

Report on Meeting to Discuss Unique Device Identification

**April 14-15, 2005
The Food and Drug Law Institute
1000 Vermont Avenue NW
Washington, DC 20005**

**by Joseph S. Arcarese
Meeting Facilitator**

Report Date: June 14, 2005

Report on Meeting to Discuss Unique Device Identification

Table of Contents

I. Background	1
II. Process	2
III. Summary of Meeting	4
A. Potential Benefits and Disadvantages of Unique Identification System	4
B. Performance-Based Standards for a Unique Identification System	7
C. Minimum Information Needed for Device Identification	8
D. Ability of Health Care Institutions to Utilize Unique Identification	9
E. The Issue of Serialization	9
F. Information Used by FDA in Determining its Course of Action	10
G. The Issue of Categorization	12
H. Minimum Data Set	14
I. Databases	14
J. Additional Consultation	15
IV. List of Attachments	16
ATTACHMENT A: Invitation Letter	17
ATTACHMENT B: List of Attendees	20

Report on Meeting to Discuss Unique Device Identification

April 14-15, 2005

**The Food and Drug Law Institute
1000 Vermont Avenue NW
Washington, DC 20005
Tel: 202-371-1420
www.fdpi.org**

**by Joseph S. Arcarese¹
Meeting Facilitator**

Report Date: June 14, 2005

The purpose of this meeting was to facilitate an open discussion between FDA and its stakeholders on the issue of unique medical device identification. CDRH was not seeking advice or consensus at this meeting, but was looking for opinions from invited individuals on an ad hoc, one-time basis. The participants were invited from the medical device industry, and research and trade associations; in addition, representatives of the Food and Drug Administration attended. The meeting was held at the request of Center for Devices and Radiological Health (CDRH) which is the Food and Drug Administration's component responsible for assuring the safety and effectiveness of medical devices. This report summarizes the results of the meeting.

I. Background

One of CDRH's most important roles in carrying out its public health mission is to assure the safety and effectiveness of medical devices used in the United States. When it becomes aware of new issues or problems relating to its mission, CDRH attempts to gather information and data in order to define and characterize the relevant parameters.

Unique identification of products in the consumer world is a well established phenomenon, as everyone familiar with grocery store scanning can attest, and this is moving into the health care world as well. For example, the Food and Drug Administration published a final regulation in 2004 requiring bar codes on the labels of most human drug products and biological products². In considering whether medical

¹ Mr. Arcarese can be contacted either through FDLI, or directly at: 12005 Suffolk Terrace, Gaithersburg, MD 20878, Tel: 301-977-4655, E-Mail: arcarese@comcast.net.

² Bar Code Label Requirements for Human Drug Products and Biological Products; Final Rule. Federal Register: February 26, 2004 (Volume 69, Number 38), Page 9119-9171

devices ought to be uniquely identified, CDRH requested that FDLI³ convene and facilitate a two-day meeting with representatives of medical device manufacturers, medical device regulatory consultants, trade associations, bar coding organizations, and other relevant interested parties with expertise in the field of the identification of products. The meeting was intended to provide an opportunity for CDRH to hear ideas and reactions from knowledgeable representatives of relevant organizations about employing a uniform system for the unique identification of medical device equipment. CDRH was interested in hearing about:

- the kinds of information that could be readily captured in such a system,
- the kinds of identification technologies (e.g., bar codes, radio frequency identification [RFID]) that could be employed,
- the advantages and disadvantages of such systems, including the patient safety implications, and
- the major bar-coding systems and device nomenclature systems that are being used by the medical device community.

CDRH was also interested in discussing the potential for developing a public-private partnership with the goal of promulgating a voluntary program for a unique identification system for devices.

II. Process

The proximate incentive for this meeting came from the success of previous meetings conducted by FDLI on other CDRH topics, in which a relatively small number of invited experts were convened at FDLI for facilitated discussions. The conversations between invited experts and CDRH staff proved remarkably fruitful in identifying issues and ideas which CDRH staff could use in formulating new program initiatives. In every case, CDRH followed up with public meetings, Federal Register publications, or other means of assuring broad public input prior to mounting a formal program to deal with the issues about which it had sought opinions.

Holding these meetings is consistent with Section 406(b) of the Food and Drug Administration Modernization Act, which charges FDA with consulting with “appropriate scientific and academic experts, health care professionals, representatives of patient and advocacy groups and the regulatory industry” when developing its plans for statutory compliance with the law. CDRH does not seek advice or consensus at such meetings, but the staff looks for opinions from invited individuals on an ad hoc, one-time basis. Once CDRH develops its specific plans regarding the unique identification of medical devices, it will seek to obtain broad public input on this issue.

Developing new program initiatives by starting to gather critical concepts with a meeting like this one has advantages for both government and the public. This methodology allows the Center to conserve valuable resources by consulting with non-government organizations and individuals for their expertise and time rather than relying solely on

³ This work was conducted under the auspices of FDA/CDRH Service Order No. A12696404 with FDLI. Mr. Arcarese’s participation in the project was under the auspices of a separate agreement between him and FDLI.

CDRH staff, ensuring that important concepts are considered at the very beginning of the process of developing a new program, rather than altering plans after lengthy, arduous, and sometimes acrimonious review processes. This methodology does not, however, obviate the necessity of participation by the general public in the process. When CDRH drafts a new program, the public is invited to offer comments, suggestions, and criticisms, especially when the program involves the publication of a formal guidance or regulation.

These facilitated conversations are unlike typical conferences. Typical conferences are usually characterized by speakers at a podium addressing a listening audience, with little provision for debate and interaction between speakers and audience other than a few questions and answers. Thus conferences primarily consist of a process of one-way communication from speaker to audience, and the audience for the most part does not actively interact with the speaker or with each other, except for what might incidentally occur informally between individuals during breaks. Unlike conferences, there are no “speakers at a podium” in these facilitated conversational meetings. All the participants are invited specifically for the purpose of actively discussing and interacting with each other, probing each other’s experiences, questioning claims and preconceived notions, and positing and debating suggested alternatives, under the general guidance of a facilitator. In this kind of environment, where the total number of participants is small enough to allow all participants to have sufficient “air time” to discuss their points of view, the accumulated wisdom and experience of all the participants is tapped. This process honors the contribution of the participants, who donate their valuable time and incur expenses to attend the meeting without recompense from FDA or FDLI, by giving them a sufficient opportunity to express themselves and to interact with other participants. This produces a very intellectually enriching experience for all. Unlike typical so-called “focus-group testing,” these facilitated meetings are not recorded, nor is there a one-way wall separating participants from silent and unseen observers. Consequently, participants feel free to express themselves candidly. Notes taken by FDA participants are used for the purpose of compiling a report which makes no individual attributions.

CDRH staff familiar with those previous meetings felt that the same approach would be helpful at this stage in their desire to investigate the issue of unique device identification, and they contacted FDLI to begin planning. Specific planning for the meetings was conducted between CDRH staff and Mr. Joseph S. Arcarese, who would be the facilitator of the planned meeting. Although now retired from full time employment with FDLI, Mr. Arcarese continues to facilitate meetings under an agreement with FDLI. He facilitated a large number of FDLI/CDRH meetings during his seven-year tenure at FDLI, and facilitated many similar meetings during his 26 year tenure at FDA’s CDRH.

Planning was conducted over a series of phone calls and e-mail communications and including a face-to-face meeting on October 18, 2005. It was agreed that Mr. Arcarese would draft an invitation letter to be sent to a variety of organizations and individuals known to be involved with the device identification issue. The language and format of an invitation letter was drafted by Mr. Arcarese, reviewed by CDRH staff, and revised

accordingly (see Attachment A). Starting on January 14, 2005, invitation letters were e-mailed to a number of organizations and individuals known to have a professional interest and expertise in the issue of device identification. In many instances, invitation letters initially addressed to particular people were passed on to others who subsequently contacted Mr. Arcarese. The list of attendees at the meeting can be found at Attachment B.

In early April 2005, Mr. Arcarese sent via e-mail to all participants and invited organizations a document that had just been completed by staff of ECRI, under contract with CDRH: “Draft White Paper: Automatic Identification of Medical Devices, Version 1.3.” This paper contains an excellent summary of the issue of medical device identification, and it formed a background for the discussions at the meeting. The latest draft of this White Paper may be obtained from ECRI directly (contact Vivian Coates, Vice President for Information Technology, ECRI—E-mail: vcoates@ECRI.org)

During the meeting, CDRH staff took notes, and the following summary was prepared based upon those notes.

III. Summary of Meeting

The world of medical devices is exceedingly diverse and complex. Under the statutory definition of “device” in the Federal Food, Drug and Cosmetic Act, products as different as bedpans and MRI machines are all considered medical devices. Descriptions and names of devices vary as well, from manufacturer to manufacturer, from user to user, and from country to country. The CDRH product coding system hasn’t changed very much over the years to keep up with this complexity, and CDRH is looking to improve its nomenclature system. CDRH also wants to learn what might be the advantages and disadvantages to having a unique identification system for medical devices.

A. Potential Benefits and Disadvantages of Unique Identification System

There are several important potential benefits to having a universally accepted identification system:

- Recalls--For companies to effectively identify individuals that have a recalled device
- Adverse event reporting and analysis. Currently, analysis of adverse event reports is limited by the fact that the specific device(s) involved in an incident are often not known with the required degree of specificity
- Registration and Listing--CDRH will began adopting electronic registration and listing, and needs a consistent nomenclature system
- Patient Safety Issues--examples:
 - Avoiding transmission of disease (e.g., which items might have been used on a patient with CJD)
 - Reuse of single use medical devices--device identification is a challenge with reprocessing of devices
 - MRI-compatible implants (e.g., leads)--leads that are MRI compatible need to be identified
- Inventory control (e.g., expiration date and lot number).

- Prevention of counterfeiting
- Possible additional patient safety benefits to unique device identification, if entered onto a medical record:
 - Tracking hazards and recalls
 - Identifying devices and supplies associated with an incident (that were being used on a patient when the incident occurred)
 - Pulling recalled devices and supplies out of the supply chain prior to being used on a patient
 - Making sure the device being implanted is in fact the device actually intended
 - Making sure anything that shouldn't be in the patient wasn't inadvertently left behind during a surgical procedure
 - Tracking devices that may have been sterilized improperly.
 - Tracking devices that may be determined to be working improperly

There are concerns raised by a unique identification system for medical devices:

- What should be done about legacy equipment
- Possible radio frequency (RF) interference from radio frequency identification (RFID) tags and the hospital environment. Many devices are capital equipment and would be found throughout the hospital.
- The logistical costs of developing an infrastructure to handle the data. Developing and implementing functional and system applications will be a challenge.
- Problem of synchronization of identification data between countries; that will require adoption of a standard nomenclature.
- Analysis of the cost vs. benefit of information proposed to be included in a unique identification system for medical devices (e.g., expiration date, lot number, etc). When FDA developed the bar code regulation for pharmaceuticals, it declined to require encoding of certain information (such as lot number and expiration date) because it concluded that the costs of encoding such information exceeded the benefit. Thus, even though some believed encoding lot number and expiration date information would be useful (particularly in product recalls and identifying expired products), the Agency believed that it could not justify such a requirement.
- Unique serialization of products is an important topic that should be evaluated. (There will be a need to track certain specific devices such as implants all the way from manufacturer to the patient, on an item by item basis, rather than lot by lot or batch by batch).
- There are significant differences between the identification needs for consumer products and health care products. For example, data elements relating to space issues and slotting fees are important for consumer products but are not so important for health care products.
- The unique identification of devices in clinical institutions has not gained universal acceptance, and the reasons for this need to be investigated. Are clinical institutions prepared to invest in the technology (e.g. bar code readers) to really use it? Is there a culture in the hospital hindering this?

- It was noted that representatives of several other interested organizations ought to be involved in this discussion. First, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) should be involved in this discussion, especially since the Commission has its own set of guidelines focused on patient safety. In addition, experts in the implementation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) should be addressed within this topic. And it was suggested that providers of the software need to analyze identification data and track devices should be involved in these discussions. Finally, it was emphasized that those who are going to use this information in the healthcare world need to be involved. Thus, representatives of hospitals and other healthcare institutions, and representatives of major healthcare provider organizations should be consulted.
- Potential benefits of unique identification of devices in the hospital environment were noted. The unique identification of devices may facilitate performance of analytics of device utilization in hospitals, something very difficult to do without unique identification. Unique identification may also let hospitals control costs and manage their inventory better than without it. While there might be resistance to the adoption of new systems needed to keep track of devices, it may help hospitals deliver higher quality care.
- Presently, many hospitals have two identification systems, one for pharmaceutical products, and one for medicine/surgical products, and these two systems don't communicate with one another.
- There are limits to what FDA can require under its statutory authority, because, insofar as devices are concerned, its authority is premised on product safety and effectiveness. Some potential benefits resulting from unique identification of medical devices may not be directly linked to that statutory authority.
- Some companies may want to encode more information than what is presently feasible on a bar code. FDA handled this issue in the bar code regulation by stating that it would not object if firms wished to encode lot number and expiration date voluntarily. However, as FDA recognized in the pharmaceutical bar code rule when it declined to require devices to bear a bar code, there are several important differences between drugs and devices. For example, unlike drugs which have a unique National Drug Code (NDC) number, devices do not have a reliable unique numerical identifier system. There is also a diffuse supply chain for medical devices even within the hospital (e.g., multiple drop points). The medical/surgical worlds needs a device identification solution specifically tailored for its needs and unique circumstances. In fact, there may be several technologies needed for different devices. A single identification technology for all devices is probably impossible. Instead, the question to ask is what kind of functionality is necessary.

- According to one participant, distributors may create their own catalog numbers for some products. For example, they may need to identify individual units when cases or boxes have been opened. In other instances, hospitals may have limitations as to the number or type of characters they can accept in their systems, and they often ask distributors to custom-fit their number so the hospital system can accept them. Consequently, it is not always possible to identify the manufacturer directly from the distributor catalog number. However, distributors do retain the manufacturer's original number in their master systems that can be cross-referenced to the distributor's number.

Distributors may add information to a UPN to meet their individual needs (for example, to identify a supply center). That additional information might be helpful to determine where a product may have gone through in the supply chain. However, some participants felt that the manufacturer-assigned unique identification should be carried all the way to where it is entered into the patient's medical record.

- One participant recommended that lack of clarity in definitions of the words "device," "product," and "supply" is a difficulty in this discussion, and that any numbering system should clearly identify the different requirements for each type of healthcare product.

B. Performance-Based Standards for a Unique Identification System

Although there seemed to be general support of some kind of universal unique identification system, industry representatives expressed their concerns for how the parameters of such a system might be imposed. As a matter of principle, manufacturers object to the imposition of technology-based standards, because the technology is constantly changing. They prefer performance-based standards.

Performance-based characteristics could be established without specifying how they should be accomplished (for example, necessary data elements for a particular type of device could be established without specifying that the identification system should be a linear bar code). In other words, the data should be specified, not the data carrier. It was suggested that industry could determine how to implement a performance standard. However, FDA learned from the public comments to the bar code regulation that hospitals and other potential end-users of a unique identification system advocated specification of a particular technology to facilitate equipment purchases; this same attitude may carry over to device identification.

It was suggested that there could be different performance standards for different types of devices (e.g., MRI machine vs. an implant), because different classes of devices have different identification needs.

It was noted that identifying devices or drugs for reimbursement purposes in electronic health care records may need to be taken into account when performance-based unique identification standards are developed. Third party payors such as the Centers for Medicare and Medicaid Services (CMS) need the information on devices and drugs used on patients in order to reimburse.

It was also noted that Japan is 17% of the world healthcare market. What Japan does regarding device identification has an effect on everyone. Consequently, in whatever it finally decides regarding the unique identification of medical devices, FDA ought to take into account what Japan does. FDA noted that representatives from the Japanese Ministry of Health visited FDA during the bar code rulemaking and had closely followed the rulemaking.

C. Minimum Information Needed for Device Identification

There was a discussion about the minimum amount of information that could be put on a device identification system and still satisfy the need to identify it properly. In this regard, electronic medical records are definitely a related matter. An electronic medical record will need to capture what kind of devices were used on a patient and/or were implanted in the patient. In order to do this, the hospital needs to be able to access the correct record for a particular patient, and then identify those devices used on and implanted in the patient. As a means of emphasizing the magnitude of the problem, it was pointed out that over 80 different stock keeping units (SKU) are needed to account for all the devices utilized in the operation to insert an artificial hip (instruments and devices). Needless to say, identifying all of them is not a trivial task if it were to be done manually, and even if it is done electronically, it would require a degree of interdepartmental coordination that presently does not exist in all hospitals. Hospitals often have discreet non-homogeneous identification systems from department to department.

Regarding the unique identification of implants, several participants felt that at least a lot number and a unique serial number are necessary. (For one large company, each of their products has a bar code with a lot number and/or serial number.) Apparently all hip manufacturers identify their hips with a UPN (universal product number), either a Health Industry Business Communications Council (HIBCC) or a Uniform Code Council (UCC) number.

Not all devices would benefit to the same extent from a unique identification system in terms of patient safety (e.g., an implant vs. a bandage). The patient safety benefit has to be evaluated for each type of device. However, it was noted that, just because the patient safety benefit of unique identification hasn't been studied in the literature, does not mean there isn't experience in the clinical environment. Should FDA wait and do more research on benefits and costs before continuing?

D. Ability of Health Care Institutions to Utilize Unique Identification

It was noted that the unique identification of devices is not the only step required to achieve patient safety or logistical benefits. It is equally important that clinical institutions have the equipment, applications, procedures and policies in place to take advantage of the information. Standards are also required to make sure that clinical institutions are interpreting the data correctly and that the data itself is correct. Also necessary is an information database so that the data associated with a particular device can be readily accessed.

One participant noted that St. Alexius Medical Center in Bismarck, ND (<http://www.st.alexius.org/>) has been bar coding everything that comes into the hospital for years, and has a wealth of experience. Dallas Children's hospital is also moving in that direction. The participant claimed that these institutions find benefits for patient safety, controlling costs, and providing justifications for third party payors. Analysis of data in these systems may be useful in answering such questions such as why one doctor's surgeries cost more than another's.

The clinician's perspective as well as the manufacturer's should be taken into account when determining device nomenclature. Device naming should not be too generic, and it should be tied to the device's usage.

Although we often refer to "hospitals" when we discuss the identification of devices in the clinical environment, we need also be concerned with non-hospital patient care settings, such as home health care, physician's office, nursing home, etc. Medical devices are being used in all kinds of areas with little or no professional health care oversight. Thus, if there is a patient care issue in discussing device identification, that discussion should take into account the location of the patient care. In many non-hospital sites, the use of standard business technologies is minimal. If the personnel in non-hospital settings can be shown how they and their patients might benefit from using the unique identification of medical devices, there may be a better chance of success.

When FDA evaluated the costs and benefits of the bar code regulation, it did not believe that physicians would be inclined to buy or use scanners in their private practices. Consequently, FDA did not require bar codes on physician samples. With regards to all of the other potential non-hospital beneficiaries, FDA lacked sufficient data to identify them as other potential beneficiaries.

E. The Issue of Serialization

As previously noted, there was apparent agreement that not all devices should have the same level of identification. The detail of identification should be related to the class of device. Not all devices need to be serialized (i.e., an individual number for each item). The question is, which devices do need to be serialized?

For example, infusion pumps are currently all serialized. But having a unique identification and a system to check two items that are similar looking to make sure the right one is being used would be helpful.

Counterfeiting of medical devices is a serious and growing problem. Serialization of devices would allow someone to ascertain whether a company actually made an item.

Research is emerging that shows sterilization for devices used on Creutzfeld-Jakob Disease (CJD) patients might be possible. A unique identification system, when used in conjunction with the sterilization process, could show that a specific device was sterilized properly.

In the DoD/UID, every specific item has a unique number on it. This kind of serialization is necessary for certain kinds of devices, but not for all types of devices. For many devices it would be helpful to just know the NDC equivalent, but for other devices, such as implants, it may be necessary to be able to identify an individual device. HIBCC and UCC both have systems for including serialization beyond what is available at the UPN level.

GTIN (Global Trade Item Number) allocation rules are on the UCC web site (www.uc-council.org) (primary identification number plus serialization). It shows who owns the number, when you take it off, what happens when you sell it. This document also talks about what happens when you make a change to a product and when it requires a new number. UCC stipulates that whoever reprocesses a product must obtain their own number for it.

There seems to be a lack of agreement as to what should be encoded at the unique identification level in addition to the standard elements provided by either of the two main coding organizations. FDA should explore what is already being done with bar codes for devices and then see what is missing.

F. Information Used by FDA in Determining its Course of Action

As part of its justification process for taking an action about unique identification of medical devices, FDA should solicit answers to questions such as:

- What are the patient safety problems that requires unique identification of medical devices?
- What kind of data is available regarding any proposed solution strategy?
 - Data regarding what's happening now (the current state of the art) with device identification
 - Data from research on the technologies and the practical application of device identification
 - Data from the analysis of disasters
- Are there industry-driven solution strategies available that could solve the identified problem?

- Should the solution strategy be implemented internationally, and should FDA be involved in this?

Regarding the problems to be solved and the data needed to demonstrate them:

- FDA would like to identify patient safety events, which devices were used, and what is the role that the devices played in that patient safety event. What is the possibility of these events recurring? Acts of omission as well as commission are important. What are the risks associated with using these devices and what kind of information would help us minimize these risks?
- Government healthcare organizations want to improve quality of care, timeliness, and effectiveness of care. Medical devices play a role in all of these.
 - Unique identification may improve the quality of care by helping ensure the use of the right device, in the right location, at the right time, in the right condition, for the right procedure, at the right anatomic site, in the right patient, by the right user (user who has been trained to use this) [“The 8 Rights”]
- Is there evidence (data) to show that unique identification of medical devices would help improve the quality of care? There is a lack of comparable literature in the device world as there was in the drug world. There are also some statutory limitations with devices that were different from drugs.
 - The AdvaMed survey mentioned in the ECRI White Paper is the most current literature
 - Many manufacturers are already using some kind of unique identification (using either HIBCC or UCC codes) all the way down to the unit packaging level.
 - If hospitals and other providers demand unique identification/bar codes, the manufactures will provide them. If you want to change the situation, make the customers demand it.

There are several types of problems for which a unique identification system may contribute to the solution:

- 1) Analysis of adverse events
 - Forensic investigation or any kind of statistical analysis requires some kind of unique identification.
 - FDA could examine the Manufacturer and User Facility Device Experience Database (MAUDE) data to determine whether identification of devices is a significant impediment to the analysis of adverse events. FDA knows there are many problems with devices in MAUDE, but in many cases it is not known with any degree of specificity which actual device was used on a particular patient
 - Linking devices to patient outcomes would be beneficial
- 2) Specific prevention of known problems (e.g., latex sensitivity; transmission of infections diseases like CJD; informing hospitals of situations where a device may have been processed that shouldn't have been)

- 3) Promotion of health (e.g., MRI compatibility. Many implants are MRI incompatible. Not knowing whether a particular implant is compatible with MRI is becoming increasingly important)
- 4) Counterfeit products. FDA recently issued a report relating to counterfeit drugs in which unique identification (specifically RFID) was discussed.
- 5) Capturing information for electronic health records
- 6) Conduct of recalls and implementing the medical device tracking requirements

What are the possible ways by which a universal unique identification system might be implemented

- Congress passes a new law.
- FDA promulgates a regulation
 - FDA can promulgate regulations based on its authority under the FD& C Act and the Public Health Service Act. FDA must perform an analysis on the impact (benefits vs. the costs), including considering the impact on small businesses.
- FDA promulgates guidance
 - FDA guidance documents are voluntary. They may be easier for FDA to process administratively than regulations, and easier to amend. Guidances can be an interpretation of a regulation or statute. Guidance represents the agency's current thinking about an issue. It provides a suggested way for the recipient to interact with the agency, or a suggested way in which regulatory obligations may be fulfilled. Guidance may incorporate a standard. It is not prescriptive, and compliance with it cannot be mandated. The mere fact that there may be no accepted voluntary standard, or that there may be a great deal of confusion about a particular matter, is not necessarily enough for FDA to justify developing a guidance document. Guidance is written by agency staff with the possibility of input by affected industry. There is always an opportunity for public comment during the process of developing guidance.
- FDA utilizes one or more voluntary approaches
 - FDA uses its position to advocate and influence changes in industry practice on this issue
 - FDA develops a consortium with industry
 - FDA partners explicitly with several relevant government agencies, including VA, DoD, CMS, FHA, HRQ, NCHS and NLM
- FDA does nothing (watchful waiting)

G. The Issue of Categorization

Recognizing that the same identification information is not warranted for all devices, there needs to be some system of categorizing devices. It was suggested that the Medical Electronic Customer Assistance (MECA) database of the Department of Defense has a wealth of categorization information in it (as much as 7 levels of detail). It is also called the Universal Data Repository or UDR. However, there is no way to consolidate the data at the present time on the

consumer supplies side. There are efforts going on within the Department of Defense, the Veterans Administration, and the Coalition for Healthcare eStandards to try to synchronize their data.

Potential Categories of Devices for the purpose of unique identification (note that not all would be required for patient safety purposes):

1. Implants
 - Permanent (≥ 30 days)
 - Temporary
 - Active (electronic or moving parts)
 - Non Active
2. Device Material (e.g., latex containing)
3. “Capital” Equipment
 - How is it defined? Would hospitals be a good place to get a definition?
 - Electrical devices are considered to be equipment
 - Break down into expendable and non expendable?
 - Life supporting and risk to patient
 - Technologically sophisticated, requiring ongoing calibration (medical equipment vs. medical products)
 - Diagnostic or therapeutic vs. orthotics or prosthetics
4. InVitro Diagnostics
5. Risk to patient
6. Infectious Risk/Sterility
7. Supplies
 - Disposable vs non-disposable
8. Single Use Only
9. Reprocessed Devices
10. Reusable Devices
11. Interoperability
 - Mechanical
 - Electrical
 - Software
12. Care Setting
 - Home use
 - Acute care
 - Long term care
 - Physician office
 - Emergency
 - Mobile equipment
13. User of device
 - Clinician (trained professional)
 - Patient, family
 - RX vs. OTC
14. Kits vs. components
15. Systems vs. components

- 16. Devices requiring expiration date or not
- 17. Devices relevant to bioterrorism or not?

It would be helpful if a matrix could be developed, showing what kind of identification information would be needed for various categories of medical products. Safety needs could be matched to the category.

As an example, take the pacing lead:

- An implantable
- Permanent
- Part of a system

H. Minimum Data Set

What is the minimum data set and level of aggregation necessary to achieve an optimal level of patient safety benefit? The answer can be summarized by: what information/data is needed by whom, at what time, and at what level of detail.

(Note: It was pointed out that a bar code would be a labeling element. FDA already has a minimum data set in its labeling regulations. However, the labeling regulation only goes down to the lot level.)

- Manufacturer
- Make
- Model
- lot number (as applicable)
- place of manufacturer
- name of product
- serial number (as applicable)
- unique description
- expiration date
- address (as applicable)
- quantity (i.e. unit)

The international requirements should be consulted to see if there are any additional minimal requirements.

There was discussion of the problem of what needs to be done with the identification of a device when there is a software or firmware revision. At that level, serial numbers could enable users to determine which device has had the update.

I. Databases

It was pointed out that bar codes ultimately point to a database, and the development of that database is just as crucial as the bar code itself. The bar code itself need not contain all necessary information as long as it points to a database containing the information needed. But the more a database is relied upon, the more infrastructure will be needed at the hospital (i.e., user) level to obtain needed information. So some intelligent decisions need to be made as to what information should be conveyed about the device in its bar code, and what information should be conveyed by an associated database.

Where would the databases reside?

- Manufacturers want to keep their information away from clearing houses because they don't want their data to become out of date.
- MECA is a federal database that we should look into
- "Daily Med," a database maintained by the National Library of Medicine.
- UCCnet has a subscribed database that aggregates information from some manufacturers that includes changes and new items. Not all manufacturers choose to participate, so this is a limitation.
- FDA staff noted that FDA has to operate somewhat differently regarding devices than drugs because there are a great many small medical device manufacturers that may not have the capitalization to join a database.

J. Additional Consultation

It was suggested that FDA needs input from the clinical world, such as the National Patient Safety Foundation, the American College of Clinical Engineering (ACCE), etc. FDA needs to test the appetite of hospitals for all the work that they would have to do in order to make a device identification system worthwhile. FDA should learn what hospitals (and other clinical environments) would do if there was a unique identification system in place.

Several participants also suggested that FDA needs to clearly define the requirements of any proposed device identification system for the sake of additional discussions. One participant noted that the term "unique" was used in the conversation in the two day meeting to mean (1) a number that uniquely identifies one product from another – that is – from a specific company, a specific product, at a specific level of packaging; or (2) a unique instance of the product – typically assigned a serial number. Whatever FDA intends for such a system ought to be made clear, so that all the commentary is on point.

It was also suggested that FDA should get input from other payor organizations besides CMS. However, some were skeptical that FDA would learn new and different information from these organizations than what it already knew, since these concerns have been documented for years. They felt that FDA might hear suggested differences in implementation, but that it would receive consensus from the clinical world about the utility of some sort of performance standard for a unique identification system.

In planning its future activities, FDA may decide to hold an additional meeting(s). The following organizations were suggested for consideration:

- Hospitals
- Hospitals software vendors
- AHA
- National Council of Pharmaceutical Drug Programs
- AAHHCP
- JCAHO

- National Patient Safety Foundation
- People from this group
- DoD and VA
- American Association of Clinical Engineers
- FHA (federal health architecture)
- Nurses
- Third party payers, CMS
- Industry who know GMP/Quality Systems

IV. List of Attachments

A. Invitation Letter

B. List of Attendees at April 14-15, 2005 Meeting

ATTACHMENT A: Invitation Letter

Dear Name:

I would like to invite you or a representative from your organization to participate in an important meeting regarding the potential development of a voluntary system for identification of medical devices with representatives of the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) and representatives of other organizations interested in this topic. CDRH has asked the Food and Drug Law Institute (FDLI), a non-profit, neutral, and non-partisan educational organization, to convene and facilitate a two-day meeting on **Thursday and Friday, April 14-15, 2005 in Washington, DC**, as a forum to discuss the benefits and disadvantages of a unique identification system for medical devices between CDRH and the industry, and the types of device-specific information that could be contained in such a system. A small number of representatives from manufacturers, medical device regulatory consultants, trade associations, bar coding organizations, and other relevant interested parties are being invited to participate in this meeting. Relevant CDRH staff will participate in the discussions. At FDLI's request, I will be the facilitator of the meeting.

Background

The National Committee on Vital and Health Statistics (NVCHS), the public advisory body to the Secretary of Health and Human Services in the area of health data and statistics, is responsible for studying issues related to the adoption of uniform data standards for patient medical record information (PMRI) and for electronic exchange of such information. NCVHS has recently advocated the concept of a single international medical device nomenclature system.

The Patient Safety Health Care Information Program at the Agency for Health Research and Quality (AHRQ) promotes and accelerates the development, adoption and diffusion of interoperable information technology in a range of health care settings. AHRQ and FDA agree that there is an urgent need for a unique identifier for medical devices.

If successful, the coupling of an internationally recognized medical device nomenclature to a unique identification system for medical devices would have significant implications for patient care and safety not only in the U.S. but potentially world-wide. Universal classification systems for medical devices would also be extremely useful in purchasing, business inventory control, and other applications.

Objectives of the Meeting

This meeting is being convened to provide an opportunity for CDRH to hear ideas and reactions from knowledgeable representatives of relevant organizations about employing a voluntary, uniform system of unique identification of medical device equipment. CDRH is interested in hearing about:

- the kinds of information that could be readily captured in such a system,

- the kinds of identification technologies (e.g., bar codes, radio frequency identification [RFID]) that could be employed,
- the advantages and disadvantages of such systems, including the patient safety implications, and
- the major bar-coding systems and device nomenclature systems that are being used by the medical device community.

CDRH is also interested in discussing the potential for developing a public-private partnership with the goal of promulgating a voluntary program for a unique identification system for devices.

You will be invited to share your suggestions, concerns, and experience regarding the issues of an international nomenclature system, and of bar coding medical devices, and your expectations of benefits and disadvantages these strategies might have for the medical device industry. You will hear what other knowledgeable people have to say about this matter. And your comments may very well influence FDA policy in the future about this important topic. The number of participants to this meeting is purposefully being kept small, so that all participants will have ample opportunity to express themselves and interact with the other participants, including CDRH staff in attendance.

Holding meetings like this one, where a small group of invited participants discuss important matters regarding the safety and effectiveness of medical devices, is consistent with Section 406(b) of the Food and Drug Administration Modernization Act, which charges FDA with consulting with “appropriate scientific and academic experts, health care professionals, representatives of patient and advocacy groups and the regulatory industry” when developing its plans for statutory compliance with the law. CDRH will not be seeking advice or consensus, but the CDRH staff is looking for opinions from the invited individuals on an ad hoc, one-time basis.

Meeting Logistics

As I said, the meeting is scheduled for Thursday and Friday, April 14-15, 2005. The meeting will convene from 9:00 AM to 4:00 PM each day. The meeting will be held at FDLI’s office located at:

1000 Vermont Ave., NW, Suite 200
Washington, DC 20005
Tel: (202) 371-1420

Lunch will be provided in order to maximize the efficiency of the meeting. FDLI is located at the corner of Vermont Avenue and K Street, not far from the White House, about 3 blocks from the Farragut North station on the Metro subway station on the Red Line, and 1 block from the McPherson Square Metro subway station on the Blue and Orange Lines. A map and list of nearby hotels is available at:
<http://www.fdpi.org/about/fdlimap.html>.

I would appreciate hearing whether you or a representative of your organization would be able to attend this meeting or not. Due to space limitations, we are purposefully

limiting attendance at the meeting by issuing only a relatively few invitations. Your participation is important to us. Please feel free to correspond with me by phone (301-977-4655) or by e-mail (arcarese@comcast.net).

Please let me know the name, title, address, phone, and e-mail address of the individual who will be coming.

I regret our inability to pay for travel expenses. Nevertheless, I do hope you or a representative of your organization can come. Your organization's participation in this informal gathering will be a valuable contribution to a very interesting discussion and to the development of government guidance.

I look forward to your reply. Thank you very much.

Sincerely,

Joseph S. Arcarese
FDLI

ATTACHMENT B: List of Attendees at April 14-15, 2005 Meeting

Arcarese, Joseph S.

Facilitator
FDLI
12005 Suffolk Terrace
Gaithersburg, MD 20878
Tel: 301-977-4655
E-Mail: arcarese@comcast.net

Bush, Laina

Senior Food and Drug Policy Advisor
ASPE, HHS
200 Independence Ave, SW
Washington, DC 20201
Tel: 202- 260-7329
E-Mail: Laina.Bush@hhs.gov

Byer, Dennis S.

Senior Director, Information Technology, Consorta, Inc.
Coalition of Healthcare eStandards
Schaumburg Corporate Center
1475 E. Woodfield Road, Suite 400
Schaumburg, IL 60173
Tel: 847-592-7866
E-Mail: dbyer@consorta.com

Chao, JD, LLM, Philip

Senior Scientific Policy Analyst, Office of Policy and Planning
FDA
5600 Fishers Lane, HF-23
Rockville, MD 20857
Tel: 301-827-0587
E-Mail: Philip.chao@fda.hhs.gov

Coates, Vivian

Vice President, Information Services and Technology Assessment
ECRI
5200 Butler Pike
Plymouth Meeting, PA 19462-1298
Tel: 610-825-6000, x5369
E-Mail: vcoates@ecri.org

Crowley, Jay

Office of Surveillance and Biologics, CDRH
FDA
1350 Piccard Drive, HFZ-500
Rockville, MD 20850
Tel: 301-594-1161
E-Mail: jjc@cdrh.fda.gov

Figarella, Lu

Senior Systems Consultant
Health Industry Business Communications Council
2525 E Arizona Biltmore Circle, Suite 127
Phoenix, AZ 85016
Tel: 602-381-1091
E-Mail: info@hibcc.org

Fitzmaurice, PhD, J. Michael

Senior Science Advisor for Information Technology
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850
Tel: 301-427-1227
E-Mail: mfitzmau@ahrq.gov

Forbes, Mary

Federal Health Architecture Program Manager
Department of Health and Human Services
Washington, DC
Tel: 202- 690-8716
E-Mail: mary.forbes@hhs.gov

Ford, Cheryl

Health Insurance Specialist/IT Analyst
CMS
7500 Security Boulevard
Baltimore, MD 21244-1850
Tel: 410-786-7415
E-Mail: cheryl.ford@cms.hhs.gov

Frahler, Jori L.

Policy Director
Medical Device Manufacturers Association
1919 Pennsylvania Ave, NW, Ste. 660
Washington, DC 20006
Tel: 202-349-7174
E-Mail: jfracrler@medicaldevices.org

Gandhi, Tarun

Product and Marketing Specialist
Defense Supply Center, Philadelphia
700 Robbins Ave.
Philadelphia, PA 19111
Tel: 215-737-2238
E-Mail: Tarun.Gandhi@dla.mil

Gatling, Jr., Robert

Program Operations Staff, Office of Device Evaluation, CDRH
FDA
9200 Corporate Boulevard, HFZ-402
Rockville, MD 20850
Tel: 301-594-1190
E-Mail: rrg@cdrh.fda.gov

Grimes, Stephen L.

Senior Consultant & Analyst
GENTECH (representing HIMSS)
139 Henry St
Saratoga Springs, NY 12866
Tel: 518-441-5617
E-Mail: slgrimes@nycap.rr.com

Hinson, John

Senior Management Analyst
Veterans Health Administration
Washington, DC 20420
Tel: 202-254-0429
E-Mail: john.hinson@va.gov

Howells, John

Director, e-Business
Healthcare Distribution Management Association
1821 Michael Faraday Drive, Suite 400
Reston, VA 20190
Tel: 703-885-0277
E-Mail: jhowells@hdmanet.org

Kessler, ScD, Larry

Director, Office of Science and Engineering Laboratories, CDRH
FDA
9200 Corporate Blvd, HFZ-100
Rockville, MD 20850
Tel: 301-827-4777
E-Mail: droseldir@cdrh.fda.gov

Lee, Donna

Chair, HealthCare Action Group
Association for Automatic Identification and Mobility
Hand Held Products, 700 Visions Drive, PO Box 208
Skaneateles Falls, NY 13153
Tel: 315-685-4368
E-Mail: Donna.Lee@handheld.com

Levin, MD, Randy

Associate Director for Medical Informatics, CDER
FDA
5600 Fishers Lane, HFD-001
Rockville, MD 20857
Tel: 301-827-7784
E-Mail: randy.levin@fda.hhs.gov

Moritz, Susan

Director of Compliance
BD Medical Systems
MC206
1 Becton Drive
Franklin Lakes, NJ 07417
Tel: 201-847-7019
E-Mail: Susan_Moritz@bd.com

Racine, David

Office of Communication, Education, and Radiation Programs, CDRH
FDA
1350 Piccard Drive, HFZ-205
Rockville, MD 20850
Tel: 301-594-3533
E-Mail: dwr@cdrh.fda.gov

Richardson, Elizabeth

Senior Clinical Informatics Specialist
ECRI
5200 Butler Pike
Plymouth Meeting, PA 19462-1298
Tel:
E-Mail: erichardson@ecri.org

Roberts, John

Director, Healthcare
Uniform Code Council, Inc.
Princeton Pike Corporate Center, 1009 Lenox Drive, Suite 202
Lawrenceville, NJ 08648
Tel: 609-620-0200
E-Mail: jroberts@uc-council.org

Rowan, Matthew

President & CEO
Health Industry Distributors Association
310 Montgomery St.
Alexandria, VA 22314-1516
Tel: 703-549-4432
E-Mail: Rowan@hida.org
fela@hida.org

Secunda, Jeff

Associate Vice President, Technology and Regulatory Affairs
Advanced Medical Technology Association
1200 G Street NW, Suite 400
Washington, DC 20005-3814
Tel: 202-783-8700
E-Mail: jsecunda@advamed.org

Thall, Irwin

RFID Manager

Precision Dynamics Corp.

13880 Del Sur St.

San Fernando, CA 91340

Tel: 818-897-1111

E-Mail: irwint@pdcorp.com

Wood, Leslie M.

Functional Analyst

Joint Medical Logistics Functional Development Center

30 Terben Court

Thurmont, MD 21788

Tel: 301-619-7827

E-Mail: LeslieWood@DET.AMEDD.ARMY.MIL

wood38@earthlink.net

Werthwine, Thomas E.

Manager, Data Standardization

Johnson & Johnson

501 George Street

New Brunswick, NJ 08901-1197

Tel: 732-524-1047

E-Mail: twerthwi@corus.jnj.com