Report on Meeting to Discuss Unique Device Identification

October 27, 2005
The Food and Drug Law Institute
1000 Vermont Avenue NW
Washington, DC 20005

by Joseph S. Arcarese
Meeting Facilitator

Report Date: January 16, 2006

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On October 27, 2005, a meeting was held at the office of the Food and Drug Law Institute (FDLI) to facilitate a discussion between the Food and Drug Administration's Center for Devices and Radiological Health (CDRH) and various 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. Participants were drawn largely from health-care related organizations. This was the second stakeholder meeting held on this subject. The first meeting was held on April 14-15, 2005, primarily by representatives of the medical device industry, and research and trade associations[2]. Representatives of the Food and Drug Administration (FDA) attended both meetings. The meetings were held at the request of CDRH which is the FDA component responsible for assuring the safety and effectiveness of medical devices. This report summarizes the results of the October 27, 2005 meeting[3].

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.

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[2] A report of that meeting, entitled "Report on Meeting to Discuss Unique Device Identification," is available at www.fda.gov/cdrh/ocd/uidevices061405.html.

[3] The meeting was originally scheduled for two days, October 27-28, 2005. However, the discussions were satisfactorily concluded after the first day.

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. In 2004, the Food and Drug Administration published a final regulation requiring bar codes on the labels of most human drug products and biological products[4]. In considering whether medical devices ought to be uniquely identified, CDRH decided to have a series of meetings with various stakeholders on the issue of unique identification for medical devices. As previously mentioned, CDRH requested that FDLI[5] convene and facilitate a two-day meeting in April 2005 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 program for a unique identification system for devices.

As a result of the success of that meeting, CDRH determined to discuss the subject of unique device identification with representatives of hospitals and other health-care institutions, in order to hear their opinions about what benefits unique device identification might provide them, and what costs might be entailed.

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

[4] 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

[5] 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.

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 these 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 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. 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 August 22, 2005, invitation letters were e-mailed to a number of health-care related 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 participants at the meeting can be found at Attachment B.

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

III. Summary of Meeting

At the outset of the meeting, CDRH staff addressed the question of whether FDA should issue a regulation mandating device identification or whether it should seek some voluntary approach. Throughout the meeting, and in subsequent communications with participants, it became clear that many organizations clearly favored a mandatory approach to this issue. However, CDRH participants were not certain whether there was enough information about the costs and benefits of unique device identification to meet Agency legal requirements for a regulatory (i.e., mandatory) approach. They explained that, while it is possible that eventually FDA will take a mandatory requirement path, at this meeting, FDA is seeking to ascertain information about unique device identification without focusing on the specific mechanism of implementing a program.

In the case of pharmaceutical identification, FDA believed it did have the legislative authority to promulgate a regulation, and it made that case that the cost of the regulation was less than the benefits that would be enjoyed. Estimating the costs and benefits is difficult and requires substantiation. In the pharmaceutical case, FDA's initiative was supported by the Institute of Medicine's report "To Err Is Human." That report asserted that bar coding of pharmaceuticals would help reduce patient deaths due to administration errors. FDA hopes that it will be able to make the case once it completes all its data

gathering, and it intends that the outcome will be beneficial for all the involved stakeholders.

A. Why shouldn't there be a Unique Identification System

The discussion of whether there ought to be a unique identification system could be opened by looking at it from the negative, i.e., why shouldn't there be such as system? A number of reasons can be posited.

In preparing and maintaining such a system, there is always the potential for the introduction of bad data that would then be used for analysis. It is difficult to purge bad data from a system. The quality of data is critical to any system, especially a centralized database, and unreliable data can undermine it. Data validation is critical.

If a voluntary system is proposed for a unique identification system, it is difficult to imagine that it would be advantageous, inasmuch as multiple systems would simply add to the complexity. In health care institutions, having to accommodate dual systems can add to increased risk and potential problems. It is hard to rely on a database that is voluntary. Consequently, the feeling is that a UI system should be either done all one way or not at all. What we have now is really a voluntary system where each manufacturer has its own system.

Whatever systems are adopted, they have to be easy for clinical personnel to use as they care for patients. Systems that do not allow for shortcuts, thus affecting timeliness of care delivery, will only make life more difficult for nurses, and will aggravate the acute nursing shortage. Extensive training will be required. From a logistical prospective, it would be better if a device is automatically recognized as soon as it enters the room, without the need for time spent in data entering.

Money is always a concern; upfront and continuing costs and questions about reimbursement may be issues affecting the introduction of any system, especially for health care settings that do not have sufficient resources to invest. However, once efficiency and effectiveness have been demonstrated with fewer instances of error, the cost savings to be gained by implementing a system of device identification will become evident.

We should try to separate implementation from the data and technology involved in a UI system. Each institution should be free to decide how best to implement it. Since technology changes, our main focus should be to decide the data elements and allow for additional elements in the future.

Among the health care representatives at the meeting, there appeared to be general agreement that, despite possible downsides, there is a need for a mandatory UI system, and that FDA should consider implementing a mandatory system of UI to avoid a "free for all" of competing systems. Indeed, despite their concerns about whether these justifications are sufficient to meet Agency requirements for the imposition of a regulation, nevertheless, CDRH staff present were sympathetic to the arguments

presented by the attendees. Since there are many implementation questions yet unresolved, it was assumed that ultimately the market would find answers to them.

B. How deep should a UI system go

The participants considered how much data should be included in a UI system, i.e., how deep should it go in identifying a particular device. We should establish a standard nomenclature first and then decide how detailed the information ought to be required for each category of device.

For example, when device recalls are announced, hospitals must do extensive research, often involving manual chart reviews. In order to simplify finding recalled devices and ascertaining which patients have them or were treated using them, there ought to be deep granularity in the data captured for many kinds of devices. But then, that begs the question, what do we need to determine the level of granularity? The level of potential risk and the likelihood of recalls might be considerations in establishing how much information ought to be required for each category of device, but it must also be kept in mind that even simple devices (e.g., gloves) are associated with some level of risk. Software in devices in the hospitals is a complicating issue, especially when it comes to identifying different software versions applied to the same hardware. Participants felt that implantable devices should have complete granularity, i.e., each item should be identified. Some feel that complete granularity should be applied only to certain types of devices, while others feel that a UI system should be designed to identify devices down to the individual item. One participant suggested that a 12 digit code may be adequate for identifying devices to this degree of specificity, citing work performed by MIT Auto ID Center David Brock and work done by EPC Global.

In any event, there should be an easy way to extract information from the identification code, so that each institution can pick off the data they feel they need for their own implementation.

There needs to be a repository of reliable data about each device with an identification number. Where the data will reside is an issue about which no consensus has yet emerged. Manufacturers generally feel that they should be each responsible for maintaining the data about their devices on their own databases, but this leaves unanswered the question of what happens to the data when manufacturers go out of business or when devices are no longer manufactured but may still be in circulation. There should be some thought given to the kind of information that could be obtained from a UID without the necessity of accessing a network (“smart” number).

DOD has a UID initiative in which devices costing over $5,000 will have to be individually identified. This is now being implemented, and some manufacturers are complaining about the requirement, and some have opted out.

In any case, whatever kind of UID system that is recommended ought to be pilot tested.

C. Additional questions

In order to organize the discussion, the following additional questions were posed:

1. What is your organization now doing in the UID area?
2. If there were a UID System, what would be the potential clinical and economic benefits?
3. Problems and obstacles
4. What data do we need vs. what do we want
5. Technology issues in the health care environment

1. What is your organization now doing in the UID area

The Department of Defense's (DoD) Defense Medical Logistics Standard Support (DMLSS) system has implemented a management tool to track relevant information about a piece of equipment. They use the ECRI nomenclature system, and every piece of equipment that comes into their system is given a number, unique to that facility. Each facility reports equipment information to a central Joint Medical Asset Repository. They do not assign numbers to items that are not routinely tracked, such as gloves. The present emphasis is on equipment maintenance and property accountability. The facility unique numbers do not relate directly to patient use. In the future, they intend to relate the equipment to the clinical situation via an electronic health record. The DoD is implementing an enterprise wide Unique Identification (UID) program for all equipment, including medical, with an acquisition cost over $5000 and selected controlled items. The Military Services may implement more stringent criteria for the UID program. Each equipment item will be assigned a globally unique Unique Item Identifier (UII) by the manufacturer or receiving activity, and will be marked using a two-dimensional data matrix bar code. All items will be registered in a central DoD data repository with associated pedigree data. A UII field will be added to the DMLSS system by October 2006 to comply with the DoD program.

Massachusetts General Hospital has a home grown system (AMM) developed by a small team. When equipment comes into the hospital, serial numbers are recorded. This data is used to track the equipment throughout the institution for maintenance purposes. They prepare annual reports in which they report their success in finding devices to test. This would be easier with an indoor global tracking system. In the operating room of the future, a tag (Radiance – active battery and Infrared) will be on each device and is read by devices on the wall to recognize the proximity of the equipment. There are constraints on the physical size of the tag because it contains a power source. In order for asset tracking to work effectively, devices need to be able to be uniquely identified. At the present time, the hospital has to give devices their own numbers and create their own data. In the future, MGH wants to use the system to determine if they have all the necessary items in a surgery before starting.

ECRI sees many individual departments managing their inventory, especially in biomedical departments. Many departments have their own databases for their devices. Data cleaning is an issue especially when data are entered via different protocols. Also, when multiple hospitals merge data into one system, this could create a data mess.

JCAHO has two applicable standards, requiring written management plans. Hospitals must have a system for acting on and monitoring recalls, and to track, maintain and test medical equipment. Implementation of a unique device identification system would help hospitals meet their obligations under these standards. JCAHO is concerned that smaller hospitals may not be able to meet their standards.
Novation serves the purchasing needs of more than 2,500 members and affiliates of VHA and University Health System Consortium. In 2004, these organizations used Novation contracts to purchase more than $23 billion in pharmaceuticals, health care equipment and supplies. Member hospitals have requested that Novation work with suppliers and regulatory agencies to further the adoption of a universal and unique identification system for medical devices. This would contribute positively to patient safety and operational efficiency. Areas of positive impact include product recalls, product shortages, inventory management, item master management and product substitutions.

Catholic Hospitals distinguish between clinical equipment and patient supplies. They outsource their clinical equipment service, and a detailed database is maintained for them. For patient supplies, they have a centralized item file that has 60,000 items in it. They use a standardized classification for the first level and then add their own identifier system. They capture all of the other data such as manufacture number etc. It is centrally maintained. They don't capture any patient information, but they do capture some physician order information. Recalls are still performed manually. They use RFID to track mobile equipment. They maintain a relationship with a 3rd party data cleansing vendor that routinely checks their transactions to see if the data entry is accurate. There are large expenses associated with these 3rd party data scrubbing companies.

Premier buys a great deal of medical/surgical equipment, and they require a UPN on all the products. They do synchronize with the GHX health care exchange. They have a large database and they synchronize with the hospitals in their system. Their operation would be simpler if there were a common identification number.

CMS recently issued draft quality standards out for comment, for durable medical equipment suppliers. This draft is available on the CMS website at http://www.cms.hhs.gov/suppliers/dmepos/compbid/dmepos_qualitystandards.pdf.

The American Hospital Association says that 40% of hospitals are using bar codes for tracking supplies. But right now, there does not seem to be many individual sophisticated tracking systems (Army/Air Force is the exception) other than what is specifically required to meet JCAHO standards. Generally speaking, there is no technological connection between equipment and the patient, so that recalls still have to be done manually. Some hospitals use third-party contractors to address maintenance of equipment, keep a database of detailed service records, etc. These contracts appear to provide excellent results with low rate of recalls. Data cleansing is a big business in which most hospitals must participate. When equipment is loaned, such as in disasters, there is generally no reliable way to track the equipment.

There are many examples of how accurate device identification and linking with patients could facilitate recalls. In one hospital, there were about 200 colonoscopy patients who had to be called back for HIV testing, due to an equipment problem. Some of them had their colonoscopies performed with a new version of a colonoscope. The maintenance staff did not realize that this colonoscope came with a water channel, and the channel consequently was not cleaned from patient to patient. When this error was discovered, all the colonoscopy patients in that department had to be brought back for HIV testing, since it was not possible to ascertain which particular patients were treated with which particular colonoscope.

2. If there were a UDI System, what would be the potential clinical and economic benefits

Ability to populate the electronic medical record with device information, and thus the particular devices used on particular patients could be identified if a recall were necessary, or as a part of the system used by clinicians when managing the delivery of care to their individual patients

- By linking device with patient, there could be improved third party payments
- If there was a UDI, more institutions would be putting into place systems that could use it in a variety of ways
- There could be cross referencing to determine comparable equipment in the event of recalls or shortages, with the ability to determine equivalent products and make automatic substitutions
- When clinical recommendations for diagnostic devices were announced, devices could be tracked that had problems associated with them
- In the case of post marketing surveillance, CMS may reimburse if they are provided with clinical data
- Counterfeit items could be discovered
- Items could be validated before they are returned to operation after servicing
- Surgical staff could know that all devices are present prior to starting an operation
- It would assist with disaster preparedness to know where devices are located
- It would provide economies in the supply chain by assuring data accuracy
- Speed of getting a device through the distribution system would be increased. This would help get the payment to the vendor quicker. Cash flow would be improved.
- Reprocessed instruments that have had defects introduced into them from the reprocessing process could be tracked
- UID would make it possible to track user education with particular devices, and pass on new instructions to users as technology changes

3. Problems and obstacles

- How can compliance be assured?
- Where will the data reside, assuming that the device bar code to a database housed somewhere? We should look at other industries to see where their data resides, e.g., Wal-Mart requires that their vendors all comply with their system

- The pharmaceutical situation may provide a model to answer some questions. For example, FDA maintains the pharmaceutical data, and manufacturers subscribe to gain access to the database. When a new drug is introduced, FDA assigns a number indicating manufacturer, drug, and size of packaging.
- An alternative strategy might be that a standard for the data be specified and that private industry is allowed to come up with the data repositories. In order for this alternative to work, there would need to be systems to deal with data when a manufacturer is sold or goes out of business.
- Besides an official nomenclature, the actual end user may have their own "practical nomenclature." End users would need to be trained to know what the official nomenclature is. This is a transitional problem. There may need to be short hand names or nicknames in the system.
- What do we do with combination products?
- Which information will be human readable vs. machine readable?
- Should ID's be on the device or the packaging or both? DOD recommends that it be on the device for the life of the device.
- Maintaining a nomenclature is very labor intensive. Consistency is very important.
- There needs to be harmonization of already existing nomenclatures into existing systems
- The FDA nomenclature needs to be harmonized with other countries. It would need to be recognized worldwide
- Lack of resources and infrastructure for certain health care centers such as nursing homes and home care
- We need a consistent way to identify hospitals and distributors. Each manufacturer gives hospitals their own number
- We need to determine what constitutes a new device when a change is made in the materials or the software is updated
- What happens when you repackage things in a hospital – taking multiple items and putting into a package or a kit? What about custom devices and configurable devices?
- Distributors can assign numbers different from the manufacturers
- Costs of the IT infrastructure to implement this and deciding what it should be
- How can compliance and QA among manufacturers be assured?
- What is the definition of unique? Do we mean by lot or by individual unit?
- Contract manufacturers and suppliers are also issues that have to be tackled.

4. What data do we need vs. what do we want

Should we specify a minimum data set for all devices and additional data sets for other identified needs?

- How do the parent-child relationships work?
- Who keeps these attributes?
- What data the device can take in and what is its output (commands that it can accept, how it can report data, how can it be controlled, etc.)
- Realizing that "the enemy of the good is the perfect," an ideal system should:

  - Be extensible to allow for additional functionality and flexible to accommodate technology development. For example, we might code for a level of specificity now that we don't presently need, but we might in the future.
  - Be open to all (publicly available) and globally available; usable by all users regardless of their current level of technology
  - Be error resistant, with a means to correct the errors in an efficient way
  - Be able to grow
  - Be able to be used by legacy systems or less sophisticated systems
  - Promote low technology solutions
  - Have an infrastructure to update and maintain the system
  - Promote patient safety
  - Note that the Coalition for Health Care EStandards (CHeS) is doing a lot of work in this area.
- There was a discussion of "smart" numbers (that provide information themselves) and 'dumb numbers' (that provide no intrinsic information but merely point to a database). There is some concern that the more information that is packed into a number, the more problems this might invite, and that it may be a better strategy to use the ID number primarily as a mechanism to point to a database. However, it might be advantageous in some situations for some basic information to be provided in the UDI in human readable form, with additional numerical information that points to a database where more information would be available.
- There are three main levels of important information that an identification number might convey: manufacturer (who made it); the item (what it is); and a third level that defines uniqueness (this could be the serial number).
- The degree of identification is up to much discussion. For some device categories, there may be no need to do serialization of every single device. For durable equipment, serialization is more important then for disposable equipment (devices that turn over rapidly). For disposable equipment, it may be sufficient to identify them just down to the lot number; it may be unduly burdensome to identify them down to the individual item. Some participants mentioned that there is a higher cost involved in individual identification, since it slows down production.
- There was a discussion of identifying devices by unit of issue vs. unit of use, since DoD will be requiring serialized identification down to the unit of issue.
- What information do healthcare providers need in a UDI system:
  - UPN
  - Manufacturer
  - Make
  - Model
  - Serial number
  - Distributor
  - Contract Manufacturer
  - Original Equipment Manufacturer VS the Distributor
  - Labeler (use the GS1 or UPN definition)
  - Places of Manufacturer

- GMDN term
- UMDS
- UNSPSC
- Date of Manufacturer
- Expiration Date
- Life Expectancy (we should determine what Japan is doing)
- Component, Kit, Parent/Child Relationship
- Number of uses allowed (reprocessing etc)
- Method of reprocessing
- FDA Approval or marketing basis
- Company generic model name
- Version, especially software
- Models within version
- Clinical attributes? (silicone, latex etc?)
- Date of last update and by whom
- Device may contain patient identifiable information (Y/N)
- It is probably best not to include clinical attributes such as allergens, or there may be no end to the information that some might wish

- Manufacturers may want the control to be able to update the databases for their own products
  - There needs to be an adaptable data set, so that if something important shows up, the manufacturer should be able to add to database
  - The system should allow adding new categories of information, indicating date and author of last update
  - Concern was expressed that all this desired information would make the system "quasi-encyclopedic." It was noted that much of the information suggested for the system is not information that FDA is requesting; but it is information that should be available if FDA requests it, since FDA itself has no central repository for all this information on all medical devices.
  - It should be noted that certain products migrate from user to user (e.g., hospital beds), making it nearly impossible for manufacturers to locate original purchasers in case of recalls
  - FDA's DailyMed provides publicly available drug information. Is there a possible analogy to the way that device information ought to be handled?
  - It is essential that the unique identification system get built . We don't want the data system requirements to prevent this from happening.
- There appeared to be general agreement that the most important items to be identified were: manufacturer, catalog number/make/model, and an ID at unit of issue or unit of use (plus possible serialization for some devices)

5. Technology issues in the health care environment

- Potential problem of RFID interference with other electronic equipment
- Where you place the UI on certain products. How would sterilization affect this?
- Human vs. machine readable (is having to use a magnifying glass all right?)
- The solution strategy has to be technology independent
- Ability to work with the current medical records which are not electronic

- Barriers to people working late at night or in emergency situations
- Possible language and education barriers
- "Something is better than nothing?

D. Next Steps

FDA continues to evaluate all options on how a system of unique device identification could be implemented. FDA plans to develop a concept paper that could be used to issue guidance for device identification based on "groupings" of devices or form the initial basis for any potential future regulatory approaches. In addition, FDA has commissioned a study of this issue which, when complete, will describe the current state of unique device identification. FDA is considering a second study which will address the costs and benefits of unique device identification. FDA plans to examine the results of these meetings while these studies are ongoing. Although individual CDRH representatives understood and were sympathetic to the discussions presented at this meeting justifying a regulation for device identification, they could not make a commitment that the Agency would find sufficient justification for a regulation. CDRH staff did say that they would suggest the possibility of publishing an Advance Notice of Proposed Rulemaking as a means of ascertaining the sense of the broad community of interested parties about a regulatory approach to this issue.

In a subsequent communication presented by nine organizations represented at the meeting, the following points were presented:

> "We appreciate the willingness of the FDA to hear the viewpoint of providers and look forward to continuing to work with the agency on this issue.
>
> We agree that the draft summary of the meeting is generally accurate, but want to stress the strong consensus within the provider community on this issue that was evident at the meeting. Our organizations support mandatory unique identification (UID) of medical devices as the transmission and translation of critical data has vast potential for improving patient safety and supply chain efficiency.
>
> A compelling patient safety interest lies in requiring identification technology (such as bar codes or RFID tags) for certain medical devices including implantable items like hip/knee prosthetics, stents and CRM pacers. Unique identification technology would facilitate and improve upon the tracking of these devices, especially in the event of a recall or other safety concern. Clearly, UID technology can improve risk management through reductions in supply chain and medical errors. Inventory and warehousing accuracy as well as product movement efficiency may be improved, thereby reducing operating costs.
>
> Hospitals are moving forward on the adoption of technology and with the current lack of a national standard have had to invest millions of dollars to create internal tracking systems for devices. It is clear this investment improves quality and

supply chain efficiency for the hospital, but a national unique identifier system would accelerate these efforts that ultimately benefit patients.

In closing, we strongly encourage the FDA to move toward a mandatory approach for the unique identification of medical devices through the Advance Notice of Proposed Rulemaking regulatory process."

IV. List of Attachments

A. Invitation Letter

B. List of Participants at October 27, 2005 Meeting

ATTACHMENT A: Invitation Letter

Dear Name:

I would like to invite you to participate or a member of your organization to participate in an important meeting regarding the potential development of a voluntary system for the unique 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 hospital and health care 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, October 27 – 28, 2005 in Washington, DC,** as a forum to discuss the benefits and challenges of a unique identification system for medical devices. A small number of representatives from hospital organizations and other relevant interested parties are being invited to participate in this meeting. 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.

A recent publication by the Institute of Medicine (Safe Medical Devices for Children), IOM recommended that:

> **As part of government and private health informatics initiatives, such as those supporting the electronic medical records, FDA should promote the development and adoption of common device coding and other standards and approaches for capturing and linking use and outcomes data 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

At a previous meeting on this topic held in April 2005, it was clear from participants at that meeting that successful implementation of a system for unique device identification requires significant input from the hospital community. A report of that meeting is available at http://www.fda.gov/cdrh/ocd/uidevices061405.html. This current meeting is being convened to provide an opportunity for CDRH to hear ideas and reactions from knowledgeable representatives of hospital based and other health care delivery organizations about employing such a system. CDRH is interested in hearing about:

- the kinds of information that could be readily captured in such a system
- hospital experience with use of identification technologies such as bar codes and radio frequency identification [RFID] and the challenges with implementing such a system
- any proposed requirements to link automated identification systems to a healthcare facility's accreditation
- documented evidence of connections between use of unique identification systems and improvements in patient safety, recall processes, cost control and third party reimbursement
- hospital plans for using automatic identification technology in conjunction with electronic patient medical records

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 or other method of identification of medical devices, and your expectations of benefits and disadvantages these strategies might have for the hospital 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, October 27-28, 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.fdli.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 Participants at October 27, 2005 Meeting

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