



February 27, 2009

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-500)
1350 Piccard Dr.
Rockville, MD 20852

Re: Unique Device Identification System; Request for Comments
[Docket No. FDA-2008-N-0661]

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To Whom It May Concern:

On behalf of the Premier healthcare alliance serving more than 2,100 not-for-profit hospitals and health systems and 54,000 other healthcare sites, we appreciate the opportunity to comment on the Food and Drug Administration's (FDA's) Request for Comments on a unique device identification (UDI) system.

Since 2006, the agency has held several public stakeholder meetings to solicit candid input on how a national UDI system for medical devices should be crafted. The current Request for Comments is the second such request issued by the agency. The Premier alliance applauds the work of the FDA and its commitment to operating in a collaborative and transparent manner. However, we believe this proposed rule is critical to advancing patient safety and long overdue. Now is the time to make decisions on how to implement a UDI system, as required by the FDA Amendments Act of 2007.

Unique device identification is the missing link to protect the safety of patients by improving processes for device recalls and corrections. The rapidly rising number of device recalls, accelerated by the increasing complexity and variety of medical devices, points to the need for UDI for effective management of recalls. More than 700 medical device recalls were issued in 2008, including more than 100 Class 1 recalls (defined as dangerous or defective products that predictably could cause serious health problems or death). Manufacturers also issue many "device corrections" that can have serious consequences for patients if not handled correctly.

Because of the absence of UDI, hospitals often must use manual and imprecise systems to identify if they have any recalled products. According to a recent survey conducted by the Premier Safety Institute, the majority of the 1,000 hospitals responding to the survey reported that they conduct manual searches of records or logs to identify patients who received a recalled device or product. (See attachment 1 for additional information.)

UDI will strengthen the ability of the FDA and manufacturers to monitor adverse events related to medical devices. A national UDI system would create a common vocabulary for reporting and enhance tracking abilities. Currently, analysis of adverse event reports is limited by the fact that the specific devices involved in an incident are often not known with the required degree of specificity. Without a common vocabulary for medical devices, meaningful analysis based on data from existing voluntary systems is extremely problematic. Reliable and consistent identification of medical devices would enable safety surveillance so that the FDA and manufacturers could better identify potential problems or device defects, similar to what is done today by the FDA for drugs.

UDI also is essential to maximizing the value of electronic health records (EHRs). EHRs will require that data standards, including those for medical devices, are in place and used by all institutions to transfer information. A common vocabulary for medical devices, using UDI, is a basic requirement that must be in place in order for healthcare providers to be able to effectively document devices in patient records. The recently enacted American Recovery & Reinvestment Act contains \$19 billion to encourage health information technology (HIT) adoption through direct grants to providers as well as Medicare and Medicaid payment incentives. In order for these systems to be fully effective, and for the federal government to maximize its investment in HIT, the FDA must implement a UDI system as soon as possible.

Our specific responses to the FDA's questions are as follows.

1. Which types of devices or particular devices should be subject to the requirements of a UDI system? Which types of devices or particular devices should be exempted?

a. Should all devices be subject to the requirements of a UDI system? Please explain your reasoning.

b. Are there types of devices or particular devices that should receive an exception from the requirements of a UDI system? If so, what types of devices or particular devices should receive an exception and why?

The Premier alliance fully endorses and supports the concept of a global UDI for all medical devices, based on the risk proportional application rules developed by industry and regulators. Premier believes the UDI should be considered for all devices to improve recall processes, adverse event reporting and patient safety. Further, a UDI for all devices would allow the healthcare supply chain to adopt consistent processes for handling and managing medical products and their corresponding information. The information included for the products should vary based upon the class of device. For example, the information needed for an adhesive bandage would be different than that for an implant device. Therefore, it is recommended that FDA require basic information for all devices, as well as a more extensive data repository for devices that are

classified as directly used on, in or with patients, and those with foreseeable interactions concerns.

2. What are the characteristics or aspects necessary to uniquely identify a device?

a. What characteristics are needed to uniquely identify a device?

The attributes or elements needed to create a UDI will vary based upon the classification of the device. Therefore it is important that the UDI system include a classification system that places the device into a class that will in turn determine the appropriate attributes. For example, the attributes for an adhesive bandage will be different than those for an implant. The UDI, at a minimum, should include manufacturer, product name, make, model, lot number, unique identifier expiration date and unit of measure. The use of a Product Data Utility (PDU) will allow users to extract additional information on the product that might not be included on the label that is attached to the product. This would result in a richer database and the ability to add additional data elements as needed and agreed upon by the industry. The PDU has been successfully used in other industries and allows all supply chain participants to synchronize their master product files, resulting in a more effective and efficient process for product identification, distribution and recalls.

b. What core attributes, elements, or characteristics of a device should constitute a minimum data set for a device identifier?

The Premier alliance supports the work done over the past several months by the GS1 Healthcare workgroup on Data Synchronization and Classification. This is a Global workgroup that has members from all healthcare sectors. This group has endorsed the use of the Global Data Synchronization Network (GDSN) as the database for storing and synchronizing product information, and has added attributes to those from other industries needed to properly identify medical devices. One key principle of the GS1 system is that the data carrier is simply a pointer to a record in a database. The amount of data to be carried should be the minimum needed to lookup and access that data. Therefore, the data carrier should carry only the 'necessary' information, while the 'supplementary' information can be referenced in the GDSN.

There are 25 mandatory attributes required to operate in the GDSN. The first eight attributes are required to register products in the GS1 Global Registry and the other 17 attributes are required to exchange data across the network (within one data pool or across two or more data pools). Of these 17 attributes, 10 require **Yes/No** responses related to the product and the other seven attributes require actual product related data. These are shown below.

| | Mandatory attributes | Description |
|----|--|--|
| 1 | GLN of source Data Pool | The data pool that serves as the entry point into the GDSN and connection to other certified data pools. (contentOwner) |
| 2 | GLN of data source | Entity that provides the global data synchronization network with Master Data. (dataSource) |
| 3 | GTIN | The Global Trade Item Number of the product (drugs, medical device, non medical supply (e.g. light bulbs). (GTIN) |
| 4 | Target Market Country Code | The country where the product is intended to be sold. (targetMarketCountryCode) |
| 5 | Target Market Subdivision Code(optional) | The code for country sub-division definition used to indicate the geo-political subdivision of the target market. |
| 6 | GPC | The Global Product Classification is the GS1 classification system used in the Global Registry. The GPC identifies a category for the product (GTIN) registered. (classificationCategoryCode) |
| 7 | State | The status of the product registered. The four states are: Registered , Cancelled, In Progress, and Discontinued. (state) |
| 8 | Date | May have a combination of the following dates: cancel, deletion, discontinued, last changed, or registration date. Applied by the Global Registry. |
| 9 | Information Provider of Trade Item | GLN and additional identification of the party providing the information of the trade item. This is the data source (informationProviderOfTradeItem) |
| 10 | Hierarchy level per GS1 code list | Describes the hierarchical level of the trade item. TradeItemUnitIndicator is mandatory. Examples: "CASE" , "PALLET". For listing refer to Appendix A. (tradeItemUnitDescriptor) |
| 11 | Brand name | The recognizable name used by a brand owner to uniquely identify a line of trade item or services. (brandName) |
| 12 | Functional Name | Describes use of the product or service by the consumer. Should help clarify the product classification associated with the GTIN. (functionaName) |
| 13 | Base Unit? (Y/N) | An indicator identifying the trade item as the base unit level of the trade item hierarchy. This is y/n (Boolean) where y indicates the trade item is a base unit. (isTradeItemABaseUnit) |

| | Mandatory attributes | Description |
|----|------------------------------------|---|
| 14 | Consumer Unit? (Y/N) | Identifies whether the current hierarchy level of a trade item is intended for a ultimate consumption. For retail, this trade item will be scanned at point of sale. At retail, this data is commonly used to select which GTINs should be used for shelf planning and for front end POS databases. This value reflects the intention of the Information Provider which may not necessarily be reflected by the retailer. (isTradeItemAconsumerUnit) |
| 15 | Despatch Unit? (Y/N) | An indicator identifying that the information provider considers the trade item as a dispatch (shipping) unit. This may be relationship dependent based on channel of trade or other point to point agreement. (isTradeDespatchUnit) |
| 16 | Invoice Unit? (Y/N) | An indicator identifying that the information provider will include this trade item on their billing or invoice. This may be relationship dependent based on channel of trade or other point to point agreement. (isTradeItemAnInvoiceUnit) |
| 17 | Orderable Unit? (Y/N) | An indicator identifying that the information provider considers this trade item to be at a hierarchy level where they will accept orders from customers. This may be different from what the information provider identifies as a dispatch unit. This may be a relationship dependent based on channel of trade or other point to point agreement. (isTradeItemAnOrderableUnit) |
| 18 | Variable Measure? (Y/N) | Indicates that an article is not a fixed quantity, but that the quantity is variable. Can be weight, length, volume. trade item is used or traded in continuous rather than discrete quantities. (isTradeItemAVariableUnit) |
| 19 | Returnable packaging? (Y/N) | Trade item has returnable packaging. Attribute applies to returnable packaging with or without deposit. (isPacakagingMarkedReturnable) |

| | Mandatory attributes | Description |
|----|---|--|
| 20 | Batch/Lot Number? (Y/N)* | Indication whether the base trade item is batch or lot number requested by law, not batch or lot number requested by law but batch or lot number allocated, or is a manufacturer assigned code used to identify a trade item's trade item on batch or lot. Differs from Serial Number which is a manufacturer assigned code during the trade item on cycle to identify a unique trade item. (hasBatchNumber) |
| 21 | Non-sold item returnable? (Y/N)* | Indicates that the buyer can return the articles that are not sold. Used, for example; with magazines and bread. This is a y/n (Boolean) where y equals right of return. This is at least relevant to General Merchandise, Publishing industries and for some FMCG trade item. (isNonSoldTradeItemReturnable) |
| 22 | Marked Recyclable? (Y/N)* | Trade item has a recyclable indication marked on it. This may be a symbol from one of many regional agencies. (isTradeItemMarkedAsRecyclable) |
| 23 | Height & UoM | The measurement of the height of the trade item. The vertical dimension from the lowest extremity to the highest extremity, including packaging. At a pallet level the trade item Height will include the height of the pallet itself. Business Rules: Measurements are relative to how the customer normally views the trade item. Needs to be associated with a valid UoM. (height) |
| 24 | Width & UoM | The measurement from left to right of the trade item. Measurements are relative to how the customer normally views the trade item. Needs to be associated with a valid UoM. (width) |
| 25 | Depth & UoM | The measurement from front to back of the trade item. Measurements are relative to how the customer normally views the trade item. Needs to be associated with a valid UoM. (depth) |

The workgroup also identified many additional attributes that will be needed for specific types of devices, and these are included as a part of the standards in the GDSN. For example, there are several attributes that are associated with safety information about the product, as well information for recalls.

The data in the minimum data set would improve patient safety by allowing the provider and electronic ordering system to check at the point of issue the device type with the clinical order, and ensure the correct device is being given to the correct patient. In addition, recalls will be far more efficient and effective, reducing the risk of patient exposure. Also, the ability to track the devices administered to the patient electronically will greatly aid efforts to monitor for adverse reactions and pass a more complete medical record to other providers.

c. What changes to an attribute, element, or characteristic associated with the unique identification of a device change should result in a new UDI?

The Premier alliance supports the system developed by GS1 for assignment of a new UDI which is identified in the GS1 system as a Global Trade Item Number or GTIN. This process has been utilized in other industries and has proven effective. The GS1 Global Healthcare group has recently reviewed and made changes to the guidelines for the assignment of new GTINs to ensure the guidelines support healthcare. A US Provider GTIN Tool Kit was released July, 2008. A US Supplier GTIN Tool Kit will be released in April 2009. The guidelines for assignment of a new GTIN can be found on the GS1 Web site under GS1 healthcare GTIN Allocation Rules.

d. Should the UDI include a component that represents package size or packaging level?

No, the UDI/ GTIN assigned and the UDI/ GTIN marked on the product should not include a component that represent a package size but should be unique to that product and package size. This UDI/GTIN would then point to a UDI data base that contains the differentiation in size. The GS1 system requires that each level of packaging be identified with a unique GTIN. manufacturers using the GS1 specification correctly develop GTINs that are unique per items and every level of packaging for that item. Receivers of these items can use the GTIN to uniquely identify their products, from unit of issue through all packaging sizes. It must be emphasized that the GTIN is a dumb number and should not be parsed. The GTIN is used as a pointer to a data base file that contains specific item attributes.

UDIs should be implemented at the package level that is issued to the patient. This would ensure the identification of the device as it is provided to the patient (right product and right patient) and minimize the errors associated with providers re-labeling devices for issue to the patient. The information included at the point of issue to the patient should be sufficient to identify the device and allow it to be linked to the provider database that would be synchronized to the product data repository (GDSN) containing a more extensive information on the device. This process would limit the required fields that are included and

marked on the device itself, but provides a process to obtain more information for different classes of devices, if and when needed.

e. To what extent would or should the list of unique device characteristics vary depending on the type of device?

The list of device attributes would vary depending upon the type or classification of device. The GDSN database provides for the various attributes needed for the many types of devices found in healthcare. The workgroup has taken the various needs of different device types into consideration as it has added attributes to the GDSN. A classification system for devices would direct the type of attributes needed for each class of device.

3. What should be the UDI's components?

a. Could existing standards, such as the standards used by GS1, Health Industry Business Communications Council (HIBCC), or others be used as a model for the UDI system? What are the advantages and disadvantages of these existing organizations and standards?

The Premier alliance supports using the existing GS1 standard as a model for the UDI system. GS1 is overwhelmingly global, is used in other industries such as grocery and retail with which hospitals already conduct business and is staffed appropriately to maintain and modify standards as needed for the healthcare industry. Establishing another system would violate the concept of standards and introduce another inefficiency into the manufacturing of medical devices and their tracking throughout the supply chain.

The FDA should not develop its own nationally unique system. Standards development is a complex endeavor that requires a structured, formalized methodology and the participation of all interested parties to ensure that the standards developed meet the intended goals. It is recommended that rather than start from scratch, the FDA should optimize the GS1 standards work already completed and the processes developed for creating those standards wherever possible, selecting both standards would sub optimize the UDI return.

b. Some identification systems currently in use employ a combination of a device identifier (meaning information that identifies the manufacturer, make, and/or model of the device) and a production identifier (meaning information that relates to the lot or serial number). What should the device "identifier" component of the UDI cover or contain?

The UDI device identifier should contain no identifier components. The UDI should contain no intelligence. It should be a dumb number without inherent logic. The intelligence should be in the data base file for the item. The Premier alliance supports the work of the GS1 Auto Identification Code (AIDC) Application Standards Team. This team addressed the details of AIDC marking requirements for

all healthcare items, including medical devices. This cross-functional, global team of 90+ members has worked for the past two years to define a risk-based approach to marking healthcare items, with the amount of data carried in the AIDC proportional to 'risk' and to the intended use of the product. The group also identified what markings are required by which supply and dispensing chain participants (for instance, hospitals may need to apply additional marks such as asset identifiers unless there is a UDI marking present which meets their needs). This Phase 1 work has now moved into the standards approval process (GSMP) and will ultimately be integrated into a new revision of the GS1 General Specifications document. The current repository for the recommended / required AIDC markings is contained in the AIDC Product Marking Grids. A copy is available at the GS1 Web site.

One key principle of the GS1 system is that the AIDC data is simply a pointer to a record in a data base. The amount of data to be carried should be the minimum needed to lookup and access that data. Therefore, the data carrier should carry only the 'necessary' information, while the 'supplementary' information can be referenced elsewhere.

c. With respect to the production identifier, we note that the statute says that the UDI may include information on the device's lot or serial number. When should lot or serial number information be required for a device? Are there particular devices for which serial numbers should be required? If yes, what particular devices should be labeled with a serial number? Please explain your reasoning.

The Premier alliance supports the work of the GS1 AIDC team. This group identified the type of devices in which the lot and serial number should be included as a part of the AIDC.

The determination of what products should be serialized is already defined in existing FDA regulations. For medical device items that are not covered by regulation, it is recommended that the FDA and the user community consider the level of information granularity they may need for specific devices (or device classes) and/or specific needs.

d. How might we ensure that UDIs, regardless of the manufacturers or devices associated with those UDIs, are uniform or standardized in their structure or composition? For example, the NDC (National Drug Code) number is always 10 digits long and always presents the labeler code first, followed by the product code and then the package code. Should we limit the number of ways that the UDI can be created or the standards to be used?

The best method to ensure that the UDI is uniformly standard is to adopt an existing standard that is already widely implemented, documented and understood by the healthcare community, such as the GS1 system. The GS1 system is globally self policing in grocery, retail and healthcare. The FDA can leverage existing documents regarding rules and guidelines for a quicker, smoother and more cost effective implementation.

The Premier alliance strongly encourages the FDA to utilize one standard that is managed by a certified standards organization. The standard for medical devices, unlike the national drug code (NDC) used with pharmaceuticals, should be a global standard due to the global nature of these products and their manufacturers. Having different standards for medical devices, food, general supplies and pharmacy products contributes to the excessive cost and confusion in the healthcare supply chain.

e. How should the UDI be created to ensure that UDIs are unique?

The UDI should be created through and adhere to a global standard that is widely understood and implemented. Ultimately, it is the manufacturer's responsibility to ensure the uniqueness of the identification numbers they assign to their products. GS1 supports manufacturers in that effort, by providing clear data standards and rules for generating identification numbers. Data standards and structured data formats are essential when it comes to ensuring uniqueness.

Medical devices lack a standard and unique identifying system that is comparable to the NDC system for pharmaceuticals. Identification systems for products are already prevalent in the grocery, food service, automotive and electrical industries. All of these industries have successfully adopted the GS1 system of identification and classification. We should not reinvent the wheel. Since the healthcare supply chain includes products from each of these industries, it makes sense to build upon what is already in place and utilize the GS1 system for medical devices. GS1 has a nomenclature system in place that is used globally and should be utilized for a national unique device identification system. This should include the use of the Global Trade Item Number (GTIN) in conjunction with the Global Data Synchronization Network (GDSN).

4. Where should the UDI be placed? What should be the criteria for alternative placement of the UDI?

The placement of the UDI will vary depending upon the type or classification of the device. It should be in a position to allow auto identification by a clinician as they are administering to a patient.

a. Should we specify where on the label the UDI must appear? If so, where should the UDI appear on the label? Please explain your reasoning.

i. Should we allow the components of the UDI to be placed separately on the same package or on different levels of packaging? For example, if the UDI consists of a device identifier component and a production identifier component, should we allow the device identifier component of the UDI to be placed in one location and allow the production identifier component to be placed elsewhere on the label or on the device? Please explain your reasoning.

No, the FDA should not specify where on the label the UDI should appear. Because of the variations and options available for data carriers, printing methods, scanning environments, etc. as well as the variations in the devices themselves and their packaging, it is recommended that the FDA not include regulations for issues like placement, size, color, font, etc. The FDA should rely on already existing commercial standards used throughout global industry. The number of bar codes [and/or RFID tags] should be applied in conformance with the GS1 Healthcare AIDC Application Standards to satisfy the intended use of the product. This standard defines when it is necessary or desirable to have more than one AIDC marking on a product, while striving toward only one AIDC mark per packaging level. This also leverages GS1 rules regarding whether the information should be concatenated into a single bar code or split into two or more bar codes.

For example, a medical device (or pharmaceutical) that is sold in both retail and hospital settings may require at least two bar codes to meet the needs of these very different stakeholders - a UPC or EAN code may be needed to enable point-of-sale scanning to support retail users, while potentially coexisting with a GS1-128 or Data Matrix barcode containing extended information to support hospital or provider users.

ii. For barcodes (whether linear or two-dimensional (2D)), should we require the UDI to be expressed in a concatenated manner (whereby the components of the UDI are expressed on the same line adjacent to each other or in a stacked manner (whereby one component of the UDI rests atop the other component)?

The FDA should not mandate concatenated or stacked bar codes but should rely on the GS1 global system standard to determine this. As long as standards for both concatenated and stacked options are provided with clear information for use, it is not necessary to mandate one format or the other. Rather, it is best to provide industry with the flexibility they need to select the best data carrier for their applications and requirements, and leave the selection for specific devices to them. The GS1 system provides these rules for selection, structure and placement.

b. Are there devices where we should require the UDI to appear on the device itself (direct part marking)? For example, it might be beneficial to put the UDI on the device itself if the device is re-processed because this might help firms identify or record how many times a particular device has been reprocessed. Similarly, certain single use devices (SUDs) sometimes are reprocessed, so a UDI on the device itself could facilitate the mandatory and voluntary MedWatch reporting relating to such reprocessed devices or facilitate other activities (such as documenting sterilization reprocessing of SUDs and validation studies) associated with SUDs. Conversely, are there devices where the UDI cannot or should not go on the device itself? If so, please describe those devices and explain why the UDI cannot or should not go on the device.

The UDI label should remain readable through the approved use and reprocessing of the device. In situations where device labeling is not feasible (e.g. small device size, irregular surface, or if labeling affects

integrity of device) there needs to be a mechanism to record the information contained in the UDI throughout the approved use of the device.

c. If we allow for "alternative placement" of the UDI for some particular devices or types of devices, what should be the general criteria for requiring "alternative placement" of the UDI, e.g., such as on the device itself or other location that is not on the label?

In general, the criteria for alternative placement may include requirements of the device; marking capabilities of the manufacturer, data capture convenience, practicality and reliability for the user, etc. However, as long as standards for alternative placement are provided, it is not essential to define conditions or criteria under which the alternative placement standards can and cannot be used. The necessity of using an alternative placement is usually determined by the manufacturer as long as it meets the requirements of the underlying global system.

d. What specific challenges or limitations exist regarding "alternative placement?" For example, placing a LTD1 in an automatic identification form on an implantable device may present issues as to whether the automatic identification technology affects the device's integrity or function. As another example, certain devices, such as software, may pose particular challenges for how to label with a UDI.

5. How should the IIDI be presented? We are aware of several automatic identification technologies in use, such as linear bar codes, 2D bar codes, and radio frequency identification. We also note that various FDA regulations and initiatives have required or recommended one or more automatic identification technologies (see 21 CFR 201.25 (bar code label requirement for human drug products); 21 CFR 610.67 (bar code label requirement for biological products); Ref. 2; and section 505D of the act (21 U.S.C. 355e) (regarding "pharmaceutical security" and specifying "promising technologies" such as RFID (radio-frequency identification), nanotechnology, encryption technologies, and other "track-and-trace or authentication technologies")). Therefore:

a. Should we require human-readable UDIs or automatic identification of UDIs or both? Are there devices where it would be sufficient to have human readable UDIs alone? Please explain your reasoning. For example, devices used in a home care setting might not need an automatic identification UDI because the home might not be equipped to read the automatic identifier. Are there situations where we should require both human-readable and automatic identification UDIs? Please explain your reasoning.

Yes, wherever possible, it is recommended that the marking of medical devices should be both human readable and encoded for automatic data capture. This is an excellent backup/redundancy in case of failure of a bar code. However, this is not always possible depending on the specific use (e.g., very small

items where space limitations prohibit visual representations of the identifier). In such instances, standards should still be developed for how to provide the information.

The Premier alliance recommends the choice of linear bar codes where possible and 2D bar codes when necessary due to print space or pack size. Premier recommends the FDA view RFID as a possibility for the future, in addition to bar codes. The choice of AIDC technology should be left to the discretion of the brand owner and/or manufacturer to most effectively balance these differences in packaging, and to best meet the needs of the supply and dispensing chain. The data requirements of the UDI also need careful consideration; a risk based approach to the data intensity (inclusion of serial number, lot number or expiration date) must be proportional to the level of patient safety risk, thus ensuring economic viability of the application.

The Premier alliance agrees with the findings of the AIDC Application Standards team developed by GS1 Healthcare. This group recommended a balance between standardized markings / standardized data, and the flexibility to choose alternative AIDC data carriers to solve challenging marking problems. There are many different AIDC data carriers in existence for one good reason – each brings specific strengths to bear in solving challenging marking problems. The GS1 AIDC 4 Application Standards represent a multi-disciplinary solution to marking the maximum number of products with the maximum level of standardization. Limitation would be detrimental to the needs of healthcare; flexibility in today's complex environment is vital. The suite of GS1 Identification Keys, symbologies and carriers enables the widest possible usage of UDI.

The Premier alliance supports the UDI being both human readable and encoded in automatic technology. The human readable information on the device should be limited to what is minimally required to properly identify the product before providing to a patient. Likewise the information encoded on the device would only need to be the minimum necessary to identify the product for safe distribution to the patient. The encoded information would allow the automated system to access a richer database on the device that would contain more extensive information to assist in recalls and other patient specific safety checks.

b. Should we specify a particular type of automatic identification technology or should we allow the automatic identification technology to vary depending on the type of device? Should we identify automatic identification standards (as opposed to specific technologies) that can be used? Please explain your reasoning. Specifying a particular type of automatic identification technology would enable hospitals and other parties who might read or use a UDI to make specific investments in scanning or reading equipment, but the technology chosen might not be easily applied to all devices (if we require the UDI to be placed somewhere other than the label.) For this question, we are particularly interested in hearing from parties who might use UDIs as well as entities that may have already adopted or installed device identification systems.

No, The FDA should not specify a particular type of automatic identification technology or data carrier. Selection of data carriers must consider the constraints of the individual application. Depending on the product and its use, some applications may permit labeling, while others may direct part marking on the device (e.g. laser etching).

UDI should be technology neutral in order to be able to accommodate all methods of labeling, marking, identifying products and software (one-dimensional linear bar code, two-dimensional bar code, RFID or other Automatic Identification and data capture media). The UDI system for medical devices will consist of a unique identification code using a globally accepted standard format. This code will allow the use of automatic-identification systems in the field where medical devices are sold, stored, installed, used, maintained, etc.

c. Should we allow the use of different automatic identification technologies to express different parts of the UDI? For example, the device identifier component might be expressed in a linear bar code and the production identifier component might be expressed in a 2D bar code. Allowing the use of different technologies for different components of the UDI may enable manufacturers to make more efficient use of label space or space on the device itself, but it also could generate confusion as to which identifier to read or scan and could necessitate the purchase of several types of reading and scanning equipment.

No, the UDI or GTIN for a particular device should be in the same identification technology (Symbology). Wherever possible identifiers (GTIN's) and attributes encoded in an AIDC carrier should be concatenated in one single carrier. Identical GTIN's and attributes could be carried by two AIDC technologies (e.g. bar code and RFID), but systems development must be considered to ensure there is no duplication of the data gathering.

The number of bar codes [and/or RFID tags] should be applied in conformance with the GS1 Healthcare AIDC Application Standards to satisfy the intended use of the product. This standard defines when it is necessary or desirable to have more than one AIDC marking on a product, while striving toward only one AIDC mark per packaging level. This also leverages GS1 rules regarding whether the information should be concatenated into a single bar code or split into two or more bar codes. For example, a medical device (or pharmaceutical) that is sold in both retail and hospital settings may require at least two bar codes to meet the needs of these very different stakeholders - a UPC or EAN code may be needed to enable point-of-sale scanning to support retail users, while potentially coexisting with a GS1-128 or data matrix barcode containing extended information to support hospital or provider users.

d. Are there existing standards or systems we should consider in establishing the requirements for how the UDI must be presented? For example, we are aware of various standards organizations, such as GS1 and the HIBCC, that exist and have specific formats or

specifications for automatic identifiers for products. Should we allow any or all of these standards to be used?

Yes the FDA should select the GS1 system. The GS1 System of standards provides an excellent framework for UDI, and is already widely used in healthcare. Therefore, it is recommended that the FDA leverage the GS1 System for UDI.

6. How should the UDI Database be developed and maintained? For parties to benefit from UDI information, it would seem necessary for those parties to know, at a minimum, the UDIs that exist, the specific device associated with each UDI, and the information associated with each UDI. It might be efficient for one entity to collect the UDIs, associate those LTDis with specific devices, and make the information associated with those LTDis publicly available. However, it is also conceivable (but perhaps less efficient or more costly) that the information could rest with individual manufacturers themselves (rather than FDA) or with a third party or third parties. Consequently:

a. How and when should we require UDIs and associated information to be entered into a database? How frequently should we require changes to a LTDis or to the information associated with or linked to a LTDis to be reported?

The Premier alliance supports the adoption and use of the GDSN system for maintaining the medical device database. This system is in existence, is global and used by other industries. The manufacturer should own the accuracy of their data and be required to keep it up to date. All supply chain participants would have access to the data which would ensure consistency.

b. Aside from information that is necessary to uniquely identify a device, what other information (if any) should be part of a UDI system database or otherwise linked to the UDIs?

The Premier alliance has been actively involved in the GS1 Healthcare Global Data Synchronization Network workgroup that has identified the required data attributes, as shown earlier, and also added more than 30 new medical device specific attributes to the current 300 plus attributes available in the GDSN. Premier strongly recommends that FDA utilize this work for the attributes. The GS1 standards process allows additional attributes to be added through their standards system, called the Global Standards Management Process (GSMP).

c. If variable data (such as a lot or serial number) is necessary to uniquely identify a device, should such data be included in a UDI system database?

Whenever appropriate, lot or serial number should be on the device and not in the database.

In closing, the Premier alliance appreciates the opportunity to provide comments on UDI and reiterates our strong support for a regulated, mandatory UDI that is globally harmonized. We look forward to

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working with you on this important issue that will ultimately improve patient safety, reduce medical errors, facilitate device recalls and improve device adverse event reporting. If you have any questions please contact Joe Pleasant, chief information officer, at 704.733.5415 or Joe_pleasant@premierinc.com or Linda Rouse O'Neill, director of federal affairs, at 202.879.8005 or Linda_rouse@premierinc.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Blair Childs". The signature is fluid and cursive, with a large, stylized initial "B" and "C".

Blair Childs
Senior Vice President, Public Affairs



Survey of nearly 1,000 hospital professionals backs need for UDI Safety Institute Device Recall Survey

On October 20, 2006, a “device recall survey” was sent via e-mail to the subscribers of Premier Inc.’s Safety Institute *Safety Share* newsletter. The survey was part of Premier’s effort to gather information on the current methods used in healthcare settings to record and track information on medical devices.

It was noted in the request for participation that the information gathered in the survey would be shared with the FDA as additional insight into how a unique device identification (UDI) system may improve patient safety by facilitating device recalls and improving medical device adverse event reporting. Premier submitted the survey results with its formal comments to the FDA on November 9, 2006.

Survey findings

1. More than 80 percent of respondents stated that a national UDI system would enhance patient safety.
2. The most common method used to record information on a patient record regarding an implanted medical device is transfer of a product label into the patient’s record (60 percent).
3. When recalls occur, nearly all hospitals are conducting manual searches of records or logs to identify patients who received a recalled device or product.

Respondent characteristics

A total of 948 individuals responded to the survey. Respondents were asked to select a job type that best represented their responsibilities. These are the job types reported by respondents:

Table 1

| Job type | Number of respondents |
|----------------------|------------------------------|
| Administration | 175 |
| Infection control | 172 |
| Materials management | 149 |
| Risk management | 120 |
| Nursing | 111 |
| Quality services | 111 |
| Surgery/OR | 93 |
| Clinical support | 81 |
| Safety | 74 |
| Pharmacy | 32 |

| | |
|-----------------------|------------|
| Facility/environment | 27 |
| Regulatory compliance | 27 |
| Physician/medical | 25 |
| TOTAL | 948 |

Table 2

| | |
|--|-------|
| 1. To the best of your knowledge, which methods or system (s) do you currently use to record information in the patient record on the medical devices that are implanted in a patient? Check all that apply: | |
| • Handwritten recording of the device in patient record | 51.1% |
| • Transfer of text label provided by the medical device company into the patient record | 60.1% |
| • Transfer of a bar coded label (or other device identifier) from the device into the patient record. | 40.8% |
| • Don't know | 19.6% |
| • Other | 8.7% |
| 2. Do you have a system or database, beyond the individual patient record, to track or record medical devices that are implanted in a patient? | |
| • Yes | 46.2 |
| • No | 20.8% |
| • Don't know or not applicable | 33% |
| 3. Which of the following systems do you use to label patient care equipment or medical devices (e.g., IV pumps) for the purpose of locating or tracking them. Check all that apply: | |
| • Manual method (e.g., handwritten or text label) | 65.8% |
| • Electronic method (e.g., bar coding) | 28% |
| • Radiofrequency identification (RFID) | 2.8% |
| • Don't know or not applicable | 15.4% |
| • Other | 6.1% |

Table 2 (continued)

| | |
|---|-------|
| 4. When there is a recall of a medical device, either implanted or patient care-related device, what method do you currently use to track or locate the device and/or the patient? Check all that apply: | |
| • Manual review of patient record | 42% |
| • Manual review of logs | 58.4% |
| • Electronic retrieval of information | 40.5% |
| • Don't know or not applicable | 16.2% |
| • Other | 5.6% |
| 5. To what degree do you believe that having a unique device identifier system would enhance patient safety by improving your current process for recording device information and tracking recalls? | |
| • None | 2.3% |
| • Minimal | 6.8% |
| • Somewhat | 27.7% |
| • Greatly | 52.7% |
| • Don't know or not applicable | 10.5% |
| 6. Are you currently establishing your own identifier for products once they are received and before they are distributed to patients? | |
| • Yes | 28.7% |
| • No | 32.2% |
| • Don't know or not applicable | 39.1% |