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November 9, 2006

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: Docket No. 2006N-0292, Unique Device Identification; Request for Comments**

AdvaMed provides this submission in response to the Food and Drug Administration's request for comments on Unique Device Identification.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,300 members and subsidiaries manufacture nearly 90 percent of the \$80 billion of health care technology products purchased annually in the United States, and more than 50 percent of the \$175 billion purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. More than 70 percent of our members have less than \$30 million in domestic sales annually. As manufacturers of medical devices our members will be significantly impacted by any new rules or policies regarding the development, coding, application, and use of unique device identifiers.

**INTRODUCTION**

AdvaMed recognizes that a carefully designed and implemented Unique Device Identification (UDI) system can add value to the medical device supply chain and recommends that a voluntary UDI system be based on existing open standards, such as those from GS1 and the Healthcare Industry Communication Council (HIBCC), and be harmonized with global standards. The UDI should not be limited to one stage of technology, e.g. linear bar coding. Compatibility with the National Drug Code (NDC) bar code is not necessary or practical especially because the NDC bar code is still undergoing revision. Electronic Health Record systems should be designed to accept UDI data to link the patient with the medical devices used during their care.

Existing labeling and reporting regulations for medical devices provide the necessary level of control to ensure patient safety. Significant patient safety issues due to a lack of a mandatory UDI system are not apparent. While there are theoretical benefits related to improved traceability resulting from reduced recordkeeping errors, we have not seen significant use errors or patient safety concerns associated with medical device identification as has been the case with pharmaceuticals. AdvaMed recommends that studies be conducted to accurately assess whether or not medical device misidentification contributes to clinical error and to what extent a mandated UDI system would enhance patient safety. Caution must be exercised when comparing the anticipated success of bar coding pharmaceuticals to a proposed system for medical device UDI.

Due to the diverse size, materials, and configuration of medical devices we believe that a UDI affixed to all unpackaged devices is neither currently economically practical nor technologically feasible.

Bringing innovation to patient care worldwide

Implementation of an automated UDI system may provide some benefits in the areas of more efficient purchasing, improved inventory control, and enhanced medical device asset utilization, provided healthcare providers invest in the technology. The concept of unique device identification, however, is not found in FDA law; the small incremental benefit of requiring UDI for devices must be weighed against the technological feasibility and cost of doing so and the fact that significant patient safety issues have not arisen in this area vis-à-vis medical devices.

AdvaMed endorses the voluntary use of a UDI with minimum data set (**data content**) comprised of (1) manufacturer identifier and (2) product number applied to product packaging. The **data structure standard** should conform to existing standards for bar codes image as established by the American National Standards Institute (ANSI), International Standards Organization (ISO), and GS1. Further we endorse the assignment of data codes established by both GS1 and HIBCC. The **data carrier** (bar code symbology) should not be restricted to a single level of technology. An unrestricted data carrier will allow for the greatest flexibility in applying the UDI to various sizes, shapes, and materials; and to accommodate the most appropriate technology for functionality in special environments.

## RESPONSES TO QUESTIONS

### 1. How should a unique device identification system be developed? What attributes or elements of a device should be used to create the UDI?

AdvaMed recommends that a process for developing a UDI system be accomplished through an industry consortium including FDA, medical device suppliers, health care providers, Automatic Identification and Data Capture (AIDC) industry representatives, and international trade organizations such as AdvaMed, Eucomed, ACCJ and MIAA. The consortium would establish or endorse standards for minimum data set, data structure, data carrier, UDI placement, and data registration. Furthermore, the consortium would establish clear objectives for the UDI program and methods to measuring whether the UDI program has met the established objectives.

In *Unique Device Identification; Request for Comments* (Federal Register Vol.71, No.155, August 11, 2006) FDA provides an example of a UDI for latex gloves. Five data elements are suggested:

- [1 - manufacturer] Acme (manufacturer number 12345)
- [2 - make and model] Great Latex Examination Gloves (product number 6789)
- [3 - size] Adult large (size number 012)
- [4 - how packaged] Box of 50 (quantity number 50)
- [5 - lot number] Lot

A unique device identification numbering schema should contain elements that identify [1] the company whose identity appears on the product's primary label and [2] an item number that identifies the product. This UDI can be linked to a database associating other pertinent data. This pertinent data may vary according to product characteristics and customer needs. The data requirements for an in-vitro diagnostic device will be different from those of an implant.

Other required data elements that define usage and track/trace attributes such as expiration date, date of manufacture, lot, batch, and/or serial number may be associated with the UDI but not necessarily part of the actual UDI number.

The Agency suggests that the UDI include a data element for unique attributes such as size or software version. In the latex glove example, this data element is identified as [3 - size] Adult large (size number 012).

If the UDI (combination of manufacturer & item number) were unique, persistent, and governed by a set of well-defined allocation rules, this attribute [3 - size] would prove to be redundant. Medical device manufacturers use different part numbers to distinguish different sizes.

Dimensions must be qualified by an expression of their measurement system. Critical dimensions for medical devices are expressed not only in English and metric but also measurement systems such as gauge size, French size, or the 0-0 system for sutures (United States Pharmacopoeia).

Often there is more than one critical dimension for a medical device. For instance, the selection of a catheter is based on a clinician's judgment that a catheter's diameter and length would be optimal for insertion in the appropriate vessel. Including dimensions in the UDI would require complicated usage rules to govern the "order" of dimensions. For example, does English always precede metric? Does diameter precede length?

Given the complications of medical device sizing, attribute [3] should not be included in the UDI schema.

The alternative schema that many AdvaMed members suggest is a UDI that includes the combination of manufacturer & item number as is employed in the GS1 or HIBC schema. These schema are currently in use to identify a multitude of medical devices.

As mentioned in the *ERG Final Report Unique Identification for Medical Devices*, the U.S. Department of Defense has also developed an identification system called IUID, Item Unique Identification. The IUID policy allows manufacturers to use the GS1 or HIBC systems as an approved form of UID. AdvaMed members recommend that FDA follows the U.S. Department of Defense example, and allow medical device manufacturers to use either the GS1 or HIBC systems to meet the identification and information needs of UDI.

## **2. What should be the role, if any, of FDA in the development and implementation of a system for the use of UDIs for medical devices? Should a system be voluntary or mandatory?**

Many medical device manufacturers have voluntarily implemented forms of unique device identification. Unique device identification identifiers should remain voluntary.

When bar coding was mandated for hospital unit dose drug packaging, a specific critical patient safety need was cited, namely, "to help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify the right drug (in the right dose and the right route of administration) is being given to the right patient at the right time." (68 FR 12500, March 14, 2003). A specific safety issue has not been cited for mandating a unique identification system for medical devices.

While the ERG Final Report, *Unique Identification for Medical Devices*, asserts that bar coding can be used as a tool to reduce medical errors, the report does not provide examples of specific medical device errors and how bar coding would resolve such errors.

The ERG Final Report cites potential benefits of a UDI system including the facilitation of recalls and the identification of compatibility issues. However, the premise for these potential benefits relies on a number of additional activities occurring. The Report states, "UDI may also improve reporting and understanding of use errors (emphasis added)." The Report also states, "UDI will help facilitate recalls *if* sufficient data can be entered and tracked through the hospital inventory (emphasis added)." Additionally, the Report states, "*If* detailed medical device information is maintained in electronic records, UDI holds the *potential to facilitate* the identification of device compatibility problems (emphasis added)."

Most of the benefits cited in the ERG Final Report are related to supply chain efficiency; making market forces the more appropriate driver for medical device identification.

To promote the safety of medical devices, FDA stated that they "would champion the development of a system to provide unique device identification." AdvaMed members recognize that industry collaboration with FDA can play an important role in promoting patient safety. AdvaMed welcomes the opportunity to work with FDA and other stakeholders to further patient safety.

AdvaMed members believe that if the UDI system were properly constructed, the medical device industry would voluntarily adopt the system with the goals to tangibly increase patient safety and reduce the stress of the healthcare professional. A poorly constructed UDI system, even if mandated by rule, would not increase patient safety.

AdvaMed members believe that a well-constructed UDI system should be global in scope. The UDI system must be compatible with international standards. A US-centric system would be a burden on global manufacturers by forcing the segmentation of inventories.

### **3. What are the incentives for establishing a uniform, standardized system of unique device identifiers?**

Improvements to supply chain efficiency will serve as an incentive to medical device manufacturers to adopt a uniform, standardized system of unique device identifiers. A globally accepted system may also aid in securing the supply chain through product authentication. Compatibility with global UDI systems and requirements will spur industry adoption.

### **4. What are the barriers for establishing unique device identifiers? What suggestions would you have for overcoming these barriers?**

#### Barrier: Label Space.

Labeling space available for printing critical information is limited. Packaging and labeling would potentially have to be redesigned for many products.

#### Barrier: Cost.

The redesign of labeling and packaging, the purchase of printing equipment, printing and verification of copy and machine-readable code, and other process changes will have a tremendous financial impact on medical device manufacturers. If technically possible, direct part marking on medical devices will also require biocompatibility and product integrity testing.

#### Barrier: The Need for New Printing Equipment

Many device manufacturers out-source product labeling. A mandate to include UDIs with lot number, for example, could have a tremendous impact on this process, as some businesses assign lot numbers at the time of packaging. Medical device manufacturers would need to purchase printing equipment rather than rely on suppliers.

#### Barrier: The Need for AIDC Technology

There has been discussion that if FDA were to specify linear bar codes for devices as they did the hospital unit dose drug packaging, hospitals could use their existing base of linear scanners. However, most medical devices are not used at the bedside but in operating rooms and ancillary departments. There has also been an increased use in hospitals of two-dimensional symbologies such as Data Matrix. To take advantage of these new technologies, hospitals will have to purchase image scanners suitable for use with 2D symbologies. AdvaMed believes that the small, installed base of linear scanners in healthcare will be replaced by image scanners through attrition and as healthcare practitioners seek more reliability in their data collection devices.

To mitigate cost and ensure the appropriate use of technology, AdvaMed members recommend that FDA champion a UDI system that does not specify a specific bar code technology.

#### Barrier: Direct Part Marking – Technology and Environment of Use Issues

Some medical devices are provided in a non-sterile package that contains bar-coding information. However, to prepare this product for surgery, the packaging and product quickly become separated. Most of these non-sterile products are marked with a human readable lot number allowing traceability to be maintained as long as hospital staffs document the information in the patient record. Automatically capturing this information would require that manufacturers provide the product in a sterile condition,

which is expensive; or manufacturers would have to mark the device with the UDI information. This is not practical due to the size limitations of some medical devices as well as the extensive amount of validation that must be conducted.

Devices that are structural supporting (e.g., orthopedic and spinal implants) might be weakened if they are marked in non-compatible ways. Extensive validations would have to take place to ensure that the safety of these devices has not been compromised by the type, location and depth of the marking. Additionally, many of these devices are contained in surgical sets that are sterilized repeatedly through steam sterilization. This repeated sterilization can have a detrimental effect on the quality of the marking and may become unreadable after time. Again, extensive validations would have to be performed to prove out this process.

Barrier: The Need for a Database Infrastructure / Impact on Medical Device Suppliers

FDA's request for comment envisions interfacing the unique device identifier (UDI) with a universal database with capabilities to access a reference data set linked to the UDI. However, unlike drug products and with the exception of OTC devices marketed in retail outlets, such infrastructure does not exist for medical devices and would take considerable time to develop.

The request for comment cites the ability to distinguish sterile and nonsterile implants as a potential use of UDIs. Without the infrastructure to hold this information, the UDI alone would not accomplish this goal.

The request for comment identifies UDIs to identify compatibility issues, such as devices, which can be used safely with magnetic resonance imaging (MRI) systems. Yet without links to patient charts from one facility to the next, such processes could not occur. The lack or adequacy of database infrastructure is a barrier to the establishment of a UDI system. Further, the cost to the device industry to maintain such information, considering the shorter lifecycle of device products versus drugs and the number of medical devices compared to drugs, must be considered.

Barrier: The Need for a Database Infrastructure / Impact on Healthcare Providers

The most significant barrier will likely be the hospitals' required infrastructure and acceptance of the new processes and associated capabilities that would need to be developed. They would require systems and equipment installation, validation and integration to utilize any UDI implemented at the manufacturer level.

**5. Have you implemented some form of UDI in your product line? Please describe the extent of implementation, type of technology used, and the data currently provided.**

Many AdvaMed members identify their packaged product with bar codes. These bar codes comply with either GS1 or HIBC industry standards. These bar codes typically contain a primary product identifier and, if applicable, lot number/serial number and expiration dates. Depending on the substrate and surface area available, bar codes are linear or 2D. AdvaMed members use direct part marking when appropriate and technologically feasible. AdvaMed members do comply with the US DoD Item Unique Identification (IUID) policy.

DEVELOPING A SYSTEM OF UNIQUE DEVICE IDENTIFIERS

**6. Should unique device identifiers be considered for all devices?**

**If yes, why? If not, what devices should be considered for labeling with a UDI and why?**

A basic, globally accepted unique device identifier can be used for all medical devices on a voluntary basis. Whether the unique identifier is printed directly on the part, or each level of packaging as well as the inclusion of other attributes (lot, serial number, or expiration date) should be determined by the risk associated with the use of the medical device. AdvaMed members recognize that identification and tracking and tracing requirements differ. Broad categories with different requirements may include: active implantable devices, implantable devices, sterile devices, and electro-mechanical devices.

Certain AdvaMed members have commented that they have performed a cost/benefit analysis for low risk, class I and class II medical devices and they recommend that all high-volume, low-cost, non-life-sustaining medical devices be excluded from any UDI mandate.

AdvaMed feels strongly that if single use devices (SUDs) are reprocessed by a third party the OEM's UDI must be obliterated and remarked with the reprocessor's UDI.

**7. At what level of packaging (that is, unit of use) should UDIs be considered? Should UDIs be considered for different levels of packaging? If yes, should the level of packaging be based on the type of device?**

The type and size of the device and the environment of use are important considerations. Other factors to consider include when and where clinicians select and authenticate product. The physical size and material composition of the medical device may dictate whether or not the medical device can be directly marked. The size of primary packaging may also limit the amount of additional information or form of machine-readable code that can be printed on the package. Package marking at different levels must be based on risk mitigation, feasibility, practicality, and device use.

**8. What solutions have you developed or could be developed for addressing the technological, equipment, and other problems that might arise in developing and implementing a UDI system (e.g., solutions for packaging issues)?**

AdvaMed members continually research the use of marking medical products and packaging such as digital printing, laser ablation, and RFID. New technologies are emerging and AIDC product life cycles are short. For this reason, AdvaMed members do not believe that the UDI should be limited to one stage of technology. Many AdvaMed members see RFID as an emerging technology that can be implemented for certain products when appropriate. Solutions adopted for one product line, such as implants, are not necessarily feasible for another product line, such as IVDs. The impact of costs associated with various solutions will vary depending on the device product line.

IMPLEMENTING UNIQUE DEVICE IDENTIFIERS

**9. What is the minimum data set that should be associated with a unique device identifier? Would this minimum data set differ for different devices? If so, how? How would the data in the minimum data set improve patient safety? What other data would improve patient safety?**

AdvaMed recommends a minimum set for the UDI of (1) manufacturer identifier and (2) product number.

The UDI system should not attempt to categorize medical devices features across manufacturers. Many medical devices cannot be compared generically as unique features affect the usability and performance of the device. For example, medication infusion pumps designed for certain care environments and specific clinical interventions. An ambulatory pump used for Total Parenteral Nutrition (TPN) in a patient's home is not interchangeable with an ambulatory infusion pump for TPN used in a hospital or skilled nursing facility setting, yet both of these devices may fall under the category of "ambulatory infusion pump". Categorization of medical devices would compromise patient safety, if both pumps had the same category and, therefore, viewed as interchangeable.

AdvaMed is not aware of any documented direct patient safety benefits of UDI. Theoretical and unsubstantiated patient safety benefits should not be used to justify a mandatory UDI system. Furthermore, for many products, technical constraints will prevent marking UDIs on the device itself, which would leave printing the UDI on product packaging as the only viable alternative. When the product packaging is discarded the UDI will be lost and device users will be unable to derive any benefit from the UDI. The UDI should not include reimbursement information. Reimbursement information changes frequently and international reimbursement standards do not exist.

**10. How should the UDI and its associated minimum data set be obtained and maintained? How and by whom should the UDI with its associated minimum data set be made publicly available?**

The UDI system should comprise a small set of equivalent, industry-accepted identification systems. See table as an example.

Issuing Agency	UDI Acceptable Data Formats
GS1	GTIN, SGTIN, EPC
HIBCC	HIBC-LIC

AdvaMed members already make their product instructions for use available electronically through web sites.

AdvaMed members recognize that standards (Adobe® Acrobat \*.pdf) and processes such as version control need to be developed to maintain the timeliness and accuracy of data. AdvaMed would welcome an invitation to participate in the development of these standards and processes.

There are viable data pools and systems dedicated to commercial transaction such as the GS1 GDSN system and the Global Healthcare Exchange (GHX). The focus of a medical device data pool linked to the UDI should be on clinical information.

A healthcare industry consortium that includes manufacturers, distributors, and healthcare providers should be formed to develop system architecture and policies for storing and sharing data. The GS1 Healthcare User Group is an industry consortium that is already in existence and is global in scope.

**11. Should the UDI be both human readable and encoded in an automatic technology? Should the UDI be on the device itself (e.g., laser-etched) for certain devices?**

There are clear benefits in the use of automatic data capture. The nature of the device and the maturity of marking technologies dictate whether any device can and should be directly marked. FDA should recognize that changes to the product itself could be more difficult than changes to packaging. The manufacturer, based on customer demand, should determine whether or not a product could be marked directly. AdvaMed members believe that the development of industry standards for identification can help healthcare providers incorporate UDI into their electronic health record and materials management systems.

The addition of a human-readable version of the UDI in close proximity to the machine-readable code may promote early adoption of UDI among users who do not have ready access to AIDC technology. FDA should recognize, however, that the transcription of a 12- or 14-digit UDI onto an MDR form is fraught with the risk of errors. Furthermore, FDA should recognize that product size and packaging may make human-readable UDI unfeasible.

**12. Should a UDI be based on the use of a specific technology (e.g., linear bar code) or be nonspecific? Please explain your response. If a bar code is recommended, is a specific type of symbology preferred, and if so, what type and why? Should the bar code be "compatible" with those used for the drug bar code rule?**

The UDI should not be limited to a specific technology. Standards for data carriers are already well established (ANSI, ISO, GS1, EPC) and well accommodated in modern AIDC technology. Hospitals are in the process of purchasing new AIDC-based technology for drug, patient, staff, and order identification which will accommodate the above mentioned standards. To limit the technology of device identification would be extremely short-sighted; severely limiting the utility and potential future expansion of a UDI system. FDA should allow the membership of the proposed Issuing Agencies to decide which technologies to allow as part of the UDI system.

UDI BENEFITS AND COSTS

**13. From your perspective, what public health and patient safety benefits could be gained from having a standardized unique device identifier system? How would such a system contribute to**

**meeting device recall and adverse event reporting requirements, and to reducing medical error?  
Please submit detailed data to support benefits you identify.**

The two reports commissioned by FDA fail to document any clearly defined public health or patient safety benefits resulting from a unique device identification system. The ECRI White Paper: Automatic Identification of Medical Devices states, “demonstrating a relationship between automatic identification technology and improving medical device safety through the prevention of adverse events is a challenge” (page 25). Theoretical benefits are described without offering data to support these benefits. For example, the ERG Report: Unique Identification For Medical Devices, states “[m]edical device UDI has the potential to yield several benefits” (emphasis added) (page 2-1). The report continues to list benefits ranging from reducing medical errors to improving inventory control to improving reimbursement to reducing product counterfeiting (page 2-1). Further, many of these theoretical benefits presuppose significant changes in the health care environment, such as adequate IT infrastructure and clinician time to access and utilize detailed medical device information.

Unlike drugs, where errors in drug interaction or misadministration are documented patient safety issues, we are unaware of patient safety problems with medical devices that would be ameliorated by the use of a UDI system.

Traceability controls currently in place allow the medical device industry to effectively trace recalled items via lot numbers and/or serial numbers. Hospitals are able to further trace to the floor or patient level. Although the ERG report stated that certain detailed data are not routinely maintained by hospitals (e.g., lot numbers) the existence of a bar coded lot number will not ensure future hospital utilization of this information.

FDA has stated that incomplete device information in their MDR system is a major impediment to “connecting the dots” in postmarket surveillance. It is difficult to understand why the reporters of adverse events will take the extra steps necessary to read a UDI when they are currently not sufficiently motivated to record an adequate description of device they feel might be defective. For the purposes of comparing patterns of adverse event reports across companies, the minimum data set we have recommended (manufacture identifier and product number) may be very helpful. If the FDA is able to translate the product number into an internationally recognized code, than comparison of adverse events across international boundaries will be possible.

**14. From your perspective, what are the set-up costs measured in time and other resources associated with the development, implementation, and use of a UDI system? Please submit detailed data to support these cost estimates.**

The set-up costs to develop and implement a UDI system will depend on the nature of the information which is encoded in the UDI, where the UDI is printed, and the length of the implementation period. There are three levels of implementation and printing a UDI at a typical healthcare product finishing facility:

Level 1: Static information – This is the basic information about the Product identity and includes manufacturer and product number. This information is reflective of the design process and only changes when a new product model is placed on the market. If the UDI appears only on product packaging, then the cost of including a UDI may be incorporated into normal business practices.

- information change on packaging "artwork"
- implementation time could be 2 to 3 years
- cost is lowest (but could be significant for smaller firms)
- may be rolled in within normal product lifecycle changes for packaging artwork

Level 2: Dynamic information – This information reflects the manufacturing process with information changing with each manufactured lot or batch. Dates of expiration or manufacture are also considered dynamic information. Dynamic information is often only known near or at the time of device finishing less than 48 hours before final release to inventory.

- implementation time is in years (2-5 years), as online systems need to be planned, purchased, installed and validated
- if online systems already exist to print lot/exp in text, adding lot/exp in a barcode implementation is similar to level 1
- cost for online system purchase and validation is in the 100s of thousands of dollars per manufacturing line - this can add up to 10s of millions of dollars per company

Level 3: Serialization – As serial numbers reflect the individual characteristics of a particular device, through association with the device history record (DHR), each unit receives a unique serial number which is often marked on the unit itself. UDI serialization is only recommended currently serialized product.

- implementation time may be similar to level 2, except additional infrastructure and time is needed for possible product redesign to accommodate UDI serial number marking on the device.
- implementation projects (redesign, online systems & infrastructure) may not always occur in parallel, therefore, a 3-7 year implementation period may be necessary
- cost for online systems are similar to level 2, even to upgrade exiting online systems due to installation and verification activities.
- cost for infrastructure depends on existing infrastructure within the corporate systems, plus linking into external systems, therefore, cost could be expected in the tens of millions of dollars per company
- cost for product redesign to accommodate on-part UDI marking is difficult to estimate but could require additional tens of millions of dollars per company

The above is for marking bar code and human readable text. RFID implementation assumes serialization, and therefore, jumps directly to level 3, as well as substantially increased inherent cost and time resources for RFID technology implementation over printed information.

The financial impact to medical devices companies is clearly significant. Implementation of human readable unique device identifiers (UDIs) alone, would require substantial investment, which includes redesigning labeling and packing to accommodate the UDI, bringing outsourced labeling in-house to print information assigned at the time of packaging, purchasing printing equipment for internal printing, and processing changes to print and verify UDIs, resulting in increased work order time. For some product lines, the entire distribution model and cost structure would require change. When technology costs are considered, such as RFID, or any other technology, the financial impact is even greater. One business line estimated 15,000 labeling pieces could require changes to accommodate a UDI.

The ERG Report has summarized that there are several potential technical difficulties, which will require significant capital investments and expenditures depending on the scope of UDI requirements. It has been roughly estimated that, for a single business unit, the capital investment will add at least 5% to the final product costs. Additionally, there could also be significant system challenges and costs with distribution if distributors were required to maintain UDI traceability throughout the supply chain for all medical devices. Although such initial costs would be borne by the manufacturers and distributors, over time these costs would be shifted to the patients, private insurers, and government. This ultimately increases the cost of healthcare with arguably no real significant benefits to patients in return.

**15. If you have already implemented a form of unique identification on your medical device labeling, what investments in equipment, training, and other human and physical resources were necessary to implement the use of UDIs? What factors influenced your decision to implement such a system? What changes in patient safety or economic benefits and costs have you observed since the institution of UDIs?**

In order to implement the use of UDIs for one class of products, it was necessary to redesign all labeling to allow for the necessary space for printing the bar code. Special printers were purchased for printing bar codes with the correct resolution and ability to print on label stock. Employees were required to train on the set-up, usage, and maintenance of the printers. Additional inspections during manufacturing were established to verify the content, readability, and correct placement of the bar code. Implementation of the

UDI was a marketing decision. The UDI was implemented to aid customers in the maintenance of their inventories, and has not been linked to patient safety issues. Global harmonization or recognition of a UDI format continues to remain a challenge to businesses that have implemented voluntary unique device identification systems.

**16. From your perspective, what is the expected rate of technology acceptance in implementing or using a UDI system?**

The rate of acceptance of any new technology is directly related to the evaluation of the cost of the technology weighed against the expected benefits of the technology. Currently the primary benefit of UDI to the device industry is supply chain logistics, either internal or in some cases customer requested. International regulatory compliance is becoming more of a factor and as a result companies are becoming more involved in pushing for adoption of international standards. It is expected that it will be at least five to seven years before most hospitals are technologically prepared to utilize the UDI systems and data to improve their supply chain logistics so that the benefit exceeds the costs. The ERG report concluded that "recalls are not so constant that [hospital] personnel are dedicated to tracking down errant materials." Thus, the benefits to recall tracking are not expected to be a significant factor in driving UDI adoption in hospitals.

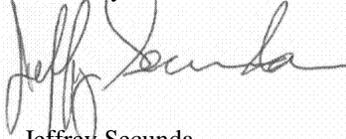
**19. What infrastructure or technological advancements are needed for hospitals and other device user facilities to be able to capture and use UDI for basic inventory control and recall completion purposes? How costly are these advancements?**

It is important to recognize that the purchasing of equipment and software is not the only cost involved with hospital adoption of UDI. The demands on clinician time are enormous; already there are widespread complaints that clinicians have less and less time for patients due to the increasing demands of paperwork and other non-clinical tasks. Patient safety benefits are the only valid justification for acquiring the clinical infrastructure necessary for hospital adoption of UDI systems.

**CONCLUSION**

AdvaMed endorses the establishment of globally compatible standards for UDI data structure based on existing open standards. Data content and the application of UDI must be based on patient risk mitigation. At a minimum, the UDI should represent the manufacturer's identifier code and product number. The application of UDI should be mandatory *only* for specific device types where a significant, well documented patient safety problem has been identified; the application of UDI has been demonstrated to be the most practical solution to the identified safety problem; and the users of medical devices have a clear incentive to utilize the UDI solution. AdvaMed encourages the FDA to seek commitments from healthcare providers to invest in the technology and training necessary for the realization of any benefit from UDI. Finally, FDA should convene a stakeholders group to establish the parameters for a unique device identification system. AdvaMed is looking forward to working with FDA and others on this complex and important undertaking.

Sincerely,



Jeffrey Secunda  
Associate Vice President  
Technology and Regulatory Affairs