ConsumersUnion
POLICY & ACTION FROM CONSUMER REPORTS

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: [Docket No. FDA-2011-N-0090] Comments on the Proposed Rule, "Unique Device Identification System"

To Whom It May Concern:

Consumers Union (CU), the public policy and advocacy division of Consumer Reports, supports comments made by the Patient, Consumer, and Public Health Coalition on the proposed rule on the unique device identifier (attached). In addition to the those comments, Consumers Union, and the patient safety advocates listed at the end of this document, would like to emphasize and add the following points with respect to the proposed regulations.

Establishing UDIs and the GUDID will improve patient safety

Consumers Union strongly supports the implementation of the unique identifier for medical devices. The adoption of a Unique Device Identification (UDI) System has the potential to improve the safety of devices used by consumers as well as to promote many significant public health objectives. A well-implemented UDI system will help consumers to more easily find information about their implant/device's safety record and to more precisely report problems that they are experiencing.

The UDI has the potential to reduce medical errors by providing accurate and specific identification of devices prior to use, ensuring that the correct device is used. Implementation of UDI along with use of automated identification capture (AIDC) technology will allow providers to secure information about a device's safety at the time of use, such as whether a device has been recalled or if there are contraindications. Implementation of the UDI will also improve the efficiency of recalls so that problematic devices can be quickly identified and taken out of distribution.

Adoption of the unique device identifier will facilitate active monitoring of device safety through post market surveillance systems such as the Sentinel system, which draws on claims data and electronic health records. Accurate identification of devices is crucial to the collection of data on safety performance. A UDI system will further allow for research on how well devices perform clinically compared to alterative devices and therapies. This in turn will provide researchers, providers, payers and consumers with data on comparative performance of devices.

In the long run, establishing a UDI system and the Global Unique Device Identification Database (GUDID) can save money by identifying adverse events sooner. Australia provides a useful example of how a unique identifier system can assist detection of problematic devices

and reduce costs. The Australian joint registry, using device identification, was able to detect problems with metal on metal hips sooner than in the U.S. As a result, Australia was able to reduce the use of these devices, reduce the number of revision surgeries and ultimately reduce the cost to the nation's health care system.

We strongly support the goals of the proposed UDI rule, but urge the FDA to strengthen the rule in the following ways:

Adoption of UDI as soon as is practicable

The unique identifier was created five years ago by Congress. It took five years since the passage of the 2007 law for this proposed rule to be released. CU supports the prioritization of the highest risk devices, be we oppose the proposal to allow seven years for the UDI to be implemented for lower risk devices -- a full 12 years after UDI was initially required by Congress. This is too long a wait for the full implementation of technology which has been in existence for decades and which has been widely used for an array of consumer products. FDA should fully implement UDIs for all medical devices prior to the next reauthorization of MDUFA (before 2017).

The rules need to be changed to fully reflect current law. As stated in the Coalition comments, CU wants to emphasize our support for implementing the UDI system for all "implantable devices" (regardless of class) and all "life sustaining and life saving" devices (Class III) as quickly as possible. New law, enacted this year, requires this to be done within two years of adoption of these proposed rules. We strongly support changing the proposed rule to require the UDI on the packaging of these categories of devices within one year of adoption of this regulation and to require the UDI to be marked directly on the Class III and implantable devices within two years, as required by law.

Include UDI in all databases

We strongly support requiring the UDI to be included in all existing and future device databases and registries, including MedWatch, MAUDE, recall databases, and registries such as the current National Joint Registry. FDA forms – online and other – should be amended to include a field or space for the UDI, so consumers and providers can accurately link adverse event reports with a specific device.

GUDID

The FDA asks if additional information should be included in the UDI and we have the following suggestions and comments:

- Consumers Union advocates public transparency in the data collection and reporting process. We strongly support making all GUDID information available to the public and recommend that the FDA provide the GUDID database in a downloadable format.

- The GUDID database should link to data in a way that is easily accessible for patients and consumers, including whether a device has been recalled, especially when recalled for reasons of safety and efficacy.

- The GUDID database should include a field that links each UDI to the corresponding PMA and 510(k) record of the approval or clearance of that device. This will enable consumers and providers alike to research the lineage of a device to determine if it has any relationship to a similar device linked to recalls or safety warnings. Further, it is important that the final rule allow for additional fields to be added to GUDID in the future, as necessary.

- Physicians and others sometimes modify devices before implantation or use. The rules should clearly require the original UDI to be documented in medical records and other databases when a device has been modified. Any modifications should be noted in the GUDID.

- Patients should be able to access any GUDID safety related information about usage of devices, such as contraindications, existence of allergens and whether devices can be safely used magnetic resonance imaging (MRI) equipment. This is particularly crucial for emergencies or anytime when the patient is unable to provide this information.

- The GUDID should include the country of origin and manufacturer of the device.

- CU supports the proposal's emphasis on using scanning equipment to enter the data into the GUDID in order to reduce the possibility of human error in entering values.

Direct marking of implantable devices

We strongly support the rule's provision for direct marking of implantable devices as this is the only way to ensure identification of these types of devices. We oppose the exception for devices intended for short term use from the direct marking requirement, as implantable these "short term" devices often remain in patients' bodies long beyond the intended period of use.

The rules should recognize that physicians and others sometimes modify a device; in such cases the rules should prohibit obscuring the UDI mark on the device.

We oppose excluding companies from direct marking when it is not "technologically feasible" [§ 801.50(e)(2)] due to cost issues. The proposed rule defines "technologically feasible" to include "circumstances, where, for a very small firm, the capital investment in technology to allow direct part marking so exceeds to [sic] benefit of applying the requirement that FDA could find direct part marking to be 'not technologically feasible.'" This would not be acceptable, for example, for devices that are to be implanted for extended periods of time or when the device user is incapacitated and unable to give details about the device. We are concerned that this creates a wide loophole since many device companies could be considered "very small firms." Marking products with unique identifiers is a staple in nearly every business in America and internationally, and these medical devices should not be an exception. The proposal further states: "FDA believes, however, when considering whether economic factors justify an exception under the 'not technologically feasible' language, FDA should retain discretion to also

consider the public health benefits of direct marking for a particular device based on its usage and risks." FDA should use this discretion with all Class III and implantable devices, putting the safety of patients before making exceptions for small companies due to cost issues.

Exceptions

There are a number of concerning exceptions from the UDI implementation timeline. The exception for devices sold in a retail environment, for example, would leave out a host of devices that can potentially cause serious damage to patients if they fail, such as insulin syringes or contact lenses. The number of higher risk devices available in retail establishments may soon be expanded to include items such as asthma inhalers, if the FDA moves forward with initiatives to expand “conditional over the counter status” to new drugs and devices. The fact that a device is purchased in a retail establishment says little about its need to be identified and integrated in the UDI system.

A Uniform Product Code (UPC) number does not in our view take the place of a UDI, because UPC codes will not be seamlessly integrated into electronic health records and the post market surveillance systems in the way same way as UDIs. Instead, use of UPC codes for devices sold in retail establishments merely creates a separate coding system for devices based on where they are sold. This undermines the value of having a truly integrated identification system by unnecessarily fragmenting the information on devices, which will interfere with effective recalls of flawed devices.

We are further concerned about exceptions for devices used for export. This could provide a loophole for manufacturers who export devices for the purpose of circumventing the requirements of the rule. The UDI must be integrated into a truly harmonized global device identification system so that devices can be tracked in an increasing globalized supply chain.

In summary, we oppose the proposed exception of devices sold in retail establishments and devices sold for export from the UDI requirements. If the FDA proceeds with the proposal to allow the UPC or other previously marked identifiers to be used in the place of UDI, the agency should require them to be included in the GUDID database.

Include UDI in medical records

Ultimately, the success of the UDI system will hinge on its ability to be integrated fully into electronic health records. Some devices will never be directly marked because it is not feasible to do so or they will be separated from packaging, so the health record will eventually be the best way to track these devices. Integration into electronic health records will further enable the monitoring of devices by the FDA’s post market surveillance system, Sentinel, which can pull information from electronic health records and claims data.

Integration of UDI into electronic health records will ultimately allow patients and providers to track the device and services associated with the device as they move through the health care system. However, since full implementation of electronic health records is years away, FDA must work with stakeholders on near-term strategies for recording UDIs in medical records so patients and providers can begin locating information about these devices as soon as possible. FDA should do more than encourage inclusion of the UDI in medical records; the agency should

actively work with CMS/Medicare to require UDIs to be included in medical records (electronic or not) and on electronic claims/billing records as soon as UDIs are available.

Outreach to consumers

FDA should plan for outreach activities that will raise awareness of the new UDI and GUDID systems, such as a public education campaign, working with health care providers to incorporate UDI and GUDID information into patient education and discharge procedures, informing the public of the benefits of the UDI when seeking information about devices, encouraging better reporting to device registries, and promoting better public awareness of registries.

Issuing agencies

We strongly support the proposal that private issuing agencies must be nonprofit; we also support allowing state agencies or the FDA to be issuing agencies. FDA should establish clear standards and regularly monitor the agencies, including periodic renewal of licenses. Further, the FDA should regularly conduct formal audits of issuing agencies to ensure the integrity of the system.

The proposed rule provides the issuing agency with much discretion to decide on the type of auto identification capture technology that will be required to read a given UDI. While the rule notes that FDA expects the issuing agency to consult with device user facilities, health care professionals and manufacturers on the adoption of technology, the rule does not specify a process for doing so. CU is concerned that there is little guarantee that technology chosen by issuers will reflect real world use of technology by caregivers, or the most optimal technology from the perspective of patient safety. As written, the rule's vagueness about how AIDC technology will be determined creates the potential for caregivers to have to deal with a confusing array of readers and scanners with attendant potential for medical errors. CU proposes that issuing agencies be required to have a more formal structure around technology adoption, with input from a broad group of stakeholders, so as to promote efficient adoption of technology that will assist in full UDI implementation. Ultimately, use of a standardized technology should be the goal.

Indicating AIDC other than a bar code

We strongly support Sec. 801.45(c), which requires indicating that a device has AIDC technologies other than a bar code. Making consumers aware of different types of AIDC technology should be a part of any public awareness campaign around UDI along with guidance on what types of facilities may be equipped with the relevant AIDC technology. Consumers are very familiar with barcodes, but may have much less experience with RFID tags and other types of AIDC technologies.

In conclusion, Consumers Union looks forward to working with the FDA to ensure that the UDI and GUDID systems are implemented quickly and in a way that will enhance safety and other information available to consumers who use all types of medical devices, particularly Class III and implantable devices. If you have any questions about these comments, please contact Lisa

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