VENABLE LLP
575 7th Street, NW
Washington, DC 20004-1601
Telephone 202-344-4000
Facsimile 202-344-8300
www.venable.com

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Via Electronic Filing

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20852

Re: Unique Device Identification
Request for Comments
Docket No. 2006N-0292

COMMENTS OF AVERY DENNISON CORPORATION

Avery Dennison Corporation ("ADC"), pursuant to Section 10.20 of the Food and Drug Administration's ("FDA") Rules[1] and through its undersigned attorney, hereby submits comments in the above-referenced proceeding.

I. STATEMENT OF INTEREST

ADC, a Fortune 500 company (NYSD: AVY), is a global leader in pressure-sensitive technology and materials science. Through its business unit, Avery Dennison RFID, ADC manufactures and markets radiofrequency identification ("RFID") products worldwide. With design, testing and manufacturing facilities located in the U.S. and Europe, ADC is a leading provider in the global RFID marketplace. ADC serves numerous markets, including those of the pharmaceutical and healthcare industries, and governmental entities such as the U.S. Department of Defense.

[1] See 21C.F.R. § 10.20.

II. THE FDA PROCEEDING

In its Request for Comments in this proceeding ("Request"), FDA solicits information concerning how a Unique Device Identification ("UDI") system for medical devices may improve patient safety, and provide ancillary benefits such as healthcare cost savings from improved materials management and detecting counterfeit devices.[2] FDA initiated this proceeding after promulgating the "Bar Code Rule," requiring barcodes on certain drugs and biological products to reduce medical errors.[3] FDA met with various stakeholders (e.g., hospital associations, device manufacturers, and other federal agencies), and commissioned experts to ascertain the interest in, and potential benefits of, a "Bar Code Rule for medical devices," i.e., UDI.[4]

FDA discovered that most stakeholders favored UDI, due mainly to the many patient safety benefits that would result from an efficiently implemented system.[5] Accordingly, FDA seeks comments on various issues pertaining to UDI, including: (a) the benefits of a standardized UDI system; (b) whether UDI should be voluntary or mandatory; and (c) whether a UDI should be based on a specific technology.[6]

III. SUMMARY OF ADC'S COMMENTS

ADC commends FDA for its leadership role in working to ensure the safety of patients in U.S. healthcare facilities. As discussed herein, a uniform system of medical device attributes will facilitate many patient safety benefits and reduce healthcare costs. In order to ensure uniform and expeditious deployment, UDI should be made mandatory.

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[2] See U.S. Food and Drug Administration, Unique Device Identification; Request for Comments, Federal Register: Vol. 71, No. 155, pp. 46233-46236 (Aug. 11, 2006).
[3] Id. at 46233; citing 21 C.F.R. §§ 201.25 & 610.67.
[4] Id.
[5] Id.
[6] Id. at 46235.

Because an effective UDI relies on detailed information about individual medical devices, it should be based on a technology that can capture and disseminate large amounts of accurate and secure data. RFID has the requisite attributes and should be the technology upon which UDI is based. Also, due to existing encryption and authentication protocols and other technological means of protecting data, patient privacy can be assured if RFID is mandated as the technology for UDI.

IV. THE URGENT NEED FOR UDI

A reliable and standardized system for identifying, tracking and tracing, and managing medical devices is critical to addressing the patient safety problems that are afflicting the U.S. healthcare industry. It is estimated that nearly 100,000 people in the U.S. die each year from hospital medical errors.[7] These errors, many of which involve medical devices, also impose severe financial strains on the U.S. healthcare system, costing approximately $17 billion yearly.[8] Healthcare facilities often have incomplete or inaccurate data about medical devices; difficulties in coordinating medical device information and the patients who use them are major causes of harmful or fatal patient errors.[9]

Healthcare facilities also incur substantial and preventable costs through supply chain mismanagement. For example, more than $11 billion in unnecessary costs were incurred by the U.S. healthcare industry in 2003/2004 due to inefficiencies related to hospital supply management.[10] These inefficiencies include inadequate theft prevention, imprecise distribution management, inability to locate critical supplies in emergency situations, and inaccurate patient billing.[11]

FDA and numerous experts in the healthcare field agree that an efficient UDI would go a long way toward increasing patient safety by reducing medical device errors and reducing costs by increasing

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[7] See Clinical Information Processing Platform, Aaventyn White Paper (Oct. 2005) at 6; see also Request at 46234.
[8] See Aaventyn at 6.
[9] See Request at 46234-5.
[10] See Aaventyn at 6.
[11] See RFID in Hospitals: Issues and Solutions, Consortium for the Accelerated Deployment of RFID Distribution (Sept. 2004) at 4-6.

supply chain efficiencies.[12] ADC concurs with those assessments, and submits that UDI should be made mandatory.

V. FDA SHOULD MANDATE A UDI SYSTEM FOR MEDICAL DEVICES

While most stakeholders in FDA's studies are in favor of UDI, some express reservations due mainly to cost and logistics concerns, and favor a voluntary approach.[13]

In order for the benefits of UDI to be realized, it must be implemented universally. Accordingly, it will be necessary for FDA to mandate UDI.

A. A Voluntary UDI will Not Result in Universal Implementation

Permitting voluntary UDI implementation will not work. As illustrated by the results of the implementation of the Bar Code Rule, UDI is unlikely to be implemented effectively without a mandate.

Despite of the fact that barcode technology has been available for decades, and, its ability to help prevent drug errors is well known, less than 100 hospitals in the U.S. had implemented barcode readers to scan drugs prior to promulgation of the Bar Code Rule.[14] The main reason for hospitals' failure to utilize barcode technology is their reluctance to expend the resources necessary to implement barcode equipment, particularly since drug companies are not required to put barcodes on their products' labels.[15]

By April 2006, after the effective date of the Bar Code Rule, more than 600 hospitals had installed barcode readers to scan drugs, and that number is expected to double over the next year.[16] Although hospitals are not covered entities under the Bar Code Rule, hospital administrators realized the

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[12] See Request at 46234.
[13] See Report on Meeting to Discuss Unique Device Identification, The Food and Drug Law Institute (Jan. 16, 2006) at 4-5.
[14] See "Bar Code Rule Could Have Benefits Beyond Safety," IHealthBeat (Feb. 20, 2004) at 1.
[15] Id.
[16] See "FDA Bar Code Rule Takes Effect," IHealthBeat (April 26, 2006) at 1.

patient safety benefits that would be realized from scanning drugs received from manufacturers who are covered by the Bar Code Rule.[17]

The "tipping point" for the hospitals' investments in barcode equipment was the implementation of the mandatory Bar Code Rule.[18] Once manufacturers were required to put barcodes on their drugs' labels, hospitals had incentive to invest in the equipment necessary to utilize barcodes for patient safety. The benefits of the Bar Code Rule became clear almost immediately; its adoption helped reduce medication errors by as much as 85% at test-bed hospitals.[19] A UDI should similarly reduce medical device errors and increase patient safety.[20]

By contrast, a voluntary UDI would provide little incentive for medical device manufacturers, distributors, and vendors to change the situation that currently exists, i.e., utilizing their own systems of supply chain management without coordinating with other supply chain parties.[21] This situation would not change appreciably unless UDI is mandated, because of reluctance from interested parties to expend the resources necessary to coordinate with each other.[22]

Typically, there are several major supply chain points for medical devices. With each entity utilizing its own supply tracking system, complications in managing millions of medical devices bound for U.S. healthcare facilities are common; resolving discrepancies with inventory counts and who is responsible for the inevitable losses can become a three-way reconciliation imbroglio between the hospitals, distributors, and vendors.

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[17] Id.
[18] See IHealthBeat, Feb. 24, 2004.
[19] See Aaventyn at 6.
[20] See "White Paper: Automatic Identification of Medical Devices," ECRI (Aug. 17, 2005) at 28.
[21] See Report on Meeting at 5.
[22] Id.

Uncoordinated medical supply chain management systems result in needless complexity, redundancy, and increased risk of bad data used for tracking and tracing.[23] Experts have concluded that it would be difficult, if not impossible, to rely on information provided by voluntary UDI systems.[24]

By mandating a UDI, particularly a UDI system based on an advanced technology such as RFID, FDA can ensure that all parties in the medical device supply chain coordinate to streamline the process. As discussed below, technological advances in RFID standards can enable manufacturers, distributors, vendors, and healthcare facilities worldwide to seamlessly track and trace medical devices from production to patient use.

B. Initial UDI Costs can be Offset by ROI & Phased-In Approach

Regarding the cost concerns expressed by some of the shareholders, the return on investment ("ROI") that a UDI will produce should more than make up for any initial costs. Installing an RFID system in a hospital, for example, can be expensive, but with the tracking and tracing capabilities of RFID, hospitals would likely see an almost immediate ROI.

Larger hospitals typically incur hundreds of thousands of dollars in annual medical device losses.[25] A UDI based on RFID will increase hospitals' supply efficiencies, which would prevent many of those losses. Consequently, at the end of the first year, an RFID system in a hospital has more than paid for itself, and the substantial cost savings will continue thereafter.[26]

Other entities such as manufacturers and distributors may not see an immediate ROI, but, improved asset tracking and materials management processes based on a UDI will save them money in the long run. As illustrated by a report provided for FDA by the Easter Research Group, implementation

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[23] Id.
[24] Id.
[25] See Agilesense Technologies Reports, www.agilesense.com/rfid/providers.htm.
[26] See "Surveys Say RFID Technology Saves Money, Helps Patients," Boardroom Minutes at www.sun.com/br/0205ezine/hcrfid.html at 2.

of a UDI system involving medical device manufacturers and distributors will result in substantial cost savings by enabling accurate and faster product delivery and improved quality control, and streamlining many steps within the distribution process.[27] The overall cost savings realized by supply chain entities should lower the cost of medical devices for healthcare facilities and their patients.

FDA can help these entities to offset initial costs by phasing in the UDI requirements over a period of a few years. For example, during the first two years after the effective date of the new rules, FDA could mandate UDI only for Class III medical devices, which are those of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.[28] During the ensuing years, FDA could require UDI for Class II and Class I devices. This phased-in approach would afford all the necessary parties sufficient time to make the necessary expenditures and preparations to implement UDI.

VI. THE BENEFITS OF UDI WILL BE BEST REALIZED IF RFID IS THE TECHNOLOGY UPON WHICH IT IS BASED

UDI will consist of creating "a uniform, standard system of device attributes," uniquely identifying a medical device at the unit level.[29] Each "attribute" (e.g., manufacturer, make, model, serial number, lot number, etc.) is symbolized by a number; when combined, the result is a series of numbers that specifically identifies a given medical device.[30]

FDA envisions that UDI could be used primarily to: (a) identify specific medical devices to facilitate adverse event reporting and locating recalled devices; and (b) reduce medical errors by

[27] See ERG Final Report: Unique Identification for Medical Devices, Eastern Research Group, Inc. (March 22, 2006) at §§ 2.2.1-2.2.2.
[28] See "Device Advice," U.S. Food and Drug Administration, at www.fda.gov/cdrh/devadvice/3132.html.
[29] See Request at 46234.
[30] Id.

interfacing with computer databases to access further information about safe device use and patients on whom a device will or has been used.[31]

RFID is ideally suited for UDI, as it can accommodate all the attributes of an individual medical device, rapidly identify specific medical devices, and efficiently convey information to health care databases to promote safe medical device use. Additionally, RFID could be instrumental in streamlining supply chain management, which will result in lower medical care costs for patients.

A. RFID Technology Overview

A basic RFID system consists of three components: (a) "passive" tags, each comprised of a microchip and an antenna;[32] (b) a reader; and (c) software/middleware and databases that act on the information. Data are transferred via low-power radio frequencies between a tag and a reader, which are tuned to the same frequency. The reader, which can be stationary or mobile, sends out a signal, which is received by all tags tuned to that frequency in the immediate area. The tags, which can be attached to virtually anything, receive the signal with their antennas and "backscatter" their stored data to the reader. The reader receives the tag's signal with its antenna, decodes it, and transfers it to the database(s).

B. RFID has the Data Capacity for UDI

An RFID tag can store a large amount of data, up to 30 times more data than a traditional barcode, which enables an RFID tag to carry a range of real time information about a medical device at multiple points within the supply chain. Utilizing the Electronic Product Code ("EPC"), RFID allows for mass serialization, i.e., the ability to store a unique serial number for an individual medical device,

[31] Id.
[32] RFID tags are characterized as either active or passive. Active tags have a battery, which runs the microchip's circuitry, and broadcasts the signal to the reader. Active tags have a read range of up to 100 feet, as compared to 30 feet or less for passive tags. Active tags are substantially more expensive than passive UHF tags, which tend to cost between 10 to 12 cents each.

which cannot be done with traditional barcodes.[33] Barcodes typically have the capacity to store only the manufacturer and product codes, which is not enough information for an effective UDI.[34]

C. RFID can be Used to Track and Trace Medical Devices Worldwide

The International Standards Organization ("ISO") recently approved EPCglobal, Inc.'s ("EPCglobal") Generation 2, Class 1 protocol standard for RFID devices operating in the UHF (860-960 MHz) band ("Gen 2").[35] Gen 2's performance and compliance features translate well to UDI. Gen 2 can, for example, accommodate at least 96 bits of information, which not only permits a large amount of information to be stored on a tag, but enables customization of content.

Gen 2 UHF tags are suitable for tagging at the item level, as well as at the case and pallet levels; technological innovations are increasing their efficiency in healthcare environments. Traditional UHF tags were thought to be less efficient than HF (13.557 – 13.567 MHz) tags and readers in "hostile environments" containing metal and water. But, advanced tag and inlay companies such as ADC have produced high-performance UHF tags that work well on a wide range of products, including those containing metal and liquids.[36]

Near-field UHF technology is being developed, which performs as well as HF around metal and liquids and in hospital environments, and has a much faster read rate than HF (up to 1,000 tags per

[33] See "Comparing HF and UHF RFID Technologies, Packaging Digest (Nov. 2004) at 5-6.
[34] See "UPC-A Symbology" at www.barcodeisland.com/upca.phtml at 1. Two-dimensional ("2D") barcodes can hold more information, but they have all the other limitation of traditional barcodes e.g., require line-of-sight with the scanner, and do not have the advanced tracking capabilities of RFID.
[35] See "The International Standards Organization has made EPCglobal's UHF Gen 2 Air-Interface Protocol a Part of its ISA/IEC 18000-6 Standard," RFID Journal (July 11, 2006) at 1.
[36] See e.g., Avery Dennison Gen 2 tags AD 420/AD 421at www.rfid.averydennison.com/us/products.

second as opposed to 200 for HF).[37] ADC has already produced Gen2 compliant, near-field UHF inlays that are specifically designed for item-level tagging of pharmaceuticals.[38]

Near-field UHF tags can be easily designed to work with metal, by allowing the metal to help couple the electrical field onto the tag.[39] This produces a very efficient performance on metal for these tags.[40]

Additionally, because near-field UHF, like HF (which is near-field only), use the magnetic field (as opposed to electromagnetic waves) to power tags, it is not subject to RF absorption, as far-field RFID can be. Hence, near-field UHF works well around liquids, and, unlike HF, it works in containers with liquids.[41]

Near-field UHF technology also works well in hospital environments. Due to its utilization of the magnetic field, near-field UHF is not susceptible to noise and interference, nor does it release RF emissions that would cause harmful interference to other devices.[42] HF has similar characteristics, but its read rate is much slower than UHF.[43]

In sum, UHF RFID is a very versatile technology for medical device tracking and tracing. When used in its conventional mode, UHF RFID travels as electromagnetic waves where an electronic field feeds off a magnetic field; both fields build up to the point where the waves radiate off into the distance. This enables long-range tag reading, which is good for tracking at the case and pallet level. And, UHF RFID can also be deployed for near-field reading at the item level, which utilizes the magnetic field and

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[37] See "A Shift to UHF Near-Field Predicted for Pharma," RFID Journal (Oct. 6, 2006) at 1; see also "RFID and UHF: A Prescription for RFID Success in the Pharmaceutical Industry," Corroborative White Paper by ADT/Tyco Fire & Security, Alien, Impinj, Intel, Symbol & Xterprise, (2005) at 16, 22.
[38] See "Wal-Mart Seeks UHF for Item Level," RFID Journal (May 26, 2006) at 2; see also "Avery Dennison Unveils New Gen2 Inlays," RFID Journal (Mar. 1, 2006) at 1.
[39] See "RFID and UHF" at 13.
[40] Id.
[41] Id.
[42] Id. at 16.
[43] Id.

does not cause harmful interference.

In addition to being ISO approved, Gen 2 conforms to the UHF radio regulations of the Federal Communications Commission ("FCC") and those of European and Asian regulatory bodies.[44] Consequently, Gen 2 UHF tags and equipment can be used nearly universally, which allows manufacturers, distributors and vendors from all over the world to coordinate the medical device supply chain using RFID.[45]

The availability of a worldwide RFID standard and the fact that RFID tag data capacity is big enough so that any tag will have a unique code, enables all parties in the supply chain to use standardized Gen 2 UHF equipment to track individual tagged medical devices they move from location to location until they end up at U.S. healthcare facilities.

Gen 2 is a truly global standard that allows users to choose UHF Gen 2 tags that can be programmed and read by any Gen 2 reader operating on any UHF frequency in the world.[46] This ineroperability promotes rapid and efficient supply chain management, product development, and better product availability.[47]

D. RFID in Healthcare Facilities

When tagged medical devices arrive at a healthcare facility's warehouse, RFID readers scan the tags and information about each individual item is entered in the facility's information management system. The tag on each device can be quickly scanned again at the various dispatch points within the facility,[48] and when the device reaches the appropriate hospital unit, the device's UDI would be matched up in the hospital's computer network with the number of the patient on whom it would be used.

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[44] See "RFID: Rapid Implementation and Regulatory Challenges," Venable LLP (Jan. 2005) at 4.
[45] Id.
[46] See "RFID and UHF" at 17.
[47] By contrast, HF has multiple, but incompatible standards. Id. at 18.
[48] For example, medical devices can be tracked throughout a hospital by installing reader antennas at key points in hospital hallways, near elevators, and in storerooms where medical equipment is kept. See "The Lahey Clinic's RFID Remedy," RFID Journal (Apr. 17, 2006) at 3.

Hence, with RFID, location data about individual medical devices, and how they are used, would be readily available in a healthcare facility's information management system.[49]

Additionally, RFID tags can be used in conjunction with an information management system to alert medical practitioners to calibration and maintenance schedules of some high-end devices, and to warn them in the event those schedules have not been observed. And, with its facility to capture large amounts of data about individual medical devices, data mining can be accomplished which can flag devices that may be about to fail.

Another important aspect of RFID is that it, unlike barcodes, does not require "line of sight." RFID tags embedded in items can also be read, whereas barcodes similarly situated cannot. Additionally, due to the "anti-collision" characteristics of Gen 2, RFID is the only existing technology that permits the simultaneous scanning of several items by a single reader. Consequently, RFID permits quick and efficient scanning of medical devices, with no need for employees to individually scan each item, as is required with barcode technology.

E. RFID will Efficiently Facilitate Adverse Event Reporting

FDA receives approximately 180,000 reports of adverse medical device events each year.[50] FDA currently uses a Medical Device Reporting ("MDR") system to obtain information about patient injuries and deaths resulting from medical devices.[51] Most of these reports are from manufacturers, and FDA has difficulty using the information provided because basic information such as model numbers and lot numbers are not provided.[52]

A UDI based on RFID would provide the necessary information to facilitate identification of devices in adverse event reports, which would allow FDA to identify dangerous devices and device

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[49] Id.
[50] See "FDA Seeks ID System for Medical Devices and Supplies," RFID Journal (August 28, 2006) at 1.
[51] Id. at 1-2.
[52] Id. at 1.

interactions, as well as any situations in which these devices should not be used. With RFID, individual medical devices would be tagged with unique EPCs containing information such as lot numbers and serial numbers, which would be read by RFID readers in various places along the supply chain and in healthcare facilities.

Hence, any device containing an RFID tag that is involved in an adverse event could be easily identified, and documented via a facility's healthcare database as to how it was used in patient care. This would allow the FDA to identify future problems with the device and quantify the adverse events related to that device.

Conversely, because of the limitation in the amount of data they can collect, barcodes cannot provide the necessary information to facilitate adverse event reports. Because only the manufacturer and product codes can be tracked via barcodes, and barcodes do not enable rapid identification or location of medical devices in situations involving a malfunctioning device from a company that produces several different models of the device, it would be virtually impossible to create a meaningful adverse event report using barcode technology.

F. RFID will Expedite Recalls of Medical Devices

RFID can also be very useful in facilitating medical device recalls. Inadequate recall responses in healthcare facilities can severely jeopardize patient safety. For example, should a certain model of a life-saving device such as a ventilator or pacemaker malfunction, there could be adverse health consequences should patients continue using that model until the defect is fixed.[53] Patient safety cannot be ensured unless all such recalled devices are promptly located and appropriate personnel informed.

Today, device recalls are very labor intensive and time consuming procedures. Hospitals typically initiate recalls by reviewing purchasing and materials management records. After determining

[53] See FDA Medical Device Recalls: Class I Recall: Ventilator (June 3, 2002), www.fda.gov/cdrh/recalls/recall-060302.html.

which devices are to be recalled, hospital staff are deployed to determine, among other things, whether recalled devices have been purchased, and where the devices have been distributed. Then, manual searches of storerooms and other parts of the hospital are conducted, in hopes of finding the devices for recall.

Because of its capacity to transmit location data about individual items to a hospital's information management system, RFID can significantly reduce the time spent identifying items targeted for recall, and locating those devices. For example, when a tagged device needs to be located, hospital staff can go to a secure Web site, enter a password, and view a floor plan of the hospital, with the locations of the devices pinpointed.[54] RFID also enables the electronic capture of serial numbers and other device information which can be matched up with patient records in an information management system. This permits hospital personnel to determine which patients are using the recalled device, so that equipment substitutions can be made.

Barcodes do not enable such ease of recalls. Because of their line of sight technology, each individual device would have to be manually scanned whenever it is moved to a new location. And, because barcodes do not have the capacity for mass serialization of individual devices, they do not provide the necessary information to determine the whereabouts of specific medical devices for recalls.

G. In-House Supply Chain Efficiencies and Counterfeit Device Prevention

Because of its ability to identify, track, and trace individual medical devices, RFID will provide healthcare facilities with many supply efficiencies that will help to reduce costs and improve patient safety. RFID has some unique applications that are particularly advantageous for the healthcare industry.

[54] See "Lahey Clinic," RFID Journal at 3.

For example, some hospitals are utilizing RFID to track the addition and removal of cardiac medical devices from storage cabinets and to assist in the billing and tracking of patient care.[55] Cardiac nurses swipe their ID cards to open a locked cabinet in which cardiac devices are stored.[56] An RFID reader scans the ID cards, and the nurses use a computer touchpad to enter the name of the patient on whom a particular device will be used.[57]

A tagged device is removed from the shelf in the cabinet, and that same RFID interrogator reads all the other tagged items remaining in the cabinet, thereby determining which device was taken.[58] The patient and medical device data go to the hospital's database, where they are analyzed and routed to the appropriate departments at the hospital for billing, inventory tracking and patient-care tracking.[59] In this way, the catheterization lab always has an accurate inventory and charges patients only for the equipment used. The cabinets also track the expiration dates of the products used.[60]

Additionally, RFID is an invaluable tool to prevent counterfeiting of medical devices. In its report on recommendations to prevent drug counterfeiting,[61] FDA stated that, "[u]se of mass serialization to uniquely identify all drug products for use in the United States is the single most powerful tool available to secure the U.S. drug supply."[62] FDA further stated that "the technology most likely to bring mass serialization into widespread commercial use is RFID . . . ."[63]

The efficiencies and capabilities of RFID are equally applicable to preventing counterfeiting of medical devices. The detailed electronic history of product shipments made possible by RFID would

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[55] See "RFID Heals Hospital's Inventory Problem, RFID Journal (Aug. 15, 2005) at 1; see also "King's Daughter Expands its RFID Tracking System," RFID Journal (June 26, 2006) at 1.
[56] Id.
[57] Id.
[58] Id.
[59] Id.
[60] Id.
[61] See Combating Counterfeit Drugs, U.S. Food and Drug Administration (Feb., 2004).
[62] Id. at 10.
[63] Id.

make it very difficult for counterfeit medical devices to enter the supply chain. The global Gen 2 standard allows for very efficient tracking of medical devices with UHF tags. By tagging devices at the manufacturing plant with a unique EPC and using RFID readers to track the devices through the various distribution points and finally to the healthcare facility, supply chain parties can ensure that medical devices used on patients are genuine.[64]

H. Privacy Concerns Regarding RFID as UDI are Unwarranted

One issue that is often raised concerning the use of RFID in medical environments is privacy, or more specifically, the perceived lack of data security. In general, the concern is that if an RFID tag is left on a medical device or a drug container after it is assigned to a patient, an unauthorized person with an RFID reader might be able to read personal information from the tag without the patient knowing it.[65]

A key concern is the bit capacity of EPCs, which enable the assignment of individual identifiers to tagged objects.[66] The perception is that RFID tags could potentially collect a great deal of personal information.[67] Consequently some privacy advocates argue that RFID should not be used in environments where sensitive personal information can be scanned by unscrupulous individuals.[68]

These privacy concerns are unwarranted, particularly with respect to RFID and medical devices. In the first place, the EPC does not contain, collect, or store any personally identifiable information.[69] Data associated with EPC are collected, stored, and protected by EPCglobal member companies in compliance with applicable laws.[70]

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[64] Barcodes, including 2D barcodes, can be easily replicated by counterfeiters, by simply scanning and printing them. Conversely, RFID tags are virtually impossible to counterfeit. Counterfeiters would have to have access to a semiconductor wafer fabrication facility in order to manufacture chips and assemble them into inlays or labels. Counterfeiters would also require significantly more time to replicate the individual EPC numbers.
[65] See Statement on the Use of RFID on Pharmaceuticals, CASPIAN Consumer Privacy, www.spychips.com.
[66] Id.
[67] Id.
[68] Id.
[69] See EPCglobal US Comment, FDA Anti-Counterfeit Drug Initiative Workshop, Docket No. 2005N-0510 (February, 2006) at 16.
[70] Id.

Gen 2 and other ISO-approved standards have secure encryption and authentication protocols, and EPC-related data are stored on servers that are beyond the firewalls of corporations and logistics provides around the world.[71] EPC tags are password protected, which means that a tag could be locked during transit between trading partners and unlocked only by authorized parties with the password for appropriate use in the supply chain or at the medical facility.[72]

Moreover, regarding tracking medical devices in healthcare facilities, patient information would be stored on the hospital's management information system, not on the RFID tags. Hospitals would cross-reference the device information contained on the device's EPC with the patient data contained on the hospital's computer system.

Under any circumstances, a hospital would protect patient privacy by ensuring that its information management system is secure; the use of RFID to track medical devices would not increase the risk of violating patient privacy. Accordingly, patient privacy should not be an issue regarding RFID as the mandated UDI.

VII. CONCLUSION

RFID is not a new technology. It was first used in World War II to help allied forces identify enemy planes. Today, RFID is widely used to make people's lives easier and safer (e.g., no-stop toll booths and secure access control for public buildings); it can do the same in the medical services sector if UDI is mandated and based on RFID. The recent flurry of interest and publicity around RFID concerns a very specific application of the technology: supply chain optimization. By using RFID to track medical devices through the global supply chain, manufacturers, distributors and suppliers will be able to manage their inventories more efficiently. This will reduce the cost of supply chain

[71] See "Radio Frequency Identification: Applications and Implications for Consumers," Federal Trade Commission (March, 2005) at 15.
[72] See EPCglobal at 10.

management, resulting in cheaper medical devices for consumers.

Most importantly, RFID could be instrumental in preventing medical errors and increasing patient safety. Facilitating efficient medical device recalls and adverse event reporting are just some of the ways in which RFID can be used in healthcare facilities to protect patients from harmful or fatal errors involving medical devices.

RFID is not intended to track people, or gather personal information about medical patients. Modern RFID technology (e.g., secure EPC) is specifically tailored to protect the privacy of those who utilize tagged products. Industry trade groups, government agencies, consumer advocacy groups and responsible RFID technology providers, including ADC, are all working hard to ensure that RFID is used solely for its intended purposes.

Respectfully submitted,

Avery Dennison Corporation

By: /s/ Ronald E. Quirk, Jr.
Its Attorney