New tracking system proposed to help recall faulty devices

A miter saw, decorative lights, socks for toddlers—these were a few of the consumer goods recalled off of shelves across the US last month because they posed a danger to users. Recalling faulty pacemakers or catheters is much more difficult, however, because no system exists for tracking medical devices on the market. In an effort to remedy that and boost consumer safety, on 3 July the US Food and Drug Administration (FDA) outlined plans to create a new comprehensive monitoring system for medical devices.

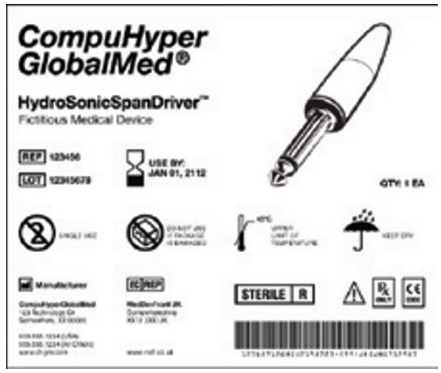
"The FDA took on something very ambitious here," says Jonathan Gaev, a senior engineer at the ECRI Institute, a nonprofit healthcare research organization based in Plymouth Meeting, Pennsylvania. "It is trying to produce something that addresses a wide range of devices, that is not unduly burdensome and that will be a big step forward for adverse-event reporting."

The proposed rule will require most devices to carry a unique device identifier (UDI) tag similar to the barcode found on most consumer products—either on the product label or packaging, or, in cases where the label and the device are likely to be separated such as implantable devices, on the equipment itself. The markings will be phased in gradually, with the riskiest devices to carry the codes within a year after the rules are finalized, which is expected to happen sometime next year. The FDA will then house those numbers in a publically accessible database. The cost for implementing the system—estimated at more than $500 million over the next decade—will be largely shouldered by device makers.

The FDA began developing the tracking system about a decade ago, in response to incidents in which healthcare facilities that received recall notices were unable to tell which device models they referred to because these products lacked a singular identifier. Congress then charged the agency with devising labeling requirements through the 2007 FDA Amendments Act, but that bill set no firm deadlines on implementation. Frustrated by the lack of progress, lawmakers included a provision in this year's FDA Safety and Innovation Act, which also reauthorized and updated the Prescription Drug User Fee Act (see *Nat. Med.* **18**, 990, 2012), that compelled the agency to release draft regulations for monitoring devices by the end of this year.

Slow and steady wins the race

According to Jay Crowley, senior advisor for patient safety at the FDA's Center for Devices and Radiological Health, the agency needed all that time to determine which devices should be tagged with UDIs and to harmonize the system with parallel efforts planned or in progress in other countries around the world. "We really wanted to be thoughtful about how we approached this, recognizing it's a significant cost and burden for industry, and we wanted the benefits to be tangible for all stakeholders," he says.



FDA

Marked change: An example of a proposed UDI.

But the devil is in the details, Gaev notes, and a few will probably need refining. For example, the draft rule doesn't require UDIs for simple devices, such as bedpans used in hospitals, or any device sold over the counter. People generally agree that it makes sense to excuse basic, low-risk devices. However, Gaev worries that the exemption for over-the-counter devices might ultimately prove too broad and fail to cover more complex devices for home use developed in the future.

Consumer advocacy groups and device manufacturers broadly welcome the initiative but say they plan to study the details and submit comments on the proposed rules. In a statement, Janet Trunzo, vice president for technology and regulatory affairs at the Advanced Medical Technology Association, a Washington, DC–based trade group, said, "We will be paying particular attention to whether the proposed rule follows a risk-based and least burdensome approach to implementing the UDI system."

Among its many provisions, the FDA Safety and Innovation Act, which President Barack Obama signed into law on 9 July, originally included a plan for a national 'track and trace' system for prescription drugs called RxTEC. However, that proposal was dropped from the final bill because legislators couldn't agree over details such as who would pay for the scheme. California plans to institute a yet more stringent track-and-trace measure in 2015; other US states and various countries around the world also intend to establish such a system.

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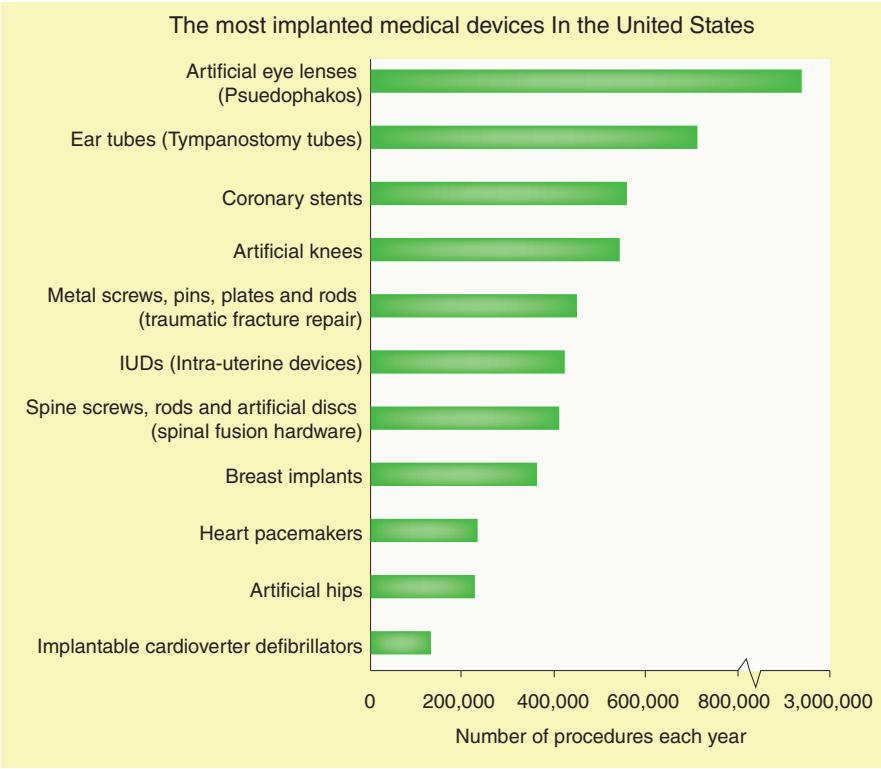

Source: /the US National Health Interview Survey