

November 7, 2012

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,

As members of the Patient, Consumer, and Public Health Coalition, which includes nonprofit organizations and individuals that represent patients, consumers, physicians, scientists, and researchers, we welcome the opportunity to comment on the proposed rule for the unique device identifier (UDI) system. The Coalition is dedicated to evidence-based medicine that is used to improve the health and safety of adults and children.

Throughout the third reauthorization of the Medical Device User Fee Act (MDUFA), we advocated for an integrated and robust post-market safety surveillance system for medical devices, including the development and implementation of a UDI system. We are writing to express our continued strong support for timely implementation of the Unique Device Identification (UDI) system and to recommend changes to the proposed rule that will benefit patients and consumers. It is essential that the UDI system be consumer-friendly so that individual women and men are able to use it to gain access to safety and effectiveness information about medical devices.

Public Health Objectives of the UDI System

The creation of an effective and efficient UDI system is urgently needed to reduce the harm to patients and consumers from unsafe and defective medical devices. The UDI system is essential because most medical devices are cleared or approved on the basis of limited or no data from clinical trials. The UDI system will strengthen two core components of the Food and Drug Administration’s (FDA) device safety system: 1) the post-market safety surveillance of medical devices, and 2) medical device recalls. Patients, consumers, health care professionals, and industry will be able to more accurately report adverse events to the FDA, and to determine if the problem seems to pertain to a design flaw or to manufacturing problems for a defined proportion of the devices. This will also facilitate faster and more efficient and cost-effective device recalls.

If medical professionals are the only ones aware of UDI numbers for devices, the efficacy of the system will depend on the record-keeping of those professionals, even after they retire or pass away. That is why it is essential for the FDA to initiate a public education and awareness campaign about the new UDI system, and ensure that patients are given the UDI information about their devices that they will need in the event of a problem or recall in the future, and are aware of where to enter their UDI into the new Global Unique Device Identification Database (GUDID). They also need to know how to find FDA safety communications about the problem, and how to report a problem using MedWatch. To ensure that all those who use or have a medical device can include the UDI in an adverse event report, the agency must update the “Suspect Medical Device” section of all MedWatch forms to include a field asking for the UDI.

UDI Timeline and Prioritization

The timeline for implementation of the UDI system is critically important; lives depend on it. We understand the need for a phased-in approach to the UDI labeling requirements that prioritizes riskier devices. We strongly urge the FDA to adopt a much more expeditious implementation schedule. With appropriate allocation of agency resources, there is no practical reason that the UDI system should not be completely implemented within 5 years.

Regarding the proposed timeline for Class III devices, we agree that the UDI should be on the package for Class III devices within 1 year. However, the timeline for having the UDI on the device itself is unacceptable. The UDI should be directly on these devices within 2 years, since the packaging of many Class III devices will be immediately separated from the device and thrown away. It is inevitable that a UDI will not be accessible for many patients if it is not on the device itself.

Regarding Class II devices, all Class II devices should not be in the same priority category, because some are much higher risk than others. That is why the Food and Drug Administration Safety and Innovation Act (FDASIA) requires that the UDI system to be implemented for all devices that are implanted, life-saving, or life-sustaining within 2 years of finalizing the rule. To accomplish this statutory goal, the agency must revise the proposed rule and require that UDI be directly on implanted, life-saving and life-sustaining Class II devices within 2 years. For the rest of Class II devices, we agree that the UDI should be on the package within 3 years. However, we strongly urge the agency to require that the UDI be directly on the device within 4 years.

Regarding the proposed timeline for Class I devices, we urge the agency in the strongest possible terms to complete implementation of the UDI system within five years. That would require that the UDI be on the package of Class I devices within 4 years and that the UDI be directly on the device within 5 years. As you know, Class I devices are sometimes subject to high-risk and

moderate-risk recalls when patients' lives are at stake. It is vital that the entire UDI system be implemented as quickly and efficiently as possible so that no one else is unnecessarily harmed.

UDI Labeling Requirements

To ensure that UDI labeling meets the needs of patients and consumers, the UDI should be easily located and readable. This will enable patients, consumers and health care providers to enter the UDI into GUDID and facilitate their efforts to find information about a device.

We support many of the agency's proposed labeling requirements, but we urge one critical change to the definition of implantable devices. We strongly urge the FDA to amend its proposed definition of implantable devices to remove the limitation to those in the body for 30 days or less. That is unacceptable, because many devices that are indicated for short-term use are often left in the body longer-term. The FDA should require that all implantable devices be directly marked with the UDI regardless of how long they are meant to be implanted.

Regarding the plain-text UDI, we strongly support the proposal that requires UDI to be printed in both AIDC technology (most likely a barcode) and an easily-readable, plain-text format. While the barcode will support efficient compliance for manufacturers and institutions, the alphanumeric code will enable patients and consumers to use the UDI system.

Regarding the direct marking of devices, we strongly support the FDA's proposal to directly mark implantable devices. However, we urge the agency not to limit direct marking to devices that are sterilized and used more than once. All Class II and III devices that are used more than once should be directly marked. As stated above, many devices are separated from the packaging and a UDI is essentially useless if it is only on packaging that has been lost or discarded. We support the direct marking exception if the FDA determines that direct marking would interfere with safe use of the device, but the threshold for that exception must be very high. We urge the agency to swiftly decide which types of devices would receive this exception, rather than allow individual device manufacturers to negotiate for exceptions during the review process.

Regarding combination products and convenience kits, we strongly support the proposed requirement that a combination product whose primary mode of action is that of a device should have a UDI and that each device constituent part of a combination product should have its own UDI regardless of the primary mode of action. We also support the requirement that each device in a convenience kit should have its own UDI, distinct from the UDI of the convenience kit. Marking the component parts of a combination product will allow health care professionals to identify which piece of the product is causing a problem and marking individual devices in a convenience kit will enable identification of devices that could be separated from the kit. These

requirements will facilitate accurate identification of a product and effective adverse event reporting and device recalls.

Regarding changes to a device, we recognize that some devices are frequently updated, thus we strongly agree with the FDA that any change to a device with the potential to affect its safety or effectiveness requires a new UDI. Due to the fact that revisions are particularly common with the 510(k) devices, it is vital for the agency to issue a clear guidance to industry as soon as possible on when 510(k) device modifications are extensive enough to require a new UDI.

Exceptions from and Alternatives to the UDI Requirements

We understand that not every device urgently needs a UDI; however, we strongly oppose the extent of the proposed exceptions. Exempting shipping containers from the UDI requirements is reasonable. However, exempting all devices sold at retail establishments has the potential to leave millions of patients and consumers without the critically important assistance that the UDI system is intended to provide. If toasters and DVD players can have a unique identification number, so can medical devices sold in retail establishments. Patient and consumer safety should be prioritized over the logistical difficulties of implementing the UDI system in these circumstances. For the UDI system to reach its full potential, retail medical devices need to be included, such as contact lens solution, crutches, insulin syringes, and glucometers. We strongly urge the FDA to narrow this exception to Class I devices sold at retail establishments that have a UPC number that could serve the purpose of a UDI in the event of a recall.

Regarding individual Class I, single-use devices, it is reasonable to exempt individual Class I, single-use devices from UDI requirements if the device package will have a UDI. While there can be serious problems with class I, single-use devices, such as contaminated adhesive bandages that can cause serious infections, placing a UDI on the box instead of on each bandage is a practical alternative to individual product labeling. In these cases, we believe package labeling will be sufficient to inform patients, consumers and health care professionals if there has been a product recall.

Regarding devices intended for export from the United States, we are concerned about the FDA's proposal to exempt devices intended for export from the UDI rule. The proposed rule states, "Through our work with the Global Harmonization Task Force (GHTF) and foreign regulatory partners, we envision that the UDI system would support global public health initiatives...including more efficient and effective cross-border identification of devices, adverse event reporting and post-market surveillance, and would improve our ability to communicate and respond to issues and concerns about devices used not only in the United States, but in other nations as well." This goal will be harder to accomplish if our exports lack UDIs. We request clarification of this proposal. Would the exception only apply to devices intended for export to

foreign nations that have device identification requirements which meet the standards of the FDA UDI system? If so, how would the FDA monitor and enforce this exception to ensure that devices exported to foreign nations without device identification requirements are labeled with a UDI?

Structure and Use of GUDID

An efficient and effective UDI system depends on the creation of a database that is accessible to patients, consumers and health care professionals as well as the FDA and manufacturers. We strongly support the requirement that manufacturers of all devices with a UDI be required to submit information about those devices to the database. The GUDID is the tool that will allow all stakeholders to contribute to and benefit from the UDI system, thus it is essential that this database be consumer-friendly and include information that is relevant to patients and consumers, that it interface with other FDA databases, and that it contain complete and timely information.

Regarding the information fields in GUDID, the proposed fields in GUDID don't provide enough information that is relevant to or useful for patients and consumers. The majority of the proposed data fields for GUDID are likely useful for hospitals and providers, such as whether a device requires sterile packaging. A woman having problems with surgical mesh, for example, also needs to be able to learn whether the product has been recalled. We strongly urge the FDA to revise the proposed data submission requirements for GUDID to include the following fields of device information essential to patients and consumers.

- **Recall Status:** We recommend a Yes/No field, which will be easily understood by patients and consumers.
- **Recall Date:** If the Recall Status field indicates "Yes," we recommend the addition of a field indicating the date of the recall with a hyperlink to the recall database or recall notification so that patients and consumers have a simple way to find more information about the recall.
- **Safety Warnings:** We recommend the addition of a field for serious safety warnings or contraindications with a hyperlink to the device label and to any FDA safety communications about the device. A woman with breast implants who is having health problems, for example, should be able to check the UDI and go to GUDID to find information about the increased risk of rupture or anaplastic large cell lymphoma, in women with certain kinds of breast implants or the recommended frequency for screening MRIs to determine whether an implant is leaking.

- Approval Date: We recommend that GUDID include a field indicating the date the device was approved with a hyperlink to the relevant 510(k) or PMA search database that can provide patients and consumers with more information about their device.
- Market Status: We recommend that GUDID include information about whether or not a device is still on the market. This is not redundant with the recall status, as a manufacturer may voluntarily stop selling a device without recalling it, and this is also information that a patient, consumer or health care provider who uses that device may need to know.

Regarding interfacing with other databases, the UDI system and GUDID have the potential to significantly improve post-market surveillance of devices, and thus safeguard patients. Our recommendation that GUDID link to the FDA recall database to provide stakeholders with additional safety information is necessary but not sufficient to ensure an integrated and robust post-market safety surveillance system that can follow a device throughout the total product life cycle. GUDID must also be able to interface with MedWatch, the Manufacturing and User Device Experience (MAUDE) database, and the new FDA Adverse Event Reporting System (FAERS) database to ensure that adverse event reports for devices with UDI's can be tied together to provide the agency with earlier notice of a potential problem.

We strongly urge that the FDA also work with the Centers for Medicare and Medicaid Services (CMS), insurers, hospitals and health care providers to incorporate UDI into electronic health records (EHR) and claims data. This will ensure that patients and providers can identify and track medical devices years after use or implantation based on a patients' health records. However, the complete integration of UDI into EHRs is years away because of incomplete adoption of required health information technology by hospitals and other care providers. To encourage greater use of mechanisms that make this information easily available in the near-term to patients and providers who need to track a device, FDA and CMS should work together and with stakeholders on strategies which support that goal, such as the inclusion of UDI in registries of patients with devices. These registries will facilitate UDI tracking between now and the complete implementation of UDI in EHRs, thus the FDA should encourage better reporting to, and increased public awareness of, patient registries.

Integrating UDIs into EHRs and claims data will also provide very useful information that could be analyzed for the millions of patients being studied in the Sentinel Initiative. Such data could be used to determine complication and revision surgery rates for specific implant models, for example, eventually saving billions of dollars and improving patients' quality of life and survival rates.

Regarding enforcement of data submission, for the first data submission to GUDID, we strongly support the proposed requirement that manufacturers must submit device identification data no later than the date the label of the device must bear a UDI. For subsequent data submissions that reflect new information about or changes to a device, we strongly support the proposed requirement that manufacturers must submit the updated information either by the date the device's updated label goes into effect or, if the information is not on the label, within 10 days of the change. Compliance with these requirements will be essential to the effective functioning of GUDID, and we urge the agency to develop a protocol and schedule for conducting regular spot checks of the data in GUDID to ensure accuracy and timeliness.

Role of Issuing Agencies

For the UDI system to work, it must be operated by the FDA and every UDI must be issued by the FDA or an FDA-accredited issuing agency. We strongly support the provisions in the proposed rule enabling the FDA to suspend or revoke the accreditation of an issuing agency if the agency fails to fulfill its accreditation responsibilities or violates the UDI system regulations. We believe the FDA should be the primary issuing agency and as such the agency will require additional funding to ensure that resources are not drained from other critical functions. However, if the FDA is not the issuing agency, the FDA must regularly monitor and evaluate the issuing agencies. We strongly oppose the accreditation schedule outlined by the FDA because it will not be sufficient to ensure the integrity and reliability of the system. We strongly urge the agency to require renewed accreditation every 3 years.

Benefits and Costs of the UDI System

There will be significant costs at the start to implement the UDI system, which are more than justified by the huge step forward that this system represents for protecting and promoting the health of all those who use medical devices. The FDA noted in the proposed rule that the cost would be less if UDIs were not directly on the devices but merely on the packaging. As we noted previously, UDIs need to be on the devices themselves. We are completely opposed to decreasing costs by removing requirements that are essential.

We understand the regulatory purpose to conducting an analysis of the cost impact of the UDI rule; however, this analysis disproportionately focuses on what the rule will cost manufacturers to implement the UDI system without factoring in the substantial cost savings to patients, consumers, health care providers and even manufacturers. The impact analysis must also reflect the significant public health benefits and cost savings created by more efficient recalls and reduced medical errors. It is estimated that the increased efficiency and accuracy of a UDI system will save manufacturers, distributors and health care providers \$16 billion annually. Moreover, patients and consumers will experience cost savings as a result of improved access to

information which will enable them to make better health care decisions and to avoid the cascade of medical costs that can flow from use of flawed devices and failure to seek prompt medical care when a flaw in a device they rely on is identified.

In conclusion, we greatly appreciate the agency's work to develop the labeling requirements and database that will facilitate use of the UDI system. Our recommendations will strengthen those efforts and are essential if the UDI system is to fulfill its goals. Please don't hesitate to contact us with any questions about our recommendations; we look forward to working with the agency to implement a UDI system that protects the public health and meets the needs of patients and consumers.

Sincerely,

American Medical Women's Association
Annie Appleseed Project
Breast Cancer Action
Center for Medical Consumers
Connecticut Center for Patient Safety
Consumers Union
National Consumers League
National Physicians Alliance
National Research Center for Women & Families/ Cancer Prevention and Treatment Fund
National Women's Health Network
Our Bodies Ourselves
Public Citizen
Reproductive Health Technologies Project
The TMJ Association, Ltd.
Truth in Medicine Incorporated
Union of Concerned Scientists
U.S. PIRG
WomenHeart: The National Coalition for Women with Heart Disease
Woody Matters