Unique Device Identification UDI

AHWP Meeting

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A Promise for Life

Overview

- History
- Value of UDI
- Current activities
- Future

History - US

- 1969 Food distribution groups agreed need of universal code
- 1972 Uniform Grocery Product Code Council formed
- 1973 Committee of grocery industry executives selected 11 digit linear bar code to serve as universal product code
- Later renamed Uniform Code Council (UCC)
- 1983 Group of device trade groups meet which leads to 1984 establishment of Health Industry Bar Code Council (HIBCC).
- HIBCC renamed Health Industry Business Communications Council

History - Global

- 1977 European Article Numbering (EAN) Association Established, later known as EAN International
- HIBICC establishes global presence
- 1977 - 2000 Plus - numerous countries adopted EAN
- 2005 EAN International and UCC joined to become GS1
- 2005 GS1 Healthcare User Group established
- 2007 GS1 Healthcare established

Drivers for UDI/Data Exchange - US

- 1993 -1995 US Department of Defense implemented requirement for bar coding for medical/surgical products (capital equipment excluded)
- 2004 - 2007 USFDA evaluates unique device identification
- 2007 USFDA authority to implement unique device identification system and require device labeling bear unique Identifier
- 2008 Premier announces five year plan to require use of GS1 Standards by 2012
- 2009 Members of Health Industry Group Purchasing Association (HIGPA) endorse use of GS1 standards by 2012

Drivers for UDI/Data Exchange - Global

- Device identifier initiatives in Japan and Turkey
- 2008/9 – GHTF Unique Device Identification UDI Ad Hoc Working Group
- 2008/9 GS1 Healthcare developed 40 additional attributes for use in GDSN (Global Data Synchronization Network)
- 2009 Global Product Classification (GPC) healthcare codes for use in GDSN

FDA believes that UDI can… 1/2

- Reduce device related medical errors - identify compatibility and interoperability issues:
  - right device for right patient (latex allergy)
  - right accessory for right device
  - MRI compatibility
- Improve identification of specific device in adverse event reports
- Facilitate more effective device recalls – identify and locate recalled devices in a timely fashion

Source: FDA – Jay Crowley

UDI can also… 2/2

- Facilitate the population of device use information in Electronic Medical Record Systems (HIT)
- Provide ancillary benefits for a wide variety of stakeholders:
  - Improve materials management and associated healthcare cost savings
  - Help track devices and identify counterfeit devices
  - Identify similar or substantially equivalent devices to avoid shortage

Source: FDA – Jay Crowley

Value for Producers and GPOs

- Public health and safety benefits
  - Medical accuracy
  - Right product in right location at right time
- Controlling costs of production and procurement
- Logistics costs
- Facilitating itemized billing and reaching the perfect order
- Support traceability

Value for Healthcare Providers

- Facilitate patient safety
- Eliminate manual data entry – electronic patient records
- Improve speed of delivery
- Reduce clinical frustration
- Improve traceability and recall capabilities
- Reduce operational expense
- Reduce costs
- Increase collaboration
- Improve analysis
- Improve business intelligence
- Improve back office productivity

Data Exchange Infrastructure

- GTIN (Global Trade Item Number) GS1- Global Data Synchronization Network (GDSN)
- LIC (Labeler Identification Code) - Universal Product Number (UPN) Repository

UDI Data Base

Device Identifier - unintelligent

Device Identification

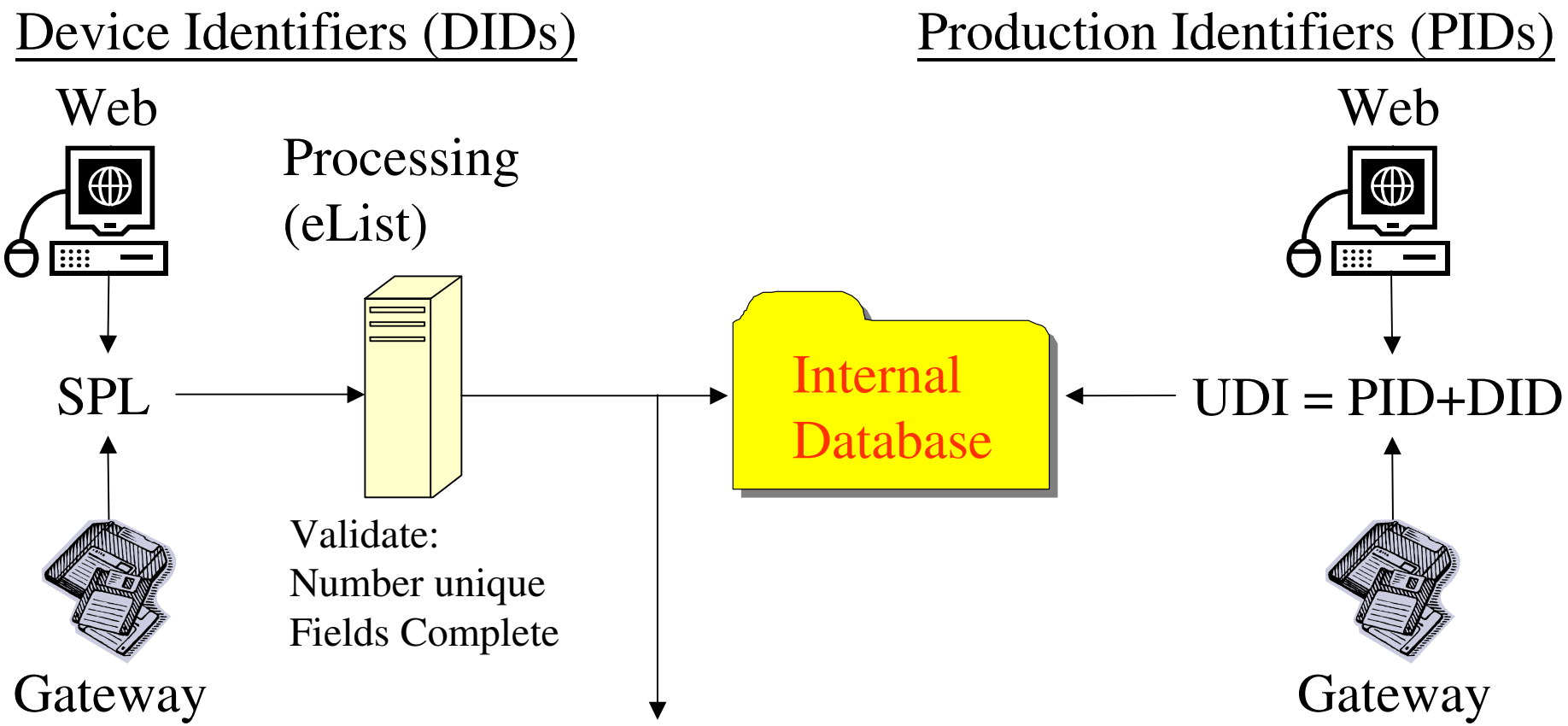
Static:

- Manufacturer, make, model
- Description
- Attributes (size, length, quantity)

Dynamic:

- Software version
- Serial/lot number
- Expiration date

UDI Data Base



Source: FDA – Jay Crowley

GPC for GDSN

- **GPC Code for Drugs: 10005845**
- Definition: Any chemical compound used in the diagnosis, treatment, or prevention of disease, and that achieves its primary intended purposes through chemical action within or on the body.
- Examples: Includes all drugs and biologicals and therapeutic nutritionals, both human and veterinary applications.

GPC for GDSN

- **GPC Code for Medical Devices: 10005844**
- Definition: Products, other than drugs, predominately designed and marketed for use in the diagnosis, treatment, or prevention of disease.
- Examples: All medical equipment, devices and supplies, from cotton balls to MRI machines, e.g. IVDs, implants, surgical instruments, exam gloves, gauze pads, suture, syringes, needles…for both human and veterinary applications. All branches of healthcare services are included: internal medicine, surgical, oncology, dental, emergency….

Data Exchange Pilots

- US Department of Defense
- Australia
- GS1Healthcare
- FDA/GHX
- Individual producers/medical facilities and within medical facilities
- Exchange of experiences and lessons learned
- Producers can use existing GDSN required and optional attributes to gain experience – do not have to wait for regulators to define
- Regulators monitor and with GHTF guidance develop global standardized data sets

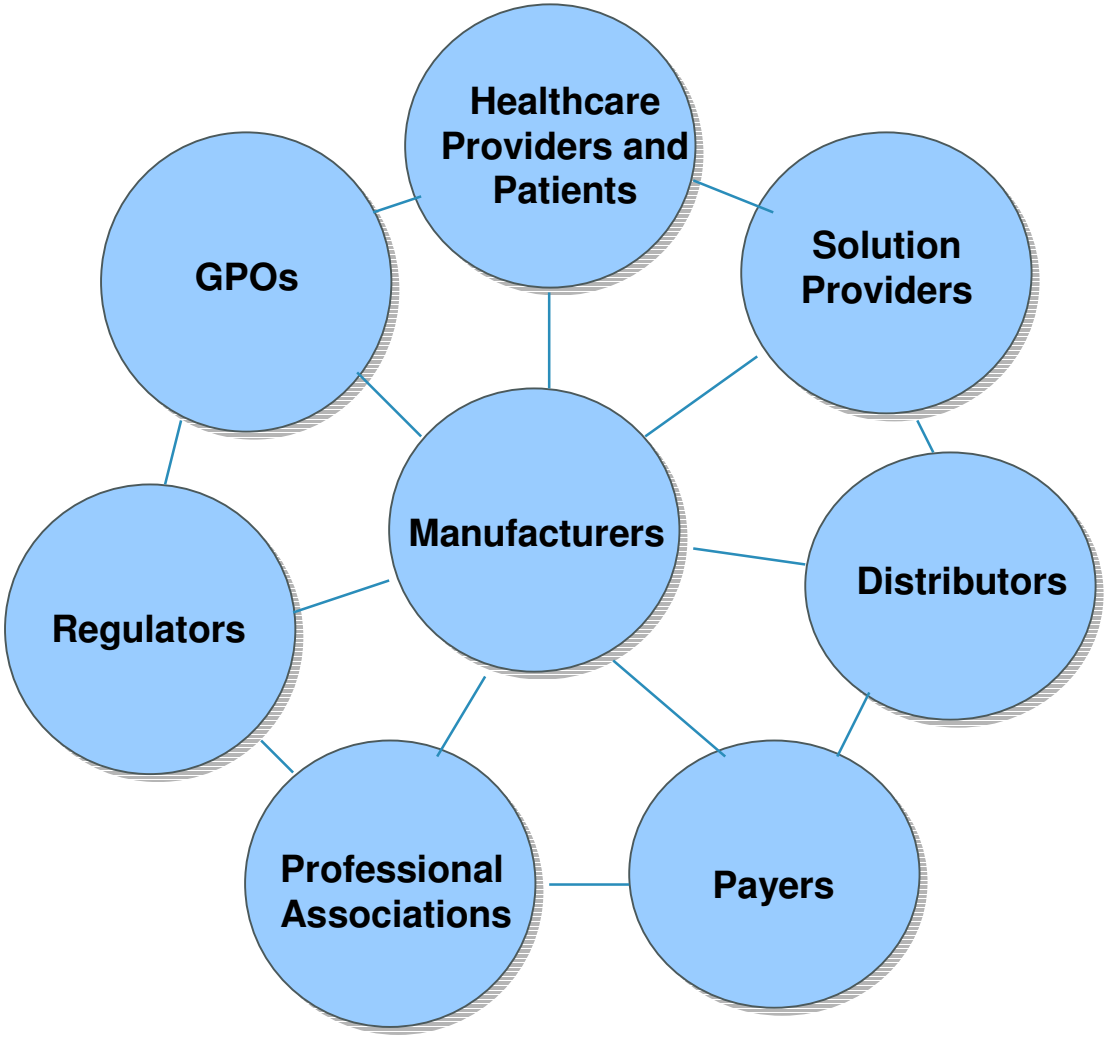
Challenges to Industry

- Long range strategies and implementation plans that reflect business structure of company
- Cost and pass-through costs
- Limited labeling space
- Level of packaging (direct device serialization)
- Lack of data base infrastructure
- Production challenges, e.g. label design and printing equipment (batch vs. online), line speeds
- Lack of customer consensus and level of auto-ID utilization

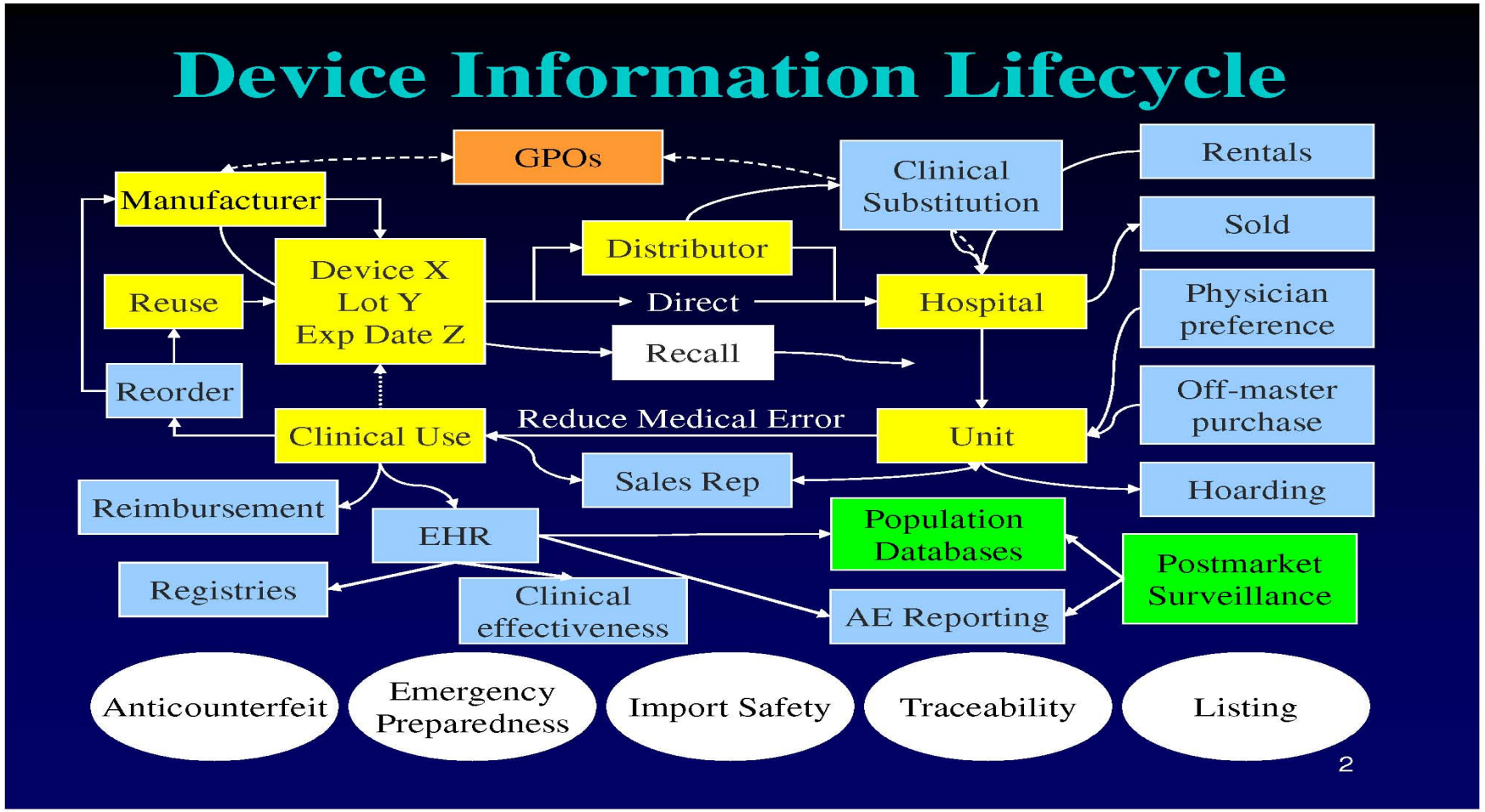
Future

- All stakeholders need to work together to develop infrastructure, procedures and processes that will aid in implementation
- End of why should I do if it will not be used thinking
- GHTF recommendations finalized
- Regulators strive for common data elements for UDI data base based on GHTF recommendations and identify options that will avoid a multiplicity of data bases that industry will have to manually forward data
- Initially keep data base requirements simple
- Standards organizations will have to update standards to provide for additional data elements
- Pilot, pilot, and pilot – Exchange information on results and recommendations

Stakeholders – UDI/AIDC



FDA View of Device/Information Flow



Source: FDA – Jay Crowley

Questions

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