Medical-Device Tracing Plan*, *available at* http://online.wsj.com/article/SB10001424052702304211804577505094143301240.html (July 3, 2012).

[8] Walsh, James, *FDA Lays Out New System to Track Medical Devices*, *available at* http://postbulletin.com/news/stories/display.php?id=1501658 (July 5, 2012).

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though there were an estimated 66,000 reports regarding faulty medical devices in 2007, half of these devices lacked sufficient indentifying information for an effective product recall.[9]

The UDI system will fill this information gap and enable doctors and patients to make more informed decisions about which devices they use. This new post-market monitoring system took years to develop because the FDA had to develop a set of standard international codes with regulators across the globe and validate the new coding system.[10]

High-Risk Devices

The FDA will begin to issue UDI tracking mandates for devices in 2014 and plans for the UDI system to be fully implemented for all high-risk devices by 2021.[11] Device manufacturers will be required to apply the UDI coding and tracking system in compliance with the FDA specifications and timelines. Low-risk devices and over-the-counter devices sold in stores (e.g., bed pans) are exempt from the UDI tracking requirement.[12] The FDA will identify ''high-risk devices'' for the UDI tracking program based upon the likelihood of a device's sudden, devastating failure, the likelihood of significant adverse clinical outcomes, and the need for prompt professional intervention. The FDA will require devices with the highest levels of product malfunctions (e.g., heart-defibrillator wires, pacemakers and stents) to be coded first.[13] At any time, the FDA may revise the list of UDI tracked devices based upon a device's premarket application, recall data, inspections, petitions, or prior post-market surveillance.[14]

At this time, the following implantable devices will require tracking under the proposed plan:

- temporomandibular Joint (TMJ) prosthesis,
- glenoid fossa prosthesis,
- mandibular condyle prosthesis,
- implantable pacemaker pulse generator,
- cardiovascular permanent implantable pacemaker electrode,
- replacement heart valve (mechanical only),
- automatic implantable cardioverter/defibrillator,
- implanted cerebellar stimulator,
- implanted diaphragmatic/phrenic nerve stimulator,
- implantable infusion pumps,
- abdominal aortic aneurysm (AAA) stent grafts,
- silicone gel-filled breast implants,
- cultured epidermal autografts,
- thoracic aortic aneurysm (TAA) stent grafts, and
- transcatheter pulmonary valve (TPV) prosthesis.[15]

Additionally, the FDA will require UDI tracking for the following devices:

- breathing frequency monitors,
- continuous ventilators,
- ventricular bypass (assist) device, and
- DC-defibrillators and paddles.[16]

Tracking Methods

Once the FDA orders a manufacturer to implement UDI coding and tracking for a certain type of high-risk device, the device must be tracked by the manufacturer from the time it is manufactured through the distribution chain, allowing all relevant information to appear on the UDI system. The FDA will not require manufacturers to use a specific method of device tracking. Instead manufacturers must establish written standard operating procedures (SOPs) which designate a method of tracking that will produce the information required by the FDA.[17] In order for the UDI regulation be effective, the ''[t]racking methods must provide critical failure information about the location of a tracked device within a short time frame.''[18] The tracking method selected by manufacturers must provide critical failure information about undistributed UDI devices within three days of an incident and provide failure information about distributed UDI devices within 10 days of an incident.[19]

Cost

The cost of the FDA's new plan is not insignificant. According to the proposal, the FDA estimates that the annual industry cost to implement the system will be approximately $68 million.[20] Over a 10 year period, the implementation of the plan will likely cost U.S. compa-

[9] *Id.*

[10] Yukhananov, Anna, Insurance Journal, *FDA Plans IDs to Track Medical Device Safety*, *available at* http://www.insurancejournal.com/news/national/2012/07/06/254653.htm (July 6, 2012).

[11] Burton, Thomas M., The Wall Street Journal Online, *FDA Unveils Medical-Device Tracing Plan*, *available at* http://online.wsj.com/article/SB10001424052702304211804577505094143301240.html (July 3, 2012).

[12] Walsh, James, *FDA Lays Out New System to Track Medical Devices*, *available at* http://postbulletin.com/news/stories/display.php?id=1501658 (July 5, 2012).

[13] *Id.*

[14] U.S. Food and Drug Administration, Medical Devices: *Medical Device Tracking; Guidance for Industry and FDA Staff*, *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071756.htm (last visited August 26, 2012).

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] U.S. Food and Drug Administration, Medical Devices: *Medical Device Tracking; Guidance for Industry and FDA Staff*, *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071756.htm (last visited August 26, 2012).

[19] *Id.*

[20] Walsh, James, *FDA Lays Out New System to Track Medical Devices*, *available at* http://postbulletin.com/news/stories/display.php?id=1501658 (July 5, 2012).

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nies a total of nearly $550 million.[21] It is not clear how the UDI tracking system will be funded.[22]

Public Comment

Since the FDA proposed its new plan to track medical devices, many have chimed in on the likely effects such tracking system will have on the healthcare industry and patient safety. Lisa Swirsky, Senior Policy Analyst for Consumer Union, states that the ''regulations are long overdue and are critical for protecting patients from faulty and dangerous medical devices.''[23] According to Ms. Swirsky, ''[e]ffective post-market surveillance of medical devices depends on having a UDI in place. Once it is fully implemented, this system will enhance the FDA's ability to identify problem medical devices more quickly and inform patients when their safety is at risk.''[24] Likewise, Janet Trunzo, Senior Executive Vice President for Technology and Regulatory Affairs for the Advanced Medical Technology Association (AdvaMed), agrees that the success of the UDI system ''depends on device users consistently and effectively utilizing the UDI system for tracking recalls, adverse event reporting, and within electronic health records.'' [25]

As the FDA gears up to finalize this new regulation by the end of 2012, the public has 120 days to comment on the proposed rule (77 Fed. Reg. 40,736, July 20, 2012), with comments due Nov. 7. The FDA will consider the comments (Docket No. FDA-2011-N-0090) before adopting it a final rule, which must happen no later than six months after the comment period.

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[21] Yukhananov, Anna, Insurance Journal, *FDA Plans IDs to Track Medical Device Safety*, *available at* http://www.insurancejournal.com/news/national/2012/07/06/254653.htm (July 6, 2012).

[22] Walsh, James, *FDA Lays Out New System to Track Medical Devices*, *available at* http://postbulletin.com/news/stories/display.php?id=1501658 (July 5, 2012).

[23] *Id.*

[24] *Id.*

[25] *Id.*