Director Jan Welch
Office of Medical Device and Radiological Health Operations
U.S. Food & Drug Administration
Silver Spring, Maryland

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We are writing on behalf of our nonprofit medical, public health, and patient advocacy organizations to request that the FDA reverse its policy to exempt many implantable medical devices from directly displaying a UDI number on the implant, and to institute a policy of improved record keeping and record retention. The current FDA Regulations are based largely on comments summarized in a 2013 Federal Register report (1) on this issue. Events which have transpired in the ensuing years have negated many of the comments that the implantable medical device UDI exemption were based upon.

Major subsequent developments are as follows:

- The lack of portability and transferability of electronic medical data.
- The large number of failures requiring explantation for certain classes of medical devices, such as prosthetic hip implants, breast implants and Implantable Cardioverter Defibrillators.
- The delayed failure rate that sometimes can be many years for certain classes of implants.
- The increased emergence of counterfeit implants, which have increased failure and complication rates.
- Technology for placement of an UDI on implantable devices.

Because of these critical safety issues, we have serious concerns about the current exemption policy as well as concerns about the integrity and retention of UDI records. We make the following recommendations to improve post-market surveillance on medical devices.

1. Evidence that conflicts with one of the basic assumptions that underlay the exemption policy.

It was stated as follows in the 2013 Federal Register: "We also acknowledge the common practice of recording information about implanted devices both in the patient's health record, and on a card provided to the patient, and we expect health care providers will incorporate UDIs into both of these types of records."

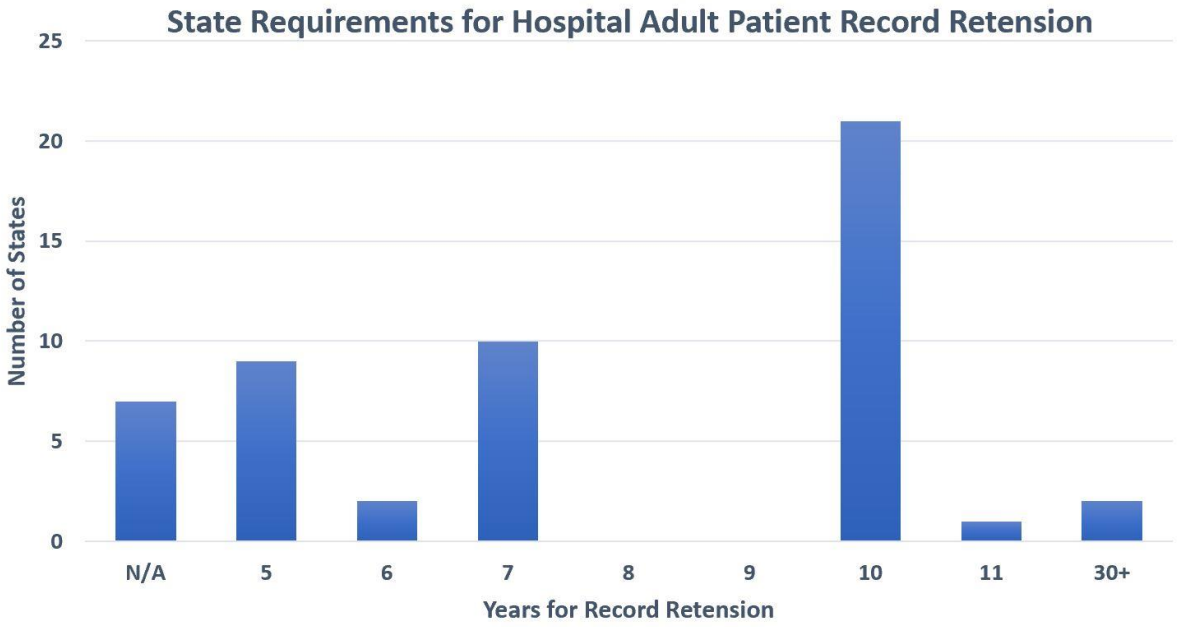
However, at the time when many implants fail, patients have moved or transferred their care to a different provider, making access to their past medical record problematic. The lack of portability of electronic medical record data from one healthcare provider to another produces a significant roadblock in locating an implant's UDI. In addition, in our experience the majority of patients are not given written material which identifies the implant device, with or without a UDI.

> **Recommendation #1: Require that manufacturers provide the patient with a card containing information regarding the implant, including the implant's name, manufacturer and UDI, become a regulatory requirement.**

Patient engagement in healthcare is of utmost importance, but healthcare literacy can vary among patients and informational cards can be misplaced. Thus, other records of an implant's UDI must also exist.

2. Varying State Requirements for Record Retention

Of the 50 states, District of Columbia and Puerto Rico, only two have mandates to preserve records for 30 years or greater the remainder are 11 years or less. Seven states having no mandates.(2) See figure below.



Because of lack of EMR portability a facility's contracting with a new EMR provider may require considerable resources to transfer records and old records may become lost.

State mandates for Physician record retention are even less rigorous. Federal record retention requirements (Title 21, Part 821.60 Subpart D) applies only to manufactures and distributors (Title 21, Part 821.25 and Part 821.30 Subpart B). There is not a requirement of manufacturers and distributors to collect patient or facility data, only data regarding the physician.

Recommendation #2: To overcome this problem, manufacturers and distributors record and maintain information of the facility in which a device is implanted in a patient; and that facility (surgery centers, hospitals, etc.) should retain records of all UDI's for implanted devices for as long as a device is in use, or for 10 years after it is explanted, returned to the manufacturer or the patient dies.

3. Deletion of Records After an Adverse Event

Unlike other medical records, it appears that Sec 821.60, Subpart D allows "persons" to erase UDI records after a severe adverse event takes place. The regulation reads: "For example, a record may be retired if the person maintaining the record becomes aware of the fact that the device is no longer in use, has been explanted, returned to the manufacturer, or the patient has died." Although "person" is not defined in the Definition Section 821.3. In Section 821.3, manufacturers are referred to as a "person" and this provision could also apply to distributors, facilities and physicians.

Recommendation #3: We strongly recommend that Sec 821.60, Subpart D, should be amended in a similar manner for record retention 10 years after an implant is explanted, returned to the manufacturer or patient death. Otherwise these is no requirement for the retention of a failed implant, a loss of information that will have an adverse impact on effective post market monitoring of implant safety.

4. Direct Marking of Implants is Crucial

In the 2013 Federal Register, it was noted "that direct marking of an implant would be useful only if the device was explanted; that the proposal is ''substantially redundant in effect''"… However, the UDI and model of an explant may not be readily available because of current shortcomings of electronic medical

records. An increase in explantations of breast implants, hip implants, and other implants has shown the importance of including UDI markings on the implant itself.

The assertion that having the markings on an explant is not very useful conflicts with the evidence from the large failure rate and revisions which require removal of the implant for some classes of implants. In addition, this information is crucial for research centers, such as Dartmouth Biomedical Engineering Center for Orthopaedics, that study the etiology of explant failures. Although it is correct that a UDI on the implant would not help in recalls, it is of utmost importance in post-market surveillance.

5. Problem of Counterfeit Devices

Compounding this issue are counterfeit devices: A UDI on an explant could readily serve as a means of differentiating a counterfeit verses an authentic device, potentially saving the manufacturer from liability.

6. Improved Technology

For many large metal devices (e.g. joint implants) there is an inexpensive technology for placing a UDI on them (see enclosed picture). In addition, electrical or complex implants which have a casing can have an UDI placed safely inside the casing.

Conclusions

In the original UDI regulations, placing the UDI directly on the implant was considered the norm. Unfortunately, that requirement has been waived in response to manufacturers' requests, failing to take into account the public health.

We strongly urge that the FDA require placement of the UDI directly on an implantable device unless the manufacturer can demonstrate that it will affect the safety or functioning of the implant, or if the size of the implant precludes such placement. Finally, there needs to be improved record keeping and record retention by hospitals and manufacturers, along with implant identifiable information given to the patient.

If you have any questions, please contact Dr. Kevin Kavanagh, Health Watch USA[sm], at healthwatchusa@gmail.com

Thank you for this consideration,

Health Watch USA[sm]
Advocating Safety in Healthcare E-Sisters (ASHES)
Breast Cancer Action,
Jacobs Institute for Women's Health
Just Call Me Ray
Medical Device Problems
The Medication-Induced Suicide Prevention and Education Foundation (MISSD)
National Center for Health Research
National Women's Health Network
Our Bodies Ourselves

Patient Safety Action Network
Patient Safety America
TMJ Association
USA Patient Network
Washington Advocates for Patient Safety

CC: The Honorable Mitch McConnell, The Honorable Rand Paul, The Honorable Lamar Alexander, The Honorable Patty Murray, The Honorable Frank Pallone, The Honorable Greg Walden, The Honorable Rosa DeLauro

References:

1) Unique Device Identification System. 21 CFR Parts 16, 801, 803, 806, 810, 814, 820, 821, 822, and 830. Federal Register. Sept. 24, 2013 https://www.federalregister.gov/documents/2013/09/24/2013-23059/unique-device-identification-system https://www.govinfo.gov/content/pkg/FR-2013-09-24/pdf/2013-23059.pdf

2) State Medical Record Laws: Minimum Medical Record Retention Periods for Records Held by Medical Doctors and Hospitals. Healthit.Gov https://www.healthit.gov/sites/default/files/appa7-1.pdf