November 7, 2012

Margaret Hamburg
Commissioner
Food and Drug Administration
Department of Health and Human Services
Room 2217
White Oak Building One
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: FDA-2011-N-0090: Food and Drug Administration; Unique Device Identification System

Dear Dr. Hamburg:

The Medical Device Initiative of The Pew Charitable Trusts, the American Heart Association and Trust for America's Health welcome the opportunity to submit comments regarding the U.S. Food and Drug Administration's (FDA) proposed rule for a unique device identification (UDI) system for medical devices, as required by section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) and reaffirmed in Section 614 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA).

The Pew Charitable Trusts is an independent, non-profit organization that applies a rigorous, analytical approach to improve public policy, inform the public and stimulate civic life. The Medical Device Initiative seeks to improve the safety of medical devices and to foster innovation that benefits patients through streamlined device approvals.

We are pleased that the FDA is working toward implementing a UDI system. Once implemented by the FDA and utilized by healthcare providers, the UDI system will be the cornerstone for significant improvements in postmarketing surveillance of medical devices.

There is broad support for UDI implementation. Many stakeholders have backed the need for a UDI system, including AdvaMed, the Advancing Patient Safety Coalition, and Democratic and Republican members of Congress.

Following are our comments, which we are grateful to have the opportunity to submit.

Objectives of the Proposed Rule

As laid out by the FDA in the proposed rule, the UDI will benefit patients and public health by: providing for more rapid identification of medical devices associated with adverse events; assisting with more rapid and efficient resolution of device recalls; and delivering an easily-accessible source of definitive device identification. Overall, we agree with these and the other public health objectives of the proposed rule that the agency has cited.

There are also other public health benefits not stated directly in the proposed rule. For example, UDI will also allow medical devices to be incorporated into the Sentinel Initiative, an important postmarket surveillance system for medical products. By proactively monitoring data from electronic health records and other sources rather than relying on spontaneous reporting from manufacturers and health care providers, Sentinel can more quickly identify safety issues. However, the system was designed initially to track drugs in the marketplace and it has been difficult to adapt Sentinel to track medical devices due to the challenge of identifying specific devices in the available electronic health records and insurance claims.

A UDI system will solve this problem by allowing information about specific medical devices to be integrated into patient health records and health insurance claims, two of Sentinel's main data sources. UDI also has the potential to improve other types of postmarketing surveillance, such as registries, by facilitating the use of electronic records to provide data to these important surveillance systems.

Overview of the Proposed Rule

The proposed rule requires: 1) that the label of medical devices and device packages includes a UDI, with certain exceptions, and that some medical devices be directly marked with a UDI, and 2) that manufacturers submit information to a new public Global Unique Device Identification

Database (GUDID) where the UDI can be linked to data about the device and accessed by the FDA and other stakeholders. When final, the rule will fulfill the statutory requirement that directs the agency to promulgate regulations establishing a UDI system for medical devices.

Timeline for Implementation of the UDI Regulation (§ 801.20)

The proposed rule states that manufacturers of Class III, II and I devices have one, three and five years, respectively, to obtain UDIs for their devices, place the UDI on the devices' label and packaging, and submit the appropriate data to the GUDID database. Manufacturers of devices that have never been classified—"preamendments devices"—are given five years to meet these requirements. Manufacturers of devices that must be directly marked are given an additional two years after the devices' label must bear the UDI to comply with the direct marking requirement. Under the proposed rule, then, seven years would elapse from when the final rule is issued until all the provisions are fully implemented.

The FDA has already acknowledged that this timeline must be revised given the requirements of the recently-enacted FDA Safety and Innovation Act (FDASIA), which requires implementation of the UDI regulations for all implantable, life-saving or life-sustaining devices within two years of the final rule. The agency has said it will produce a list of the medical devices that are captured under this definition.

We recognize the burden that complying with the UDI requirements will place on manufacturers and support the FDA's efforts to implement the rule in a staged manner, targeting devices where the most public health benefits are expected to be realized. Applying the rule to a smaller number of devices at first will also help the agency and manufacturers identify and correct any challenges in obtaining a UDI and submitting the required information to the GUDID database. Finally, directly marking implantable devices may pose significant technical difficulties, and we support giving manufacturers time to ensure that they have been overcome.

However, given the amount of time that has elapsed from when Congress first mandated that the FDA issue the UDI rule and the public health benefits that are anticipated, the current timeline is unnecessarily lengthy. We are particularly concerned that the proposed rule grants

preamendments devices the same amount of time to comply as Class I devices. Examples of preamendments devices include automated external defibrillators, metal-on-metal hip implants and other devices that have been associated with significant adverse events. These high-risk devices should be subject to the UDI requirements sooner than lower-risk devices, such as stethoscopes and knee braces.

Recognizing the value in staging the requirements, but mindful of the public health benefits that will accrue once the rule is finally implemented, we urge the FDA to adopt the following timeline:

- **Class III devices: one year for the UDI to appear on the device label, and three years for direct marking (if the device meets the criteria for direct marking);**
- **Implantable, life-saving and life-sustaining devices that are not Class III: two years for the UDI to appear on the device label, and three years for direct marking (if the device meets the criteria for direct marking);**
- **Remaining Class II, Class I and preamendments devices: three years for the UDI to appear on the device label, and four years for direct marking (if the device meets the criteria for direct marking).**

This timeline would maintain the highest priority for those devices that are the highest risk and would ensure that all medical devices have at least three years before the direct marking requirements apply. Requiring that all medical devices have a UDI in a reasonable timeframe is critical so that the public health objectives laid out by the FDA—including adverse event reporting and improving the recall process—are met.

Direct Marking of Devices (§ 801.50)

We support the agency's proposal to require direct marking of the UDI on 1) implantable devices, 2) re-sterilized devices intended to be used more than once, and 3) standalone software.

Implantable devices must have direct marking due to the nature of their use. The implanted device will inevitably be separated from the label and packaging, and the UDI may not be available to the patients or clinicians when it is needed—if, for example, a patient is being

treated at a healthcare facility different than the one where the device was implanted. The proposed rule provides important flexibility in how the device will be directly marked. For example, under the rule, an artificial hip could be directly marked using Radio Frequency Identification (RFID), so that the device could be identified without surgically removing it.

In addition to the devices identified for direct marking in the proposed rule, we recommend that the FDA expand the direct marking requirement to include all Class II and Class III devices intended to be used more than once. The UDI labeling requirement as proposed is insufficient for the many medium and high-risk devices that are routinely separated from their packaging upon delivery to health care facilities and may be used on many patients over a lengthy time period. The FDA will not meet the public health objectives laid out in the proposed rule unless Class III and II devices used more than once are directly marked.

For example, the proposed rule states that healthcare facilities will be required to include the UDI when reporting an adverse event. For products such as infusion pumps that are separated from their labeling, it will be impossible for healthcare facilities to meet this standard unless the infusion pump has the UDI directly marked. Similarly, it may be difficult for a healthcare facility to effectively conduct a recall on a device used multiple times if the device is not directly marked. Infusion pumps have been subject to numerous Class I recalls (i.e., those that represent the greatest threat to human health) over the years and many of the current problems with conducting recalls will persist unless the devices themselves are directly marked.

Exceptions (§ 801.30)

We support the agency's efforts to provide exceptions to the UDI requirements if there is not a public health rationale for complying. For example, we agree with the proposal to except Class I devices that FDA has determined are exempt from good manufacturing practice requirements, as this would require a significant investment by manufacturers for what would likely be a negligible public health benefit. We also support FDA's proposal to except individual Class I, single-use devices distributed together in a single package which are not intended or promoted for individual sale (such as individual gloves within a box of gloves).

However, we have significant concerns about some of the other exceptions proposed, as well as the transparency of FDA's process for granting exceptions on a case-by-case basis.

1. *Exception for medical devices sold at retail establishments.*

   The current rule provides an exception from the UDI requirements for all devices sold at retail establishments. As written, this exception would apply even if these products are delivered directly to hospitals and other health care facilities, and would otherwise be required to have a UDI. **We urge the FDA to remove this proposed exception.**

   If a device is determined to carry sufficient risks that it would otherwise require a UDI, the fact that it is sold in retail establishments does not obviate the public health rationale for the UDI. Such an exception would result in a missed opportunity to streamline adverse event reporting and improve the FDA's ability to alert providers and the public about device recalls affecting devices sold in retail settings.

   The proposed exception is especially concerning for higher-risk products. Some devices sold in retail establishments are truly life-saving and life-supporting, such as automated external defibrillators (AEDs) and glucometers, but would be exempt under the proposed rule. The FDA issued a Class I recall of a large group of AEDs earlier this year because the device could fail unexpectedly, rendering the AED ineffective during a rescue attempt. This is but one example of the devices that are widely available in retail establishments and which would benefit from a UDI to aid their recall and prevention of serious adverse events.

   We strongly recommend that the FDA give manufacturers of devices sold in retail settings the option of meeting the UDI requirements via utilization of the Universal Product Code (UPC). Most, if not all, devices sold in retail establishments already contain a UPC barcode on the label. The UPC is operated by GS1, one of the standards organizations that FDA has indicated will also likely be an accredited issuing organization for UDI. This will help to ensure that the UPC is able to satisfy the technical criteria necessary for use as a UDI.

2. *Direct marking exception for medical devices implanted for less than 30 days.*

   The proposed rule provides an exception to the direct marking provision for devices intended to be implanted for fewer than 30 days. **We urge the FDA to remove this proposed exception.**

   Much of the rationale for requiring the direct marking of devices intended to be implanted for more than thirty days also applies for medical devices intended to be implanted for fewer than thirty days. An individual with any type of implantable device may seek care at a location different than where the device was implanted. Direct marking with RFID or other technology could allow that facility to obtain key information about the device that would otherwise be inaccessible. Additionally, if an implanted device needs to be surgically removed at a different facility, direct marking will ensure that the facility will have the necessary information about the device to submit an adverse event report (if appropriate) or take other actions.

   Additionally, many devices are used off-label. The fact that a device is intended for short-term use is no guarantee that the product will not be implanted for more than 30 days. For example, an FDA communication released in 2010 found that retrievable inferior vena cava filters (medium-risk devices implanted near the heart) intended for only short-term use were regularly left implanted for longer than 30 days. The FDA received hundreds of adverse event reports associated with these devices between 2005 and 2010, many of which the agency suspected may have been related to use of the filters for longer than the intended period.

   The problem is exacerbated by the fact that the label for a device rarely indicates how long the product is intended to be implanted. Clinicians themselves may not be aware of the appropriate length of time to use a particular implant. The use of implantable devices in real-world settings can evolve rapidly, resulting in widespread use of various types of implantable devices for longer than intended. **We therefore recommend requiring all implantable devices to be directly marked with the UDI, except in cases where it is not technically feasible.**

3. *Process for granting an exception*

   We support the FDA's proposal to allow requests for exceptions from UDI labeling requirements in cases where it is not appropriate, but we recommend that the FDA make public the rationale behind the exceptions the agency grants via the proposed request process. In keeping with the FDA's commitment to transparency, it is important that the public have access to the reasoning behind excepting certain products from this important regulation. Similarly, in cases where the agency allows an alternative to the UDI or requires additional safeguards to ensure the adequate identification of the device through its distribution and use, the public should also have access to a detailed summary of the additional safeguards, the alternative identification and the rationale behind the decision.

The GUDID Database (§ 830.31)

A functional GUDID database is central to the UDI system. **We support the general framework for implementation of the database in the proposed rule and believe the proposed data fields reflect the most useful information.** We have the following recommendations related to the GUDID database:

1. *Recalls*

   The GUDID database will be a critical source of data for healthcare providers, including hospitals and clinicians, and consumers. **As such, it is imperative that the database includes an alert if a device has been recalled for a clinically significant reason and provides easy access to additional information.** Requiring providers and consumers to go to a different database to assess whether a device has been recalled is an unnecessary step that could result in the inappropriate use of recalled devices.

   Given the public health importance of this element, the FDA should bear the responsibility for ensuring that devices that have been recalled are appropriately and clearly identified in the database. The agency should have the discretion to determine whether any particular recall is clinically significant and should appear in the database.

2. *Access to other databases from the GUDID database*

   In the proposed rule, the agency acknowledges that it will be important to allow users to access other FDA databases from the GUDID database. However, the proposed rule does not give any indication of the FDA's thinking as to how this will be implemented.

   In order to maximize the value of this new undertaking, the process must be a smooth as possible. **For each listing in the GUDID database, we propose that there be a direct link that takes the user to the medical devices premarket application or 510(k) notification letter.**

   Additionally, if the medical device is, or has been, subject to a post-approval study or 522 study, there should be a link from the GUDID database to the study information.

3. *Process to update fields*

   As UDI is fully implemented and user experience with the GUDID database accumulates, there may be cases where stakeholders and the FDA agree that it would be useful to update the GUDID database by altering or expanding the required data fields for all medical devices or for a specific type of medical devices. For example, further experience and research may indicate that an additional data field for a subset of devices would provide valuable information to clinicians and the public**. We urge the FDA to clarify the process by which changes to the fields in the GUDID database would occur and to identify a nimble, non-regulatory mechanism to achieve this goal if the changes would affect a limited number of devices**. Finally, we encourage the FDA to identify a process by which the public and health professionals could recommend changes to the GUDID database to the agency.

4. *Frequency of database updates*

   The FDA has not provided a clear timeline on how often the GUDID database would be updated. We see no reason that changes to GUDID cannot be made public in real-time. **We urge the FDA to clarify in regulation that changes submitted by manufacturers to GUDID will be accessible via the public database in real-time.** Hospitals and other

healthcare facilities will be relying on the accuracy of the information and updates should be available as soon as they are submitted.

5. *Development of public interface*

   The proposed rule does not articulate the agency's plan for how it will engage stakeholders, particularly non-industry organizations, on the development of the GUDID database public interface. **In order for the database to be accessible for consumers, clinicians and the public, it is critical that the FDA work closely with stakeholders throughout the design process. We urge the agency to detail how this collaboration will occur in the final rule.**

UDI Issuing Agencies (§ 830.100)

The proposed rule allows multiple agencies to issue UDIs. We are aware that many medical device companies have already adopted one of the leading device identification standards issued by GS1 or HIBCC. We agree that it would be counterproductive at this time to require replacement of effective systems already in place by permitting only one agency to issue UDIs.

However, increasing the number of standards further can create confusion and technical problems. Thus, if the number of issuing agencies grows beyond the current threshold, we would be concerned about the impact on healthcare facilities. **We urge the FDA to limit the number of standards used by issuing agencies to those that hospital systems and other providers are able to accommodate with existing technology.**

Date on the Device (§§ 801.18 and 830.10)

The proposed rule requires a standard format for dates provided on a device label or package. The required format—Month, Day, Year (e.g., JAN 21, 2012)—is different than the International Standards Organization (ISO) date standard ISO 8601 format commonly required for medical devices sold outside the United States—Year, Month, Day (e.g., 2012-01-21). These conflicting format requirements would force manufacturers to develop separate labels for devices sold in and outside the United States. Medical device companies are part of a global industry and a requirement for two separate date/labeling formats is costly and inefficient. Requirements should be aligned where there is not a clear public health reason for doing otherwise. **We recommend**

that the FDA require the adoption of date standard "ISO 8601", which would harmonize date standards with label requirements for medical devices sold outside the U.S.

Changes That Result in a New Version or Model (§ 830.50)

The proposed rule states that a "change [to a device] that could significantly affect the safety or effectiveness of the device" should initiate assignment of a new UDI. This phrase is the same language used by the FDA to describe when a new premarket submission is required for a device. However, the phrase "could significantly affect the safety or effectiveness of the device" has been the subject of extensive discussion in the context of premarket submissions. The FDA recently issued and subsequently withdrew a guidance document describing current thinking on this subject and manufacturers have requested updated information.

Given this context, we therefore recommend that the agency not rely on this language for UDI decision-making. If the intent is to link a new premarket submission to a new UDI, then the proposed rule should clearly state that. **We believe that any manufacturer that submits a new premarket submission for a device modification should obtain a new UDI for that product.**

Uptake of UDI

The proposed rule describes the UDI system and the FDA's role in its operation. Labeling a device with a UDI and linking it to the GUDID database are the first steps. To achieve the public health objectives of the UDI rule, the identifier must be incorporated into records at the clinical facility and provider levels, e.g., in inventory and electronic health records, and in claims data. For example, the Sentinel system will only be able to incorporate medical device data if UDI is included in electronic health records or insurance claims data. We recognize the work that the agency has already done in this area with the Brookings Institution and other parties and encourage these conversations to continue.

There are many potential avenues to achieve adoption of the UDI, but providing clear incentives to use UDI through other federal efforts is one strategy that should be pursued. UDI should be

part of the ongoing efforts of the Office of the National Coordinator for Health Information Technology (ONC) to encourage widespread adoption of electronic health records.

We urge the FDA to collaborate with other agencies and organizations responsible for electronic health records, such as the ONC. Specifically, the FDA should encourage the ONC to include UDI as a criterion for certification of electronic health records.

Enforcement

We applaud the agency for clearly stating in the rule that devices that do not meet the standards of the regulation will be considered misbranded and that failure to comply is a prohibited act. **Given the public health importance of this rule, we urge the agency to take prompt action if manufacturers are not in compliance.**

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In order to maximize the public health benefit of this important initiative, it is critical that the FDA finalize the regulation as quickly as possible. FDASIA requires that the final regulation be issued within six months of the close of the comment period, and we trust that the agency will meet this deadline.

Thank you for your consideration of our comments. Should you have any questions, please contact Josh Rising at 202-540-6761 or jrising@pewtrusts.org.

Sincerely,

The Pew Charitable Trusts
American Heart Association
Trust for America's Health