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**FDA PROPOSES UNIQUE DEVICE IDENTIFICATION  
SYSTEM FOR MEDICAL DEVICES**

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With a view toward more accurate tracking and reporting of adverse medical device events, on July 10, 2012, the Food and Drug Administration (“FDA”) issued a proposal to establish a unique device identification system. That proposal responded to an amendment to the Federal Food, Drug and Cosmetic Act, directing the FDA to promulgate regulations that will require certain medical devices to bear a unique device identifier (“UDI”). The UDI is an identifier that specifically identifies a medical device through its distribution and use and consists of a general number that specifies the version or model of the device (the “device identifier”), together with certain variable information, including the specific lot or batch, serial number, expiration date or date of manufacture of the item (the “production identifier”).

The system proposed by the FDA will require both the label of the device and the device package to include the UDI, subject to limited exceptions and exemptions. The UDI must appear in both plain text and through automatic identification and capture technology and device labelers must adhere to specific labeling and data submission requirements. Dates are required to conform to a standardized format. The proposal mandates that device identification information for each UDI must be included in a new database, the Global Unique Device Identification Database (“GUDID”). Exemptions to the proposed system include devices (other than prescription devices) that are sold at retail establishments, devices that are delivered directly to hospitals and other health care facilities and Class I devices that the FDA has exempted by regulation.

The proposal requires the UDI to be issued under a system operated by the FDA or an FDA-accredited issuing agency, to conform to specific international standards and to utilize only specific characters and numbers. It also outlines eligibility standards for FDA accreditation of organizations. The proposal requires the submission of information sufficient to fully and accurately identify a device; once adopted, the system will enable this information to be freely and publicly available through the GUDID, which will operate as a single authoritative source of data.

Prior to the proposal, the FDA partnered with industry groups to conduct a series of pilot tests. It gathered information from the medical device industry, hospitals, payors and other stakeholders through public workshops and a public information solicitation. Through its work with the Global Harmonization Task Force and other foreign regulatory partners, the FDA sought to craft a proposal that facilitates cross-border device identification, reporting of adverse events and post-market surveillance. By conducting a comprehensive pre-proposal analysis, the FDA hoped to capture as many industry concerns as possible upfront to (hopefully) pave the way for a straightforward adoption process.

No formalized system presently exists for the tracking of medical devices and their side effects, adverse effects and/or recall data. The FDA notes that, despite this, private entities have implemented their own device identification systems. The FDA estimates that approximately 30% to 50% of all medical devices now used in the United States include labels that conform to one of two systems. These include GS1, an international not-for-profit association that operates a system with a Global Trade Identification Number (“GTIN”) to identify devices, and the Health Industry Business Communications Council (“HIBCC”), which operates a system that utilizes a Health Industry Bar Code (“HIBC”) for device identification. According to the FDA, these systems have successfully enabled hospitals, nursing homes, healthcare professionals and industry to track devices. The FDA will allow the continued use of these existing systems, contingent upon their obtaining FDA accreditation under the proposed standards.

The proposed system, once implemented, aims to achieve the following public health objectives:

- To reduce medical errors because the UDI that connects to the GUDID facilitates the fast identification of a device
- To simplify the integration of device use information into data systems
- To facilitate quicker identification of devices that have adverse events attached to them
- To assist in the quicker development of solutions for reported problems
- To aid in the rapid resolution of product recalls
- To facilitate more effective communication between the FDA and the general public about safety alerts and public health notifications
- To provide an easily accessible source of definitive device information

The law requires the FDA to issue the final rule six (6) months after the close of the comment period, or no later than May 7, 2013. The FDA proposes staggered effective dates, such that the phase implementation will proceed over a period of seven (7) years, beginning with the medical devices that carry greater risks. Upon full implementation, the rule will apply to Class I, II and III medical devices. Note that the FDA amended the proposal on November 19, 2012 to modify the timeframe for implementation of the rule requirements relating to implantable, life-saving (life-supporting) devices. The FDA provided a 30-day comment period relating only to the amended text; the amended proposal did not extend or reopen the comment period relating to the July 10 proposal.

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