FDA Public Meeting on Unique Device Identification

October 25, 2006

Gaithersburg Marriot Washingtonian Center
Gaithersburg, Maryland

Meeting Summary

Submitted to
U.S. Food and Drug Administration
Center for Devices and Radiological Health

October 31, 2006

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FDA held a public meeting on October 25, 2006 to discuss the issues associated with the development, identification, and use of a unique device identification (UDI) system and the use of various automatic identification technologies. The meeting, which included vendor displays, was held in Gaithersburg, Maryland.

Welcome, Introduction, and Format for the Meeting

Dr. Larry Kessler, Director, Office of Science and Engineering Laboratories (OSEL), Center for Devices and Radiological Health (CDRH), opened the meeting. He welcomed attendees and introduced Dr. Janet Woodcock, FDA Deputy Commissioner for Operations.

Dr. Woodcock underscored the importance of the meeting for public health. She stated that developing and implementing a UDI system could help stem the tide of medical errors. Dr. Woodcock assured attendees that FDA recognizes the complexity and diversity of the medical device industry. She advised them that FDA is seeking, early in the process, input from partners on a range of solutions for a quality system that is uniform, low cost, and global.

Dr. Kessler then presented the meeting format; four panels, each followed by audience questions, comments, and open discussion. He explained that the goal of the first panel would be to explore the benefits and costs of a regulatory solution and that the remaining three panels would be devoted to mechanistic efforts required to develop a system.

The Benefits and Costs of a UDI System

The presenter for the first panel was John Eyraud, Eastern Research Group, Inc. Panel members included Jon White, Agency for Healthcare Research and Quality (AHRQ); Dr. Marcel Salive, Centers for Medicare and Medicaid (CMS); Michelle Allender, Bon Secours Health System; Joe Pleasant, Premier, Inc.; and Paul Pandisco, Johnson and Johnson.

Mr. Eyraud identified public health and patient safety benefits of a UDI system: better identification of devices in adverse events; more rapid, accurate recalls; and enhanced capability for post-market surveillance. Based on conversations with hospitals, he presented preliminary estimates of UDI system costs and savings. Mr. Eyraud also noted possible UDI related challenges for manufacturers including IT system development and lengthy implementation times.

Jon White, AHRQ, questioned whether it is the absence of data that limits care. He welcomed discussion on UDI associated costs and tradeoffs.

Dr. Marcel Salive, CMS, discussed the challenge the Centers face in measuring effectiveness among devices to ensure patient safety and to get the best value for health care dollars spent.

Michelle Allender, Bon Secours Health System, noted that a UDI system would benefit health care providers in the field who often must track recalled devices manually.

Joe Pleasant, Premier, Inc., echoed UDI system benefits included in Mr. Eyraud's presentation. He stressed the critical need to establish UDI standards in a synchronized way to achieve an efficient, cost effective system.
Paul Pandisco, Johnson and Johnson, presented the "manufacturers' case" for UDI system development: proceed in a considered, systemic way; consolidate efforts and include federal partners; develop from provider to point of use; make global in nature; design for adoption and understand incentives for adoption.

Dr. Kessler opened audience discussion by noting time FDA has spent with federal partners to move the UDI initiative forward. Subsequent discussion focused on federal activity to further realization of the electronic medical record (EMR) and how perhaps UDI system development can plug into that process. Participants commented, and panelists concurred, on the need to work in synchronistic fashion to avoid developing a system that conflicts with existing systems. International partners in the audience highlighted the importance of consolidating standards given global distribution and use of devices.

Design and Implementation of a UDI System
Chuck Franz, Cook Group, Inc., served as presenter for the second panel. Panel members included Michael Dempsey, Partners Health Care; Lu Figarella, HIBCC; Leighton Hansel, Abbot Laboratories; and John Terwilliger, UCC.

Mr. Franz' overview of a UDI system implemented by the Cook Group included the company's choice of barcode over RFID (radio frequency identification) due to lower cost and wider global acceptance. In his presentation, he covered required costs, barcode elements, and implementation timeline.

Michael Dempsey, Partners Health Care, described his company's "positive identification standard" first implemented for drugs in an effort to reduce medication errors. He categorized the system, now expanded to employees, patients, and devices, as a "pretty vital and powerful tool."
Lu Figarella, HIBCC, stressed that identifying the level of uniqueness for devices is very important; unless like items can be distinguished from one another, users will reap some, but not all, benefits from the system.
Leighton Hansel, Abbott Laboratories, stated that the need to produce an enduring, global solution; the need to involve everyone, including non traditional partners along the supply chain; consideration of existing standards; and incentives required to drive adoption should all be part of discussion of UDI system development.
John Terwilliger, UCC, echoed Mr. Hansel's comment about the need to recognize existing standards. He pointed out that RFID gets at the serialization issue and could save effort. He also noted that identifying all devices would be the ideal but an exception rule could be proposed in some areas.

The audience discussed the challenge of developing standard data requirements in a world of many already existing systems. A participant noted that thought must also be given to presentation of data so that it is universally readable. Other issues discussed

included the need to put UDI on the unit of use to avoid burdening hospitals with an added process and the necessity of including home use devices in the system.

The Development, Maintenance, and Use of a Repository
Kathleen Garvin, DOD, was presenter for the third panel. Panel members included Jonathan Sherman, DOD; Dr. Randy Levin, FDA; Steven Stemkowski, Premier, Inc.; and Jon White, AHRQ.

Ms. Garvin provided an overview of the vision and components of DOD product data utility (PDU) system. She provided an example of a minimum data set for a PDU and the benefits of "right" data to patient safety. She stated that FDA can drive a mandatory, comprehensive UDI system.

Steven Stemkowski, Premier, Inc., stressed the importance of the minimum data set without which it is not possible to assess adverse outcomes and make comparisons. He recommended adding serial number, expiration date, lot number, and way of classifying devices to the minimum data set described by the Kathleen Garvin.
Jonathan Sherman, DOD, outlined the DOD equipment identification system. He noted that a UDI system would speed up the recall process within the DOD by eliminating manual searches for devices.
Jon White, AHRQ, noted that he saw a commitment to a collaborative process that works for all stakeholders, stakeholders who have diverse needs. To underscore the key importance of process to UDI system development, he gave three related examples of successful federal collaborative processes.
Dr. Randy Levin, FDA, emphasized that a UDI system requires well defined rules, a central authority to make people follow rules, and a standard process to implement.

The audience discussed the challenge posed when software linked to devices is upgraded but the device remains unchanged. Participants mulled whether to put required data on devices or to simply use a "smart number" that directs users to additional information available elsewhere. The challenge posed by countries with varying environmental regulations on device use and disposal was also discussed.

The Use of Automatic Identification Technologies
Jim Keller, ECRI, served as presenter for the fourth panel. Panel members included Dr. Julian Goldman, Partners Healthcare; Ilisa Bernstein, FDA; Ann Ferriter, FDA; John Terwilliger, UCC; and Lu Figarella, HIBCC.

Mr. Keller presented a summary of an ECRI white paper on automatic identification of medical devices based on a review of identification technologies and analysis of available literature. He compared the use and potential benefits of the bar code and RFID system technology. ECRI has concluded that automatic identification of medical devices has tremendous potential though diversity on a variety of levels will make universal implementation difficult and costly.

Dr. Julian Goldman, Partners Healthcare, asked the audience to consider UDI one piece of a larger system that would probably cover most devices, including those used in the home. He concluded that for patient safety and efficiency, it is time to act to develop a UDI system and that FDA can provide leadership.
Ilisa Bernstein, FDA, provided detail on the FDA bar code rule for prescription and over the counter drugs used in hospitals and movement on electronic pedigree for prescription drugs.
John Terwilliger, UCC, stressed that in developing a UDI system creativity is not the issue, mass adoption is. He encouraged use of existing standards with allowance for adoption of new ones as technology evolves.
Lu Figarella, HIBCC, agreed that data should be separate from the data carrier. He urged that system solutions include choices for application.

Audience discussion centered on the extent of the counterfeit drug problem and on efforts to develop a drug pedigree. Asked to make the case for a medical device pedigree, FDA pointed to better use-error reporting and enforcement, to equipment calibration and maintenance, and to more accurate assessment of the scope of device associated infections.

Other Presentations from the Public
Following the panel presentations, time was allotted for presentations from the public. Representatives from nine organizations addressed the audience: Novation, Partners Healthcare, National Electronic Manufacturers Association (NEMA), NFD, a DOD contractor, Siemens, Villanova University School of Business, and Fast Track Technologies.

Speakers generally supported development of a UDI system, citing both heightened patient safety and supply chain efficiency, and the coming advent of the EMR. They envisaged a system that was practical, flexible, commercially robust, not burdensome, and global. Their concerns included possible conflict with existing systems, costs, compromised patient privacy, older devices that might need to be grandfathered-in, and problem posed by software linked to devices.

Next Steps and Wrap Up
At the close of the meeting, Dr. Kessler thanked presenters and FDA partners for their participation and urged everyone to submit comments on a UDI system by the November 9th deadline. He reassured the audience that FDA does indeed recognize the diversity of the device industry and products and the importance of linking UDI system to safety performance. He challenged all to think of a system for the future.

Dr. Daniel Shultz, CDRH Director, offered final remarks. He too thanked participants and noted, “There is only one way to get collaboration and that is to show up. The first step is gathering together and putting the issue on the table.” He stressed that a UDI system is a major part of CDRH’s postmarket strategy and that FDA is committed to vigorously pursuing realization of the system, now and in the future, with input from government, industry, and global partners.