Nothing is more difficult to undertake, more perilous to conduct or more uncertain in its outcome, than to take the lead in introducing a new order of things. For the innovator has for enemies all those who have done well under the old and lukewarm defenders amongst those who may do well under the new.

Niccolo Machiavelli (1523)

Unique Device Identification Update on US and Global Activities

Jay Crowley
Senior Advisor for Patient Safety
Food and Drug Administration
jay.crowley@fda.hhs.gov
301-980-1936

Current Device Identification

- Non-standard device identification systems; standards used in different ways
- Not necessary unique or unambiguous
- Does not include all necessary levels of uniqueness
- Manufacturers' own number/catalogue number
- Distributors' – apply different, proprietary number; lot or serial number not captured
- Hospital – yet different identification number/code
  - Information on use not usually captured
  - Control numbers rarely captured

Future Device Identification

Develop a system to identify medical devices, which is:
- Consistent
- Unambiguous (differentiates among all dimensions)
- Standardized
- Unique at all levels of packaging
- Harmonized internationally

And facilitates the:
- **Storage,**
- **Exchange, and**
- **Integration of data and systems**

UDI Can Improve… Visibility

- Medical device recalls
- Adverse event reporting and postmarket surveillance
- Tracking and tracing, supply chain security; and anti-counterfeiting/diversion (location systems)
- Comparative effectiveness (e.g., registries)
- Disaster/terror preparation and shortages/substitutions
- Reduce medical errors
- Documenting medical device use in patient's EHR/PHR, hospital information systems, claims data
- Sentinel Initiative - strengthening FDA's ability to query data systems for relevant device information

FDA Amendments Act of 2007

September 27, 2007, the FDAAA signed into law:

The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.

GHTF UDI ADWG

- Formed October 2008
- EC Chair (Laurent Selles)
- Members US (FDA, AdvaMed), Europe (EC, Eucomed, EDMA), Japan, Canada
- AHWP recently joined (China)
- Public Document – available at: www.ghtf.org/documents/AHWG-PD1-N2R1.doc
- Washington April 2010; Brussels June 2010
- Final guidance due for Nov 2010 SC meeting

Establishing a UDI System

Combination of 4 distinct steps:

1. Develop a standardized system to develop the unique device identifiers (UDI)
2. Place the UDI in human readable and/or AutoID on a device, its label, or both
3. Create and maintain the UDI Database
4. Adoption and Implementation

1ˢᵗ – Developing the UDI

- Develop UDI code according to ISO 15459 [GS1, HIBCC]
- Created and maintained by the manufacturer
- Concatenating Device and Production Identifier
- Device Identifier (DI): [static] Manufacturer, make, model [i.e., each catalogue number]
- Production Identifier (PI): [dynamic] if currently serialized – serial number; if currently identified at the lot, the lot number, and expiration and/or manufacturing date

2ⁿᵈ – UDI Application

- Applied at all levels of packaging, down to the lowest level (the patient use level or unit of use)

- Human readable and/or encoded in a form of automatic identification technology

- Direct Part Marking (DPM) for some devices

- No specific technology would be identified (technology neutral)

- Identify a series of standards (linear barcode, 2-dimensional barcode, RFID)
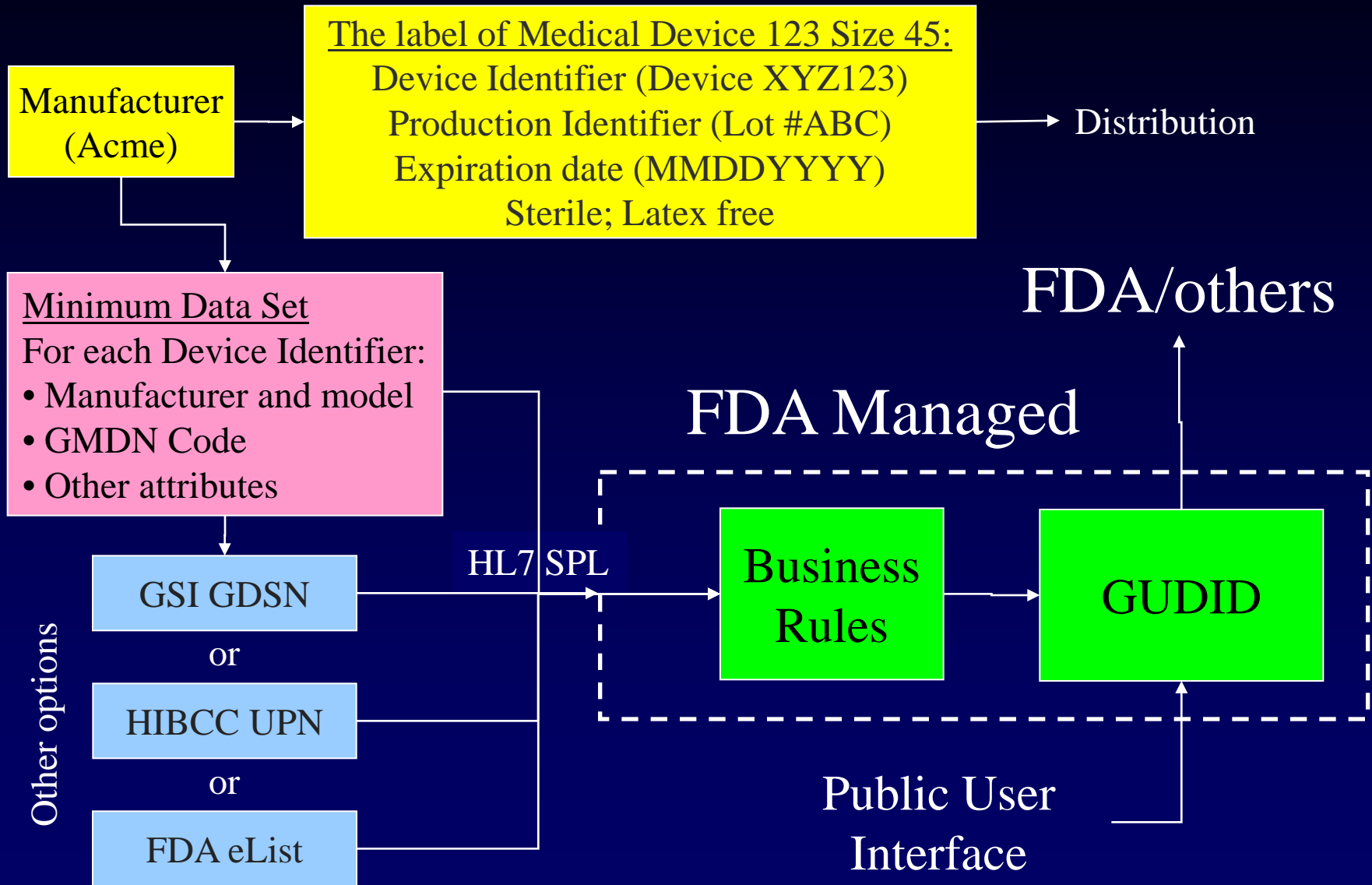
Risk-based Approach

- Production identifier reflects current control (label) – not requiring serialization.
- Granularity of marking based on risk of device - UDI for some devices on multi-packs or higher levels of packaging
- Not all devices require production identifiers
- Take into account realities of retail environment
- Implementation based on risk – premarket class III first; then class II, and finally class I.

3rd - UDI Database Development

- Device Identifier Type/Code [GTIN, HIBCC]
- Manufacturer; Contact name, phone, email
- Brand/Trade Name; Make/model
- Size (e.g., diameter, length)
- Packaging level/quantity
- Control – Lot/Serial Number; Exp., Manuf. Date
- GMDN Classification code and term
- Storage condition (e.g., temperature; humidity)
- Single Use
- Sterility; Restricted Use
- Contains latex

Global UDI Database

Manufacturer (Acme)

The label of Medical Device 123 Size 45:
Device Identifier (Device XYZ123)
Production Identifier (Lot #ABC)
Expiration date (MMDDYYYY)
Sterile; Latex free

Distribution

Minimum Data Set
For each Device Identifier:
• Manufacturer and model
• GMDN Code
• Other attributes

Other options

GSI GDSN

or

HIBCC UPN

or

FDA eList

HL7 SPL

FDA/others

FDA Managed

Business Rules

GUDID

Public User Interface

HL7 SPL

- Working with HL7 SPL r5 Team to model UDI GHTF data elements
- Definitions
- Representation of Various Product combinations
- Identifying a Product without packaging
- Defining System requirements for UDID and internal FDA Product Information Database
- Accept , Store and Transmit HL7 SPL message

GMDN

- Development of global nomenclature to support regulatory and research activities.
- Preferred terms provide high degree of specificity
- Used for signal detection and device comparisons during data surveillance and analyses
- New governance model and activities in place
- Sustainable funding model under development
- Used with UDI/UDID to provide multiple levels of use (general → specific)

UDI Database Pilot – Phase 3

- Purpose: Assess the feasibility of collecting, storing, and retrieving UDI data from initial creation (manufacturer) to point of use (hospital) .

Results:

- Data suppliers (manufacturers) had concerns about data definitions, obtaining the data from various sources and manipulating for UDI upload.
- Participants confused about the purpose/use of UDID.
- Users (hospitals) liked UDID – it provided data they regularly need - e.g. information related to recalls and identifying alternate products/manufacturers for recalls.

UDI Database Pilot – Phase 4

Purpose: Assess how UDI data will impact FDA device information use in current systems

Method:
- Vendors submit data via spreadsheets
- FDA analyze data for completeness and accuracy
- FDA analyze data for impact on current systems
- FDA use results to inform development of UDI Database

Results: Pending

4th – Adoption and Implementation

- Resolve technology issues – barcodes, RFID, DPM
- Develop appropriate UDI Database
- Combination products/kits
- Facilitate distributor uptake and use
- Facilitate hospital uptake and use
- Facilitate use of UDI throughout device lifecycle
- Drive integration – MMIS-Clinical
- Drive appropriate use of UDI in EMRs
- Determine appropriate role in reimbursement
- Address privacy concerns

Limitations of UDI and UDID

- UDI is a foundational element – it unambiguously identifies a specific device (at its unit of use).
- Benefits accrue only if used by all stakeholders.
- UDID contains only "static" identifying and product information.
- UDID does NOT contain production information, such as lot or serial numbers – and is NOT track/trace or other similar purposes requiring the full UDI.
- UDID provides link to product information- not a replacement for Recalls/Adverse Event Databases.

Unique Device Identification

www.fda.gov/MedicalDevices/
DeviceRegulationandGuidance/
UniqueDeviceIdentifiers

Email: cdrhudi@fda.hhs.gov