APS Advancing Patient Safety Coalition

Unique Device Identification for Medical Devices

Unlike medications, medical devices are not identified in a systematic and consistent manner. The resulting *ad hoc* approach results in increased clinical risks to patients. These clinical risks are: possible implantation of a defective or recalled product, inability to track the recipient of a faulty product (recalls) and inability to track adverse events appropriately. Therefore, a defective device could remain undiscovered for a longer time and the ability to assess a device's effectiveness is compromised today because of the lack of a uniform, unique numbering system for medical devices.

Unique identification of medical devices is a 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 600 medical device recalls are issued each year and, over the past four years, there have been over 60 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. As one hospital executive stated, "This creates a significant work load impact, but more importantly, there is a significant risk of missing a patient who may have received a defective device. This is of tremendous concern to the caregivers."

Unique device identification will strengthen the ability of 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 (such as MAUDE and MedSUN) is extremely problematic.
- Reliable identification of medical devices would enable data mining so that FDA and manufacturers could better identify potential problems or device defects. Today this is done by FDA for drugs.

Unique device identification is a key step in reducing medical errors and improving patient safety

- Correctly identifying devices, tracking them through the healthcare system and informing the proper practitioner about any potential dangers will reduce errors and improve patient safety.
- Specifically, UDI would improve patient safety and reduce errors by doing the following:
  - Facilitating the identification of device compatibility problems
  - Ensuring that the right device is available to the right patient at the right time
  - Providing the ability to trace contaminated instruments or equipment back to patients
  - Making sure no devices are left behind in patients during a surgical procedure

Unique identification of medical devices will complete the electronic health record

- Electronic health records (EHR) will require that data standards—including those for medical devices—are in place and used by all institutions in order to transfer information.
- Having a UDI for medical devices is a basic requirement that must be in place before automated identification systems are fully effective.
- A common vocabulary for medical devices is necessary for healthcare providers to be able to effectively document devices in patient records.

APS Advancing Patient Safety Coalition

March 22, 2012

The Honorable Jeff Merkley
United States Senate
313 Hart Senate Office Building
Washington, D.C., 20510

Dear Senator Merkley:

The Advancing Patient Safety Coalition is committed to improving patient safety through the establishment of national unique device identification (UDI) system. As prominent hospital, physician, nursing, research, quality and patient advocacy organizations, we are writing to express our strong support for the Ensuring Safe Medical Devices for Patients (S.2193) bill. We commend you for introducing this legislation which will help protect the safety of patients, reduce medical errors and strengthen the ability of the Food and Drug Administration (FDA) and manufacturers to monitor adverse events.

The Food and Drug Administration Amendments Act of 2007 requires the FDA to issue a regulation implementing a mandatory national UDI system. While the FDA has developed a proposed rule on UDI, it has been held up in the Office of Management and Budget (OMB) clearance process for over six months. We applaud you for recognizing the immediate importance of establishing a UDI system by introducing legislation that would require the FDA to issue a final rule by December 31, 2012, and implement the rule no later than one year after the date the final rule is released.

As the nation struggles to find ways to achieve savings while improving quality in the healthcare system, the creation of a medical device tracking system is a critical missing piece. Unlike virtually every other product on the market in America, there is no uniform identification system for medical devices. The lack of such a system means that most hospitals are left to manually enter data about devices and review countless records and patient charts when recalls occur—a labor-intensive process that poses a high risk for overlooking affected patients. The rapidly rising number of medical device recalls, accelerated by the increasing complexity of the variety of medical devices, adds urgency to the need for an effective UDI system which will promote a better managed system of recalls and corrections, and effectively match each patient to the device prescribed.

The resulting *ad hoc* approach not only results in increased clinical risks to patients, but also creates an estimated $16 billion in costs annually due to inefficiencies in the medical products supply chain. The efficiencies gained through UDI will allow providers to reinvest in initiatives to improve the quality and safety of care.

Finally, an effective UDI system is essential to maximizing the value of electronic health records (EHRs) by enabling standardized tracking of devices. EHRs will require that data standards, including those for medical devices, are in place and used by providers to transfer information.

We thank you again for introducing the Ensuring Safe Medical Devices for Patients bill and stand ready to assist you in any way to ensure passage of this important legislation.

Sincerely,

AARP
Alliance for Advancing Nonprofit Health Care
Alpha-1 Association
Alpha-1 Foundation
American Association of Neurological Surgeons (AANS)
American Association of Orthopaedic Surgeons
American Heart Association
American Nurses Association
Association for Healthcare Resource & Materials Management
Association for Professionals in Infection Control and Epidemiology (APIC)
Association of American Medical Colleges
Catholic Health Association of the United States
Congress of Neurological Surgeons (CNS).
COPD Foundation
Federation of American Hospitals
Georgia Hospital Association
MedicAlert Foundation
National Association for Continence
National Association of Public Hospitals and Health Systems
Novation
Peacehealth
Premier healthcare alliance
Society for Cardiovascular Angiography and Interventions
Texas Health Resources
Truth in Medicine Incorporated
University HealthSystem Consortium
Valley Health System
VHA Inc.
West Virginia United Health System

APS Advancing Patient Safety Coalition

September 19, 2011

The Honorable Jacob J. Lew, Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Director Lew:

The Advancing Patient Safety Coalition is committed to improving patient safety through the establishment of a national unique device identification system. As prominent hospital, physician, nursing, research, quality and patient advocacy organizations, we are writing to express our strong interest in seeing the Office of Management and Budget (OMB) release the proposed rule on the unique device identification (UDI) system for medical devices. The Food and Drug Administration Amendments Act of 2007 requires the Food and Drug Administration (FDA) to release a regulation implementing a UDI system.

It is imperative that OMB work expeditiously to release the proposed UDI rule, as the rule is critical to patient safety improvement initiatives and medical error reduction. Unlike other products on the market in America, there is no uniform identification system for medical devices. The resulting *ad hoc* approach results in increased clinical risks to patients and an estimated $16 billion in costs annually due to inefficiencies in the medical products supply chain.

The rapidly rising number of medical device recalls, accelerated by the increasing complexity of the variety of medical devices, strongly points to the need for an effective UDI system which will promote a better managed system of recalls and corrections, and effectively match each patient to the device prescribed. Due to the absence of a UDI system, providers must often use manual and imprecise systems to identify products that are recalled as well as provided to the patient adding unnecessary costs and delays to the healthcare system.

Finally, an effective UDI system 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 providers to transfer information. The efficiencies gained through UDI will save the healthcare system billions of dollars, which providers could reinvest in initiatives to improve the quality and safety of care.

We look forward to hearing about OMB's plan for releasing the proposed rule on a UDI system for medical devices, and we ask that you provide us with an update on where OMB is in the process.

Sincerely,

Alliance for Advancing Nonprofit Health Care
Alpha-1 Association
Alpha-1 Foundation
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American College of Obstetricians and Gynecologists
American Heart Association
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COPD Foundation
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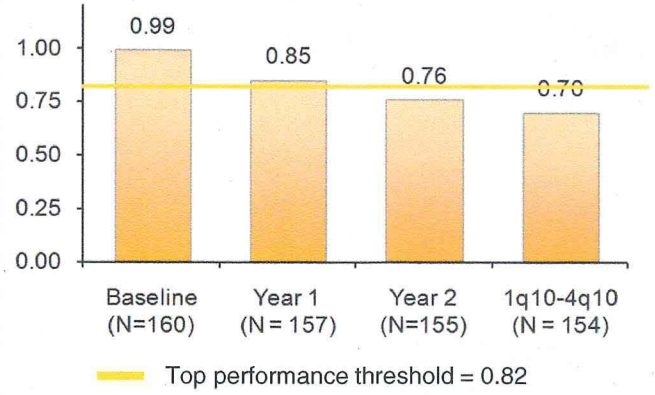
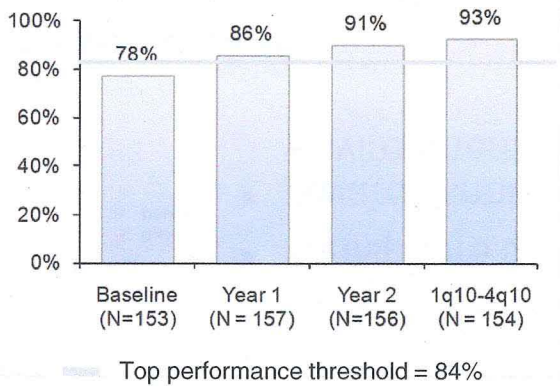
MedicAlert Foundation
National Association For Continence
National Association of Public Hospitals and Health Systems
Novation
Peacehealth
Premier healthcare alliance
Society for Cardiovascular Angiography and Interventions
Texas Health Resources
University HealthSystem Consortium
Valley Health System
VHA Inc.
West Virginia United Health System

QUEST: Real, sustained improvement in quality and cost

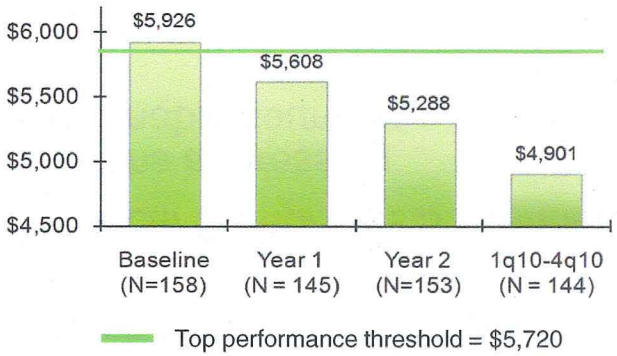
Trends for Mortality Among QUEST Participants



Trends for Evidence Based Care Among QUEST Participants



Trends for Cost of Care per Patient Among QUEST Participants

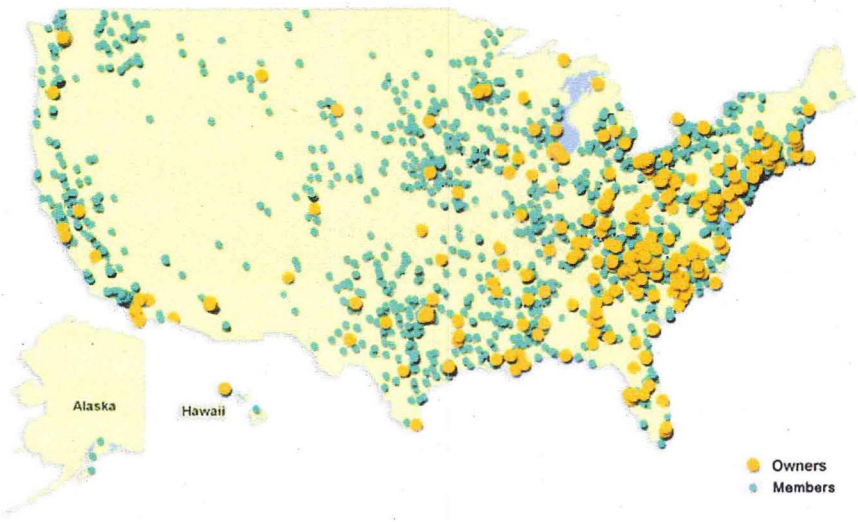


	Year 1	18 Months	Year 2	30 Months	Year 3
Lives Saved	8,118	12,285	17,264	20,314	24,820
Dollars Saved (millions)	$685	$1,307	$2,098	$3,152	$4,450
Patients receiving EBC	18,359	31,090	44,629	60,247	75,638

If all hospitals across the country achieved these gains, an estimated **87,250 lives** and **$34 billion** could be saved each year.

Premier healthcare alliance:

Uniting a fragmented healthcare system



- Uniting more than 2,500 hospitals and nearly 80,000+ alternate sites of care
- $40+ billion in annual group purchasing volume
- Nation's largest clinical/operational/supply chain comparative databases
- "Gold standard" code of conduct
- 2006 recipient of Malcolm Baldrige National Quality Award
- Ethisphere's Most Ethical Companies 5X winner
- Award winning programs addressing environmentally sustainable sourcing

Cost Reduction

Group Purchasing & Supply Chain Improvement, Labor Management

Quality Improvement

Quality Measurement & Benchmarking, Safety Surveillance, Premier Research Services

Risk Mitigation

Liability, Benefits & Risk Management

Public Affairs

Shaping policy and advocating for members

Implementation Engine

Comprehensive, accelerated approach to improving financial, operational and clinical performance.

Right Patient, Right Time, Right Device:

The Value of Creating A National Unique Device Identification System

Premier, Inc.
444 North Capitol St., NW
Suite 625
Washington, DC 20001

Right Patient, Right Time, Right Device:
The Value of Creating A National Unique Device Identification System

Executive Summary

A patient today faces a significant risk that a recalled medical device could be used in his or her treatment because there is no way for a provider to quickly and reliably identify a recalled device. Unique device identification (UDI), which is applying a uniform and transparent system to identify devices, will strengthen the ability of the Food and Drug Administration (FDA) and manufacturers to monitor adverse events related to medical devices. A national UDI that is coordinated with a global system would create a common vocabulary for reporting and enhance tracking abilities. Moreover, this system will reduce the cost of healthcare.

Although many device manufacturers bar code their products, an industry-wide device identification system with a common vocabulary does not exist, preventing hospitals from consistently tracking their overall device inventory. The lack of an industry-wide device identification system also burdens FDA resources – the agency must weed through large data bases of reported device problems from physicians and patients to identify trends that need follow up.

UDI will also greatly benefit the U.S. healthcare supply chain through increased efficiencies and improved order accuracy, which will result in substantial savings of an estimated **$16 billion annually**. The efficiencies gained and savings realized as a result of UDI will benefit all stakeholders in the supply chain, including healthcare providers, distributors and manufacturers. Patients will be the ultimate beneficiary of a more efficient supply chain system because providers will be able to track recalled products more accurately and improve the quality, safety and affordability of care they provide their patients.

To date, numerous studies and pilots in other industries have demonstrated the savings and efficiencies gained through supply chain data synchronization. In fact, unique identification and data synchronization have been embraced by 20 other industries because of the savings and improved efficiencies obtained. It is long past time for our health system to implement such proven methods of data synchronization.

- Wal-Mart decreased item maintenance **from 15-30 days to 1 day.**
- Procter & Gamble **saved $3 million in administrative costs** that had been devoted to manual information synchronization.
- Sara Lee reported a 59 percent reduction in cost mismatches after the initial 90 days of their price synchronization pilot.

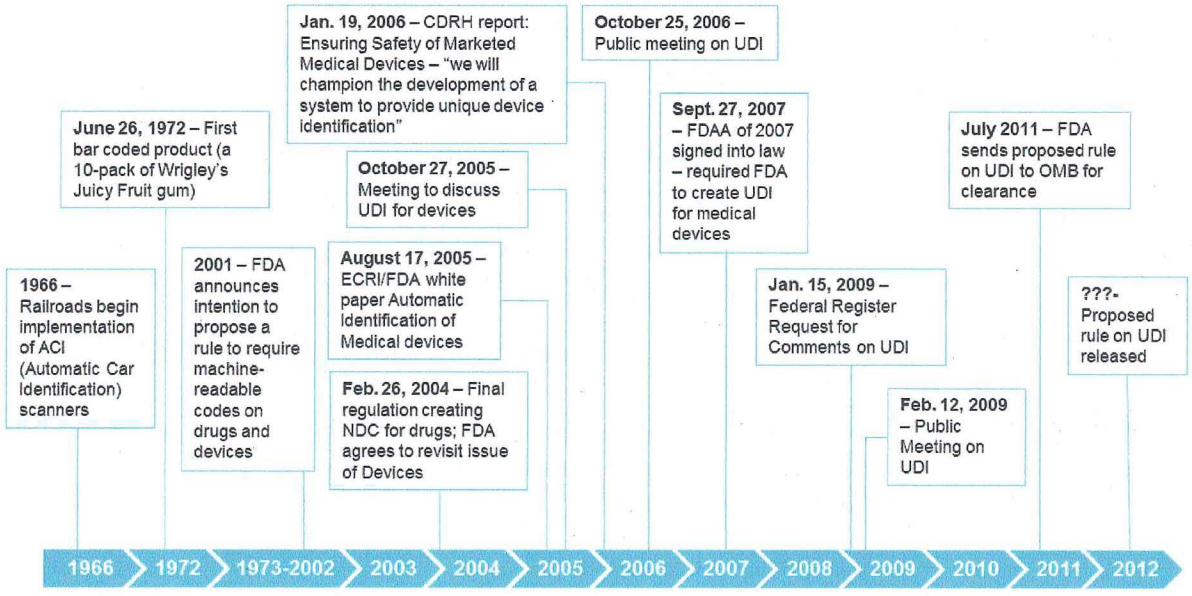
Right Patient, Right Time, Right Device:
The Value of Creating A National Unique Device Identification System

Introduction:

A patient today faces a significant risk that a recalled medical device could be used in his or her treatment because there is no way for a provider to quickly and reliably identify a recalled device. Moreover, without an appropriate identification and tracking system, a defective device could remain undiscovered for a longer time, which is a significant patient safety concern. Additionally, the ability to assess a device's effectiveness is compromised today because, unlike other products in America, no uniform, unique identification system exists for medical devices.

Unique device identification (UDI) will strengthen the ability of the Food and Drug Administration (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. According to the FDA, they received 66,000 adverse event reports, but 15 percent lacked a model or catalogue number, 50 percent lacked lot or other identifier and 10 percent lacked both.

The FDA has been working on this issue for more than eight years. In that time, the agency has held several public stakeholder meetings, solicited comments and commissioned several studies. Patients cannot afford to wait any longer.

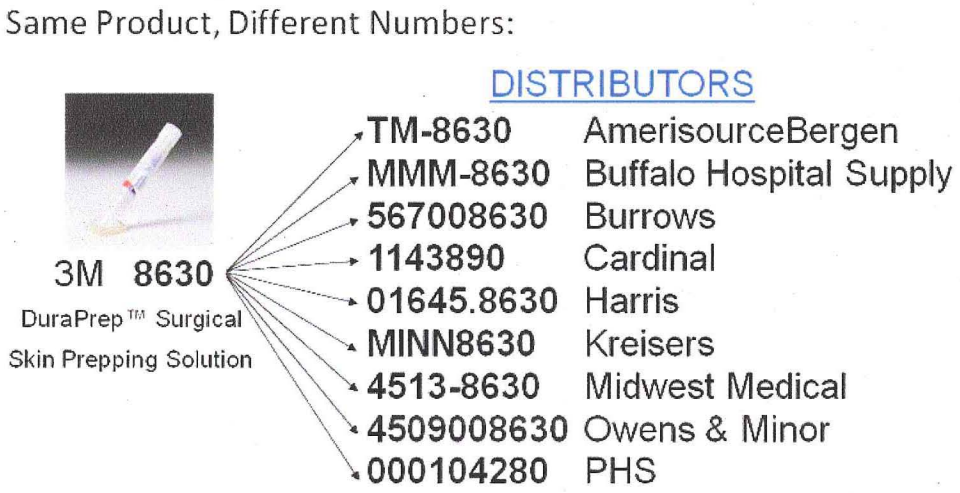


Patient safety case – it's a win-win:

Every year, more than 1,000 medical devices are recalled – many of which can potentially cause serious health problems or death. Manufacturers also issue countless device corrections each year that have serious health implications for patients, such as adding new instructions to devices to prevent device misuse and potential harm.

Even safe medical devices can pose dangerous health threats to patients if used together with other incompatible devices or machinery. For instance, certain pacemakers can negatively interact with the magnetic fields in magnetic resonance imaging (MRI) machines, causing life-threatening injuries – and even death – to thousands of patients undergoing routine imaging procedures. Without an industry-wide identification and tracking system for medical devices, however, healthcare providers cannot identify device incompatibilities in time to avoid these devastating patient safety errors.

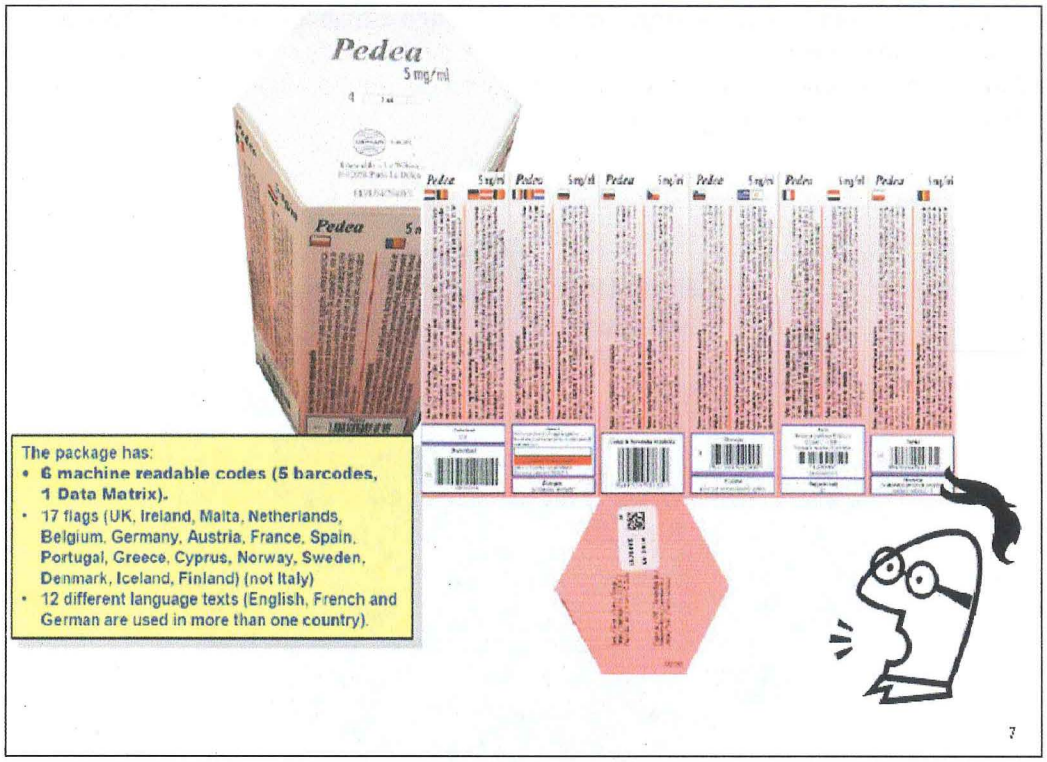
Although many device manufacturers bar code their products, an industry-wide device identification system with a common vocabulary does not exist, preventing hospitals from consistently tracking their overall device inventory. As a result, most hospitals are left to manually enter data about devices and review countless records and patient charts when recalls occur – a labor-intensive process that poses a high risk for overlooking affected patients. The diagram below provides an example of how one product gets renumbered in the healthcare supply chain. This makes it very difficult to track and efficiently handle recalls.



... plus different numbers in each Hospital Group's MMIS

The lack of an industry-wide device identification system also burdens FDA resources – the agency must weed through large data bases of reported device problems from physicians and patients to identify trends that need follow up. FDA must then flag potential device defects for the public.

This is also a global problem and represents a significant burden to global manufacturers when trying to address country by country requirements for identification and marking. The example below demonstrates this problem.



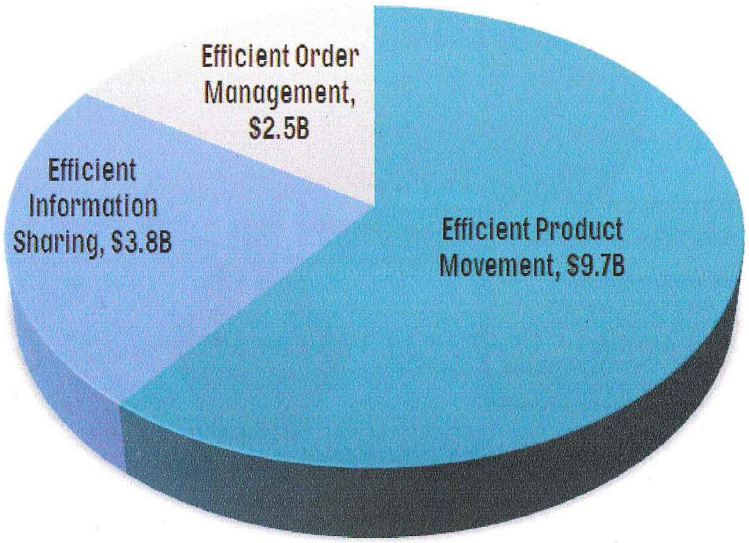
UDI and Supply Chain Savings:

UDI will also greatly benefit the healthcare supply chain through increased efficiencies and improved order accuracy, which will garner substantial savings of **$16 billion annually**. Specifically, UDI will result in accurate orders through improved catalog management and electronic order management, efficient product movement throughout the supply chain, improved inventory management and efficient information sharing.

Other industries have embraced this concept with the grocery industry leading the way on uniquely identifying products through the use of a Unique Product Code (UPC) and automatically identifying the products through bar codes over 30 years ago. On June 26, 1972 the first bar coded product identified with a UPC (a 10-pack of Wrigley's Juicy Fruit gum) was scanned at a check-out counter at a Marsh supermarket in Troy, OH. Since its inception, use of the UPC and bar code identification has grown well beyond the grocery industry so that today, there are over one million companies in more than 100 countries in over twenty different industry sectors enjoying the benefits of scanning bar coded products. It is time the healthcare sector followed suit.

In 1996, the Efficient Healthcare Consumer Response (EHCR) released a study entitled "*Improving the Efficiency of the Healthcare Supply Chain*" stating that $11 billion a year of supply chain costs are avoidable process costs, which could be saved through improved efficiencies. These savings were tied to the adoption of a healthcare identifier, universal product number, identification standards and electronic data interchange and bar coding. This study was recently updated by Arizona State researchers and now estimated supply chain savings total **$16 billion annually for a potential 10 year impact of over $150 billion in savings**.

The majority of the supply chain savings are gained through efficient information sharing, efficient order management and efficient product movement (see chart below). However, there are additional opportunities for savings through physical distribution, transportation, order management and inventory management.



Additionally all the stakeholders—healthcare providers, manufacturers and distributors—in the supply chain stand to share in the savings if the identification standards listed above are realized. However, the biggest beneficiary of a national UDI system will be patients. UDI will enable providers to more accurately and efficiently track medical device recalls, more accurately and improve the quality and safety of care they provide their patients. It will also allow electronic health records to be accurately populated so data to track adverse events and conduct comparative effectiveness research is reliable.

Where are the savings?	
Healthcare Providers	41%
Distributors	26%
Manufacturers	33%

Supply chain studies and pilots demonstrate savings:

As previously mentioned, numerous studies and pilots have been conducted regarding the savings gained through supply chain efficiencies and the creation of a national UDI system.

University of Arkansas: In a 2009 comprehensive survey entitled "*The State of Healthcare Logistics*" conducted by researchers at the University of Arkansas, it was determined that the healthcare supply chain is very inefficient. **In fact, the survey found that the average healthcare provider spends more than $72 million a year on supply-chain functions, which is nearly one-third of their annual operating budget.**

The lack of data standardization was the main obstacle to a mature or extended supply chain. Approximately 75 percent of survey respondents said the lack of data standards is a barrier to their ability to collaborate with other organizations in the healthcare supply chain. Data standards would increase compatibility, reduce redundancy and improve exchange and efficiency.

"Right now, all manufacturers, distributors and providers do not use the same system to identify items, whether they be surgical scissors, heart monitors or cafeteria trays," said Heather Nachtmann, associate professor of industrial engineering. "In short, the health care supply chain is starved for accurate and accessible data, which are the primary barriers to efficiency, collaboration and standardization. Perhaps, needless to say, this is an extremely expensive problem."

Department of Defense (DoD) Data Synchronization Pilot Program: Launched in December 2006, this pilot is the next step in DoD's ongoing, congressionally funded program to test a healthcare "product data utility" (PDU) to reduce healthcare costs, improve business processes and ultimately improve patient safety. In the first phase of the PDU program, the DoD synchronized product data from 23 medical manufacturers, two major distributors and 30 military hospitals, **and identified $10.1 million in savings for the hospitals to date**. The DoD standardized product identification and usage, and created a robust data bank containing more than one million medical/surgical items, including 165,000 synchronized records that represent 93 percent of DoD's most-used medical products.

By synchronizing data, the DoD had better visibility of product and associated contracts/pricing vehicles. EZSav, an application DoD developed to take advantage of the good data, showed customers alternatives for better pricing and also recommended ecommerce sources, eliminating manual contracting for those items. DoD has **saved $35 million purely on price reductions** by buying smarter for the 40 DoD hospitals currently participating. This doesn't take into account the savings accrued in time eliminated doing manual purchases when shifting to ecommerce (prime vendor or web based ordering).

If all participants in the supply chain use the same information, the process of managing the information can be automated. With the implementation of the global trade identification number (GTIN), DoD was able to readily reconcile supplier products to their system products. With this process, there was an estimated **50 percent time savings** in both contract price loads and new item profile data loads.

Premier Purchasing Partners: Premier Purchasing Partners is part of the Premier healthcare alliance, which serves more than 2,200 not-for-profit hospitals and health systems and over 63,000 non acute settings. Premier Purchasing Partners, which aggregates the healthcare provider purchasing power and contracts with suppliers for medical products, conducted a targeted impact study of the potential savings of UDI on

Premier Contracting/Sales Submission process. It was concluded savings would be obtained in several ways:

- Money can be saved on efficiencies if UDI was implemented in the Premier contracting process of over **$50,000 annually**. However, this only looks at efficiencies gained and doesn't remove steps from the process which would likely occur if UDI were implemented so savings could be significantly higher.
- Money can be saved on efficiencies if UDI was implemented in the Premier sales submission process of approximately **$250,000 annually**. However, this only looks at efficiencies gained and doesn't remove steps from the process which would likely occur if UDI were implemented so savings could potentially be significantly higher.

**It should be noted that this Premier savings analyses are based on looking at one process within Purchasing Partners and does not look at other Purchasing Partners activities such as data acquisition, market baskets, revenue reconciliation, contracting management processes, etc. Therefore, the total savings could be significantly higher.*

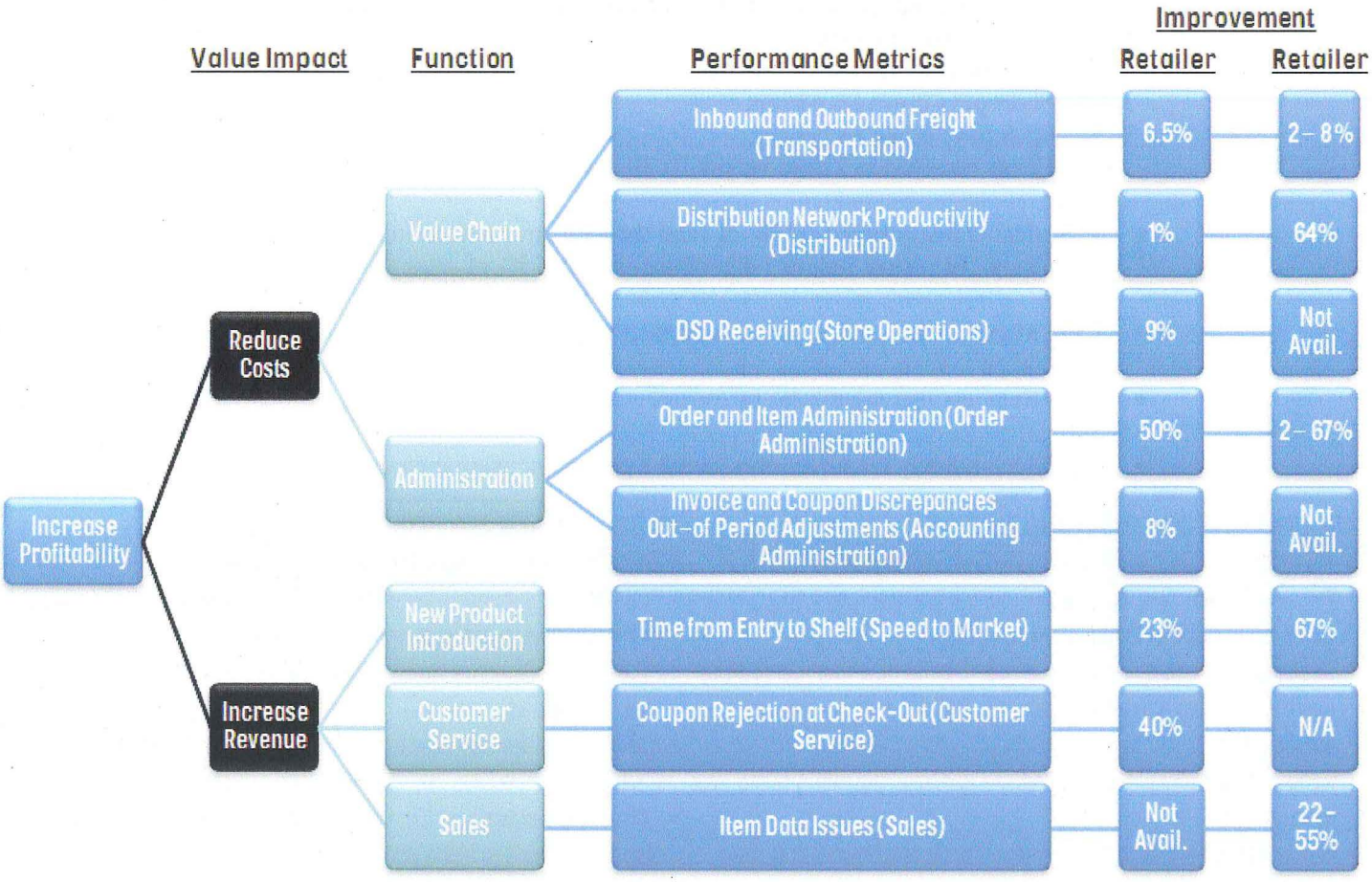
Global Benefits:

Other countries and companies with a global presence have looked at the issue of data synchronization and have demonstrated its benefits from a global economic aspect. Additionally, as medical device manufacturers distribute products world-wide, a single global unique device identification system would provide additional efficiencies for companies in terms of tracking shipments and reducing the instances of counterfeit products.

Cap Gemini Case Study: In a 2003 case study performed by CapGemini under the leadership of the Global Commerce Initiative (GCI) Steering Group, it was demonstrated that adopting and implementing a global data synchronization program would lead to a **1 percent to 3 percent savings in supply chain costs**. In 2005, GCI and CapGemini conducted a study entitled, *"Global Data Synchronization at Work in the Real World: Illustrating the Business Benefits."* Researchers looked at several different industries and found all benefited from global synchronization. Some notable findings are as follows:

- Dutch retailer Albert Heijn improved productivity in their data management department by 30 percent.
- Wal-Mart decreased item maintenance from 15-30 days to 1 day.
- Gillette Venezuela improved order-processing productivity and eliminated master data discrepancies by aligning product information with their trading partners.
- Johnson and Johnson decreased out-of-stocks by 2.5 percent by virtually eliminating data integrity issues.
- Procter & Gamble increased purchase order accuracy by 3 percent by focusing on aligning obsolete products with La Fragua in Guatemala.
- Unilever Columbia significantly reduced data inconsistencies and improved new item speed to market by 2 to 3 weeks.
- U.S. retailer Wegmans Food Markets increased store sales by reducing speed to market on new items by two weeks.

Accenture Report: An August 2006 Accenture report entitled "*Synchronization—The Next Generation of Business Partnering*" clearly confirms that companies that take action are making progress and achieving real results with global data synchronization. Suppliers and retailers that have collaborated and taken an integrated approach to data synchronization have realized **even greater benefits** than originally expected.



Validation from other markets:

As mentioned previously in this paper, unique identification and data synchronization have been embraced by 20 other industries because of the savings and improved efficiencies obtained. Several highlights are described below:

- Item synchronization pilot between Procter & Gamble and their customer H.E. Butt.
  - ✓ 75 percent reduction in invoice deductions due to invoice pricing and product delivery discrepancies
  - ✓ 30 percent improvement in the number of accurate purchase orders received
  - ✓ 80 percent improvement in "speed to retail" for new items, price changes, and promotions (reduced the average time required to communicate and execute changes from 10 days to 2 days)

- Procter & Gamble also saved $3 million in administrative costs that had been devoted to manual information synchronization.

- In the food industry, Sara Lee reported:

  - ✓ 59 percent reduction in cost mismatches after the initial 90 days of their price synchronization pilot
  - ✓ Item mismatches were eliminated
  - ✓ Short pays down 86 percent
  - ✓ Over pays down 81 percent
  - ✓ Errors resolved in 2 days versus 10-30 days

- Electrical industry saved 1.75% of sales through error reduction and improved efficiency. Electrical industry distributors saved .75% of sales annually.

- CPG Manufacturers increased new product market share by 5-15 percent.

- CPG Retailers increased sales by 6 percent due to product visibility.

- Electrical industry manufacturers saved 1 percent of sales annually.

MANUFACTURER BENEFITS REALIZED:

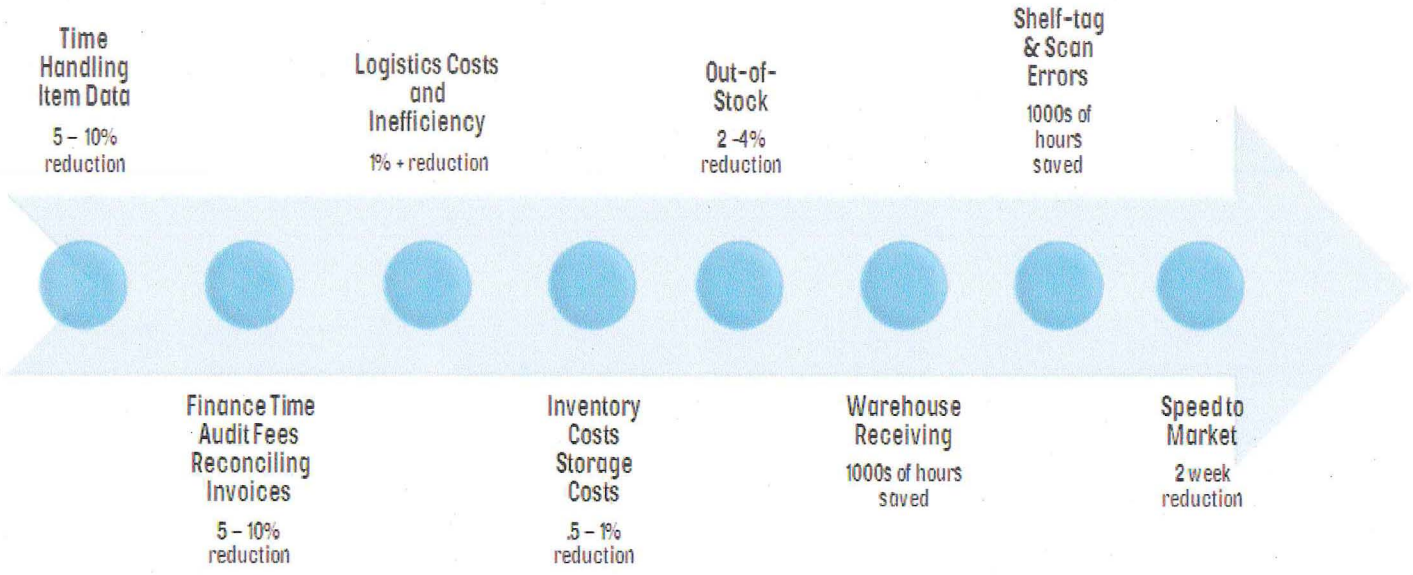
- Three to 5 percent reduction in shelf out-of-stocks
- Two-week reduction in speed to market for new items – i.e., 14 extra days' sales of faster-moving items
- Seven to 13 percent reduction in sales force time communicating basic item information to customers, following up, resolving queries, etc.
- Reduction in call center and website queries regarding basic item information
- Five to 10 percent reduction in sales force and accounting time spent dealing with invoice disputes
- Reduction in invoice write-offs incurred as a result of data discrepancies
- Elimination of basic item data errors, currently found in up to 8 percent of total purchase orders
- 0.2 - 0.7 percent reduction in outbound logistics costs
- 0.5 percent reduction in inventory

RETAILER BENEFITS REALIZED:

- Three to 5 percent reduction in shelf out-of-stocks
- Two-week reduction in speed to market for new items – i.e., 14 extra days' sales of faster-moving items
- 10,000-30,000 hours saved in store labor costs resulting from shelf-tag and scan errors
- 5,000-10,000 hours saved in merchandising and data entry time dealing with new item introductions and updates
- 1,000-2,000 hours saved in finance time dealing with invoice disputes related to basic item information
- Reduction in invoice auditor fees
- One-half to 1 percent reduction in inbound freight costs
- 1,000-2,000 hours saved in warehouse and DSD time dealing with item discrepancies
- One percent reduction in inventory

A.T. Kearney: In 2002, the Grocery Manufacturers of America-Food Marketing Institute Trading Partner Alliance requested A.T. Kearney to conduct an independent review at six pioneering companies to establish a quantification of the costs and benefits of data synchronization. Three leading manufacturers and three leading retailers were selected to participate in the initial case studies – Ahold, USA, Kraft Foods, Nestlé Purina PetCare, Procter & Gamble, Shaw's Supermarkets and Wegmans Food Markets. All six have been pioneers in implementing data synchronization and represent a broad spectrum of size, from relatively small regional players to large diverse conglomerates. The following

chart outlines the areas where improvements were achieved and the level of improvement.



Conclusion:

UDI is crucial for providers to ensure the right device gets to the right patient at the right time, which ultimately improves the quality of care for patients. UDI is also an important part of increasing the efficiency and accuracy of device recalls, improving adverse event monitoring and accurately populating electronic health records. Also, as described above, UDI is essential to realizing the estimated $16 billion in supply chain savings.

Given its impact on a broad range of factors—from improving patient safety to reducing costs—in the healthcare industry, it is critical the regulatory process move forward as expeditiously as possible.