

Summary of HDMA Presentation for July 26 Public Meeting Regarding Bar Code Labeling Requirements

The HDMA speaker would be Robert Schwartz, current HDMA Chairman of the Board and President of the Barnes Division of H.D. Smith Wholesale Drug Company.

Mr. Schwartz will present an overview of HDMA and its membership, discuss the current state of the industry's acceptance of bar codes, and describe the technology available to support this initiative. Mr. Schwartz will also highlight the benefits of bar coding, provide industry statistics related to bar code usage in the manufacturer, distributor and customer settings and explain the impact changes to identification systems would have on the healthcare supply chain.

HDMA's Support of Efforts to Reduce Medical Errors and History with Bar Codes:

HDMA has been an active participant in the National Coordinating Council for Medication Error Rates and Prevention since 2000. We have been pioneers in promoting the usage of bar code standards in the healthcare industry since the early 90's. We have worked collaboratively with the Health Industry Business Communications Council (HIBCC) and the Uniform Code Council (UCC) to develop voluntary guidelines for the industry, and have developed an industry position on the usage of bar codes

Current State of the Industry and Technology Capabilities

Mr. Schwartz will review a flow map showing the entire pharmaceutical distribution chain, noting the places where a bar code labeling requirement would have the most impact. He will discuss current levels of bar code usage, providing statistics related to manufacturer, distributor and pharmacy settings.

Benefits of Bar Coding

Mr. Schwartz will discuss the benefits of bar coding in ensuring the accuracy of medication identification and administration and improving efficiencies within the medication-use process, monitoring of drug-use trends, and overall efficiencies in the supply system and public health and patient safety.

HDMA's Position on Bar Codes

- Identify all levels of packaging, (SKUs, inner packs and shipping cases) with a barcode symbol or symbols that comply with the HDMA Numerical and Automatic Identification of Drug Products Guideline, as revised.
- Use the National Drug Code (NDC) as defined by the Food and Drug Administration (FDA) as the preferred numbering system for drug products.

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- Follow bar code standards published by the Uniform Code Council (UCC) for OTC drug products and Health Industry Business Communications Council (HIBCC) for medical-surgical devices for all packaging levels.
- Apply bar code labeling as early in the supply system as possible, e.g. manufacturing or packaging.
- Conduct appropriate symbology evaluations to determine optimal technology in applying and scanning bar codes.
- Implement bar coding of unit of use and small packages (goal: to have all drug and device products used at the patient bedside carrying a barcode).
- Use bar codes internally wherever possible. Use of bar codes to identify healthcare products has been shown to reduce labor costs in distribution and dispensing while, at the same time, reducing errors.

Impact of Bar Code Changes

Mr. Schwartz will discuss the potential impacts of a bar code requirement on the health care distribution chain. He will discuss the large costs that would be incurred if lot number and expiration date were required as part of the bar code label, as is being discussed. He will discuss the HDMA view that FDA be flexible as to symbology chosen. He will describe the overall huge economic impact on manufacturers and distributors in the areas of packaging technology, equipment components, integration of computer systems, and other implementation costs.

FACSIMILE COVER PAGE

To : Mary C. Gross
Sent : 7/11/2002 at 4:29:16 PM
Subject : Proposed presentation for July 26, 2002, public meeting on bar code labeling

From : Stuart Creque
Pages : 21 (including Cover)

Dear Ms. Gross:

Per my earlier e-mail and voicemail messages, I would like to make a presentation on behalf of findtheDOT to the public meeting to solicit comments for the development of a regulation on bar code labeling for human drug products on July 26 in Bethesda. The proposed presentation is attached (I have sent it to you via e-mail as well).

I believe we can present this in the space of 20 minutes. If less time is available, we can edit it down. Please call me at (510) 377-4658 to confirm. Thank you for your consideration.

Best regards,

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An Alternative Machine- Readable Coding Scheme for Unit Dose Medications

**Presentation to
the US Food & Drug Administration
July 26, 2002**

**Presenter: Stuart Creque
VP, Business Development
(510) 302-3463 ext 204
stuartc@findtheDOT.com**

Presentation

- ***Patient Safety Depends on Verifying the “Five Rights” of Medication Administration***
- ***Quality Depends on Measurable Systems***
- ***Bar Codes and the Bad Trade-off***
- ***Bar Code Legacy Systems: What Do They Have in Common?***
- ***The Answer: a Linking Code***
- ***Comparing Med Dots to Bar Codes***
- ***The Med Dot Patient Safety Solution***
- ***Solution Architecture & Its Advantages***
- ***Cost Advantages***
- ***Licensing Med Dots Industrywide***

“Five Rights” of Medication Administration



- Right patient
- Right medication
- Right dose
- Right time
- Right route – delivery method (oral, injected, etc.) and site (right or left eye, etc.)

Quality Depends on Measurable Systems

- The value of the system lies in verifying 100 percent of medication administration actions and recording (measuring) every one of those actions
 - Measurement is critical to subsequent root-cause analysis and other systemic approaches to error prevention
 - The measurement gives a denominator to calculate true error rates
- Every patient caregiver (RN, LVN/LPN, etc.) must have a validation and measurement tool

Bar Code-Based Approaches

Data about medication is embedded in the code

- Implies generating & printing codes on the fly
- New data requirements = new codes on packages
- More data = bigger code
- Still requires lookup from database to compare content of code to medication order

The Bad Trade-off of Bar Codes

Symbol size vs. cost of equipment

- 1-D (traditional) bar codes require large packaging area
 - Increases costs of packaging, storage, transportation
 - Require laser scanners for maximum reliability and convenience
- RSS or 2-D (matrix) codes require less packaging area
 - Decreases packaging & related costs
 - Substantially increases system implementation costs due to more sophisticated, expensive readers

No Good Answer with Bar Codes

- *With traditional bar codes, packaging costs (including retooling production lines) dissuade manufacturers and hospitals have difficulty justifying moderately expensive bar code readers*
- *If the manufacturer tries to reduce packaging costs using RSS or matrix codes, the hospital is even less able to afford to implement the system due to the prohibitive cost of the code readers*

The Bar Code Legacy Vendors

- Baxter (Deerfield, IL) – Autros™
- Becton, Dickinson (Franklin Lakes, NJ) – BD.id-Rx™
- Bridge Medical (Solana Beach, CA) – MedPoint™
- Cardinal Health (Dublin, OH) – Pyxis division – VeriFive™
- McKesson (San Francisco, CA) – Horizon Admin-Rx™
- Siemens Health Services (Malvern, PA) – Med Administration Check

What Do They Have in Common?

- All offer similar solutions
- All use 20-year old industrial bar-code technology
- Total market share is 3%

The shortcomings of bar codes compromise patient safety: 97% of US hospital patients don't have protection against bedside medication errors

The Answer

A new code symbol and reader with these ideal characteristics:

- A “linking code” that links the medication to a database entry that can be dynamically updated
- Large code space: every dose of every medication gets a unique serial number *(critical in the era of genomics)*
- Small size: fits onto economically-sized unit dose packages with little, if any, redesign
- Low-cost reader: equipping every patient caregiver with a code reader is affordable
- Ease of operation: doesn't require careful alignment, extensive software training

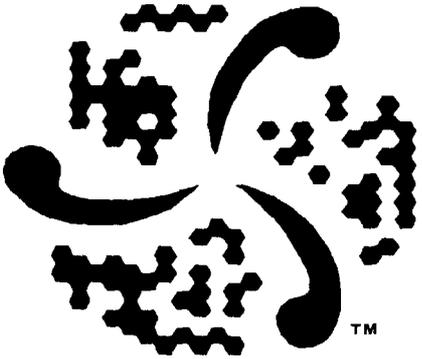
Advantages of a Linking Code

- Static information (e.g., manufacturer, NDC number, lot, expiration date, etc.) can be added to database at any time
 - *Codes can be pre-printed on packaging material, then associated to specific product/plant/line/lot/date information after packaging run*
- Dynamic information (e.g., sales history, medication order details, dispensing history, administration details, genomic customization, lot recalls, etc.) can be tracked for each individual dose
- Same code symbol can be used to identify patient, caregiver, port on IV or other line, etc.
- Same code symbol on paperwork and accessory cards permits automatic charting, documentation, charge capture, etc.

Med Dots v. Bar Codes

Bar codes are missing these five critical features:

- **Small** — 5 mm diameter
- **Reliable** — Forward Error Correction; round shape can be read at any angle
- **Low Cost Reader** — a personal reader can sell for under \$100.
- **Encrypted** — unique and encrypted
- **Huge Code Space** — 500 unique Med Dots for every human being on Earth, every day, for 1,000 years



Enlarged Med Dot

Functional Comparison

Existing Approaches



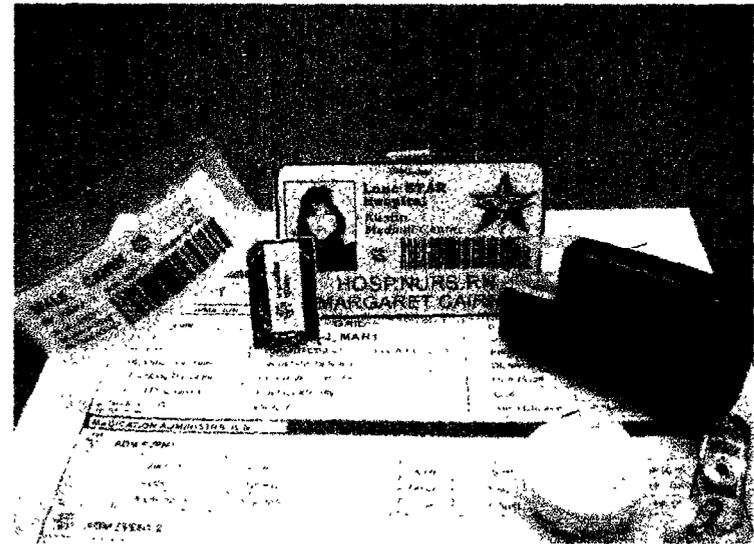
Med Dot Solution

Cost	Bar code readers cost \$300 to \$1150 each.	Wireless Med Dot readers cost \$100.
Ease of Deployment	Other systems require expensive and potentially interfering 802.11 hospital-wide wireless network Extensive training required.	No new network required. The wireless link is direct to the nurse's station PC—30 foot range, in 900 MHz ISM band. Minimal training required.
Compatibility	1-D bar codes are 20X times larger and require secondary drug packaging to hold the large bar code label.	Small (5 mm), round Med Dot fits on unit-dose packaging.
Ease of Use	Industrial bar code scanners weight 8 oz to 2.5 lbs. Often must be attached fragile PDA. Multiple steps are required to scan a bar code.	Dedicated wireless Med Dot reader weighs 1.25 oz. Shirt-pocket friendly. No keyboard. No docking. Automatic data synchronization and recording.
Safety All Five Rights	Existing systems often miss key rights (such as omission, abuse, or wrong time) because bar codes are not unique nor specific to patient.	Each Med Dot is unique to a single-dose for a single patient. Prevents abuse, and tracks errors to the cause of the error.
Expandability	Bar code systems are force-fit into other applications within the hospital.	Med Dots naturally fit into billing, ordering, and other hospital applications.

Med Dot Patient Safety Solution

Med Dots in a Patient Medication Safety System

- Medications are prepared in the hospital pharmacy in unit doses.
- Each dose is marked with a “Med Dot” (unique machine-readable code)
- The nurse taps the Med Dots with her “Dot Finder” (compact wireless reader)
- The electronic Dot Finder provides instant validation of all five rights.
- The system automatically records details of medication given (patient, nurse, time, drug, dose, route, notes)



Solution Architecture

