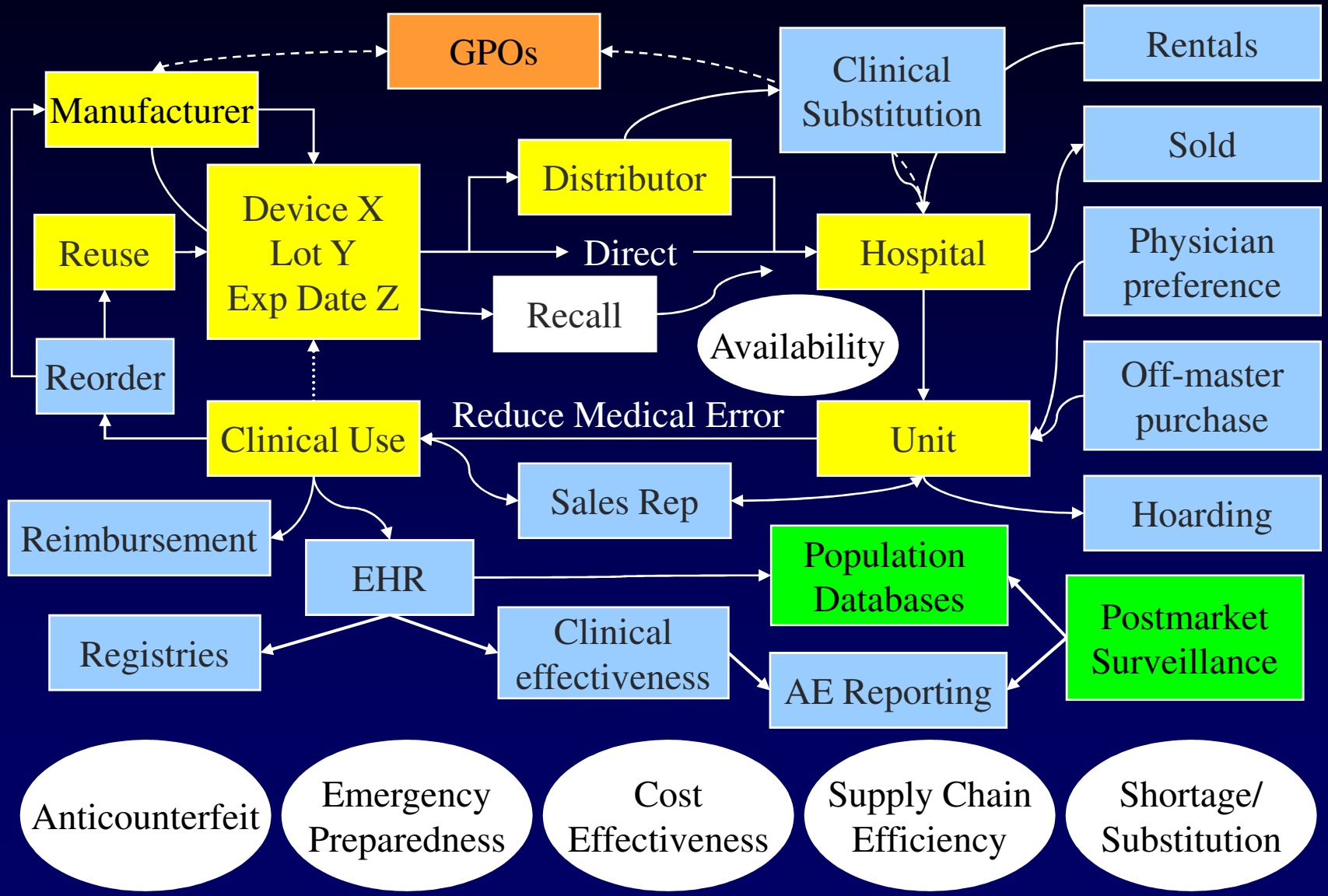
Unique Device Identification

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

Device Information Lifecycle



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

Current Device Identification

Business Name	Item Number Type	Item Number
BD	**Mfg Catalog Number**	**329461**
BD	**GTIN**	**00382903294619**
BD	**GTIN**	**30382903294610**
BD	**GTIN**	**50382903294614**
Cardinal Health	**PV Order Number**	**BF329461**
Owens & Minor	**PV Order Number**	**0722329461**
Owens & Minor	**PV Order Number**	**0723329461**
American Medical Depot	**Vendor Catalog Number**	**777127217**
American Medical Depot	**Vendor Catalog Number**	**777127218**
Government Sci Source	**Vendor Catalog Number**	**FSC1482679CS**
Government Sci Source	**Vendor Catalog Number**	**FSC1482679PK**
Alliance Joint Venture	**Vendor Catalog Number**	**888021932**
Thomas Scientific	**Vendor Catalog Number**	**8938M25**
Thomas Scientific	**Vendor Catalog Number**	**8938M28**
VWR International	**Vendor Catalog Number**	**BD329461**

Current Device Identification

B D Vacutainer Div.	B-d Diagnostics	B-D Sup Chain Svcs	BD / Elastic Health Support	BD Blood Collection Products
B D Acutecare	B-D Labware	B-D Vascular Access	BD Acutecare	BD Convention Needles
B D Diagnostic	B-D Micro Biology Systems	B-D Primary Care	BD Hospital Div	BD Critical Care
B Dickinson	B-D Microbiology	BD Bioscience	BD Biosciences	B-D Primary Care Diag
B&D	B-D Microbiology Systems	B-D / Visitec	BD Diagnostic Systems	BD Diagnostic
B-D	B.D. Microbiology Systems	Bard-parker Respiratory Systems	BD dba Becton Dickinson And Co	BD Diagnostic Instrument Syst
B-D Acutecare Div. Of B-d	B-D Primary Care Diagnostics	BD	BD Bioscience Pharmigen	B-D Sharps Disposal Systems

National Drug Code (NDC)

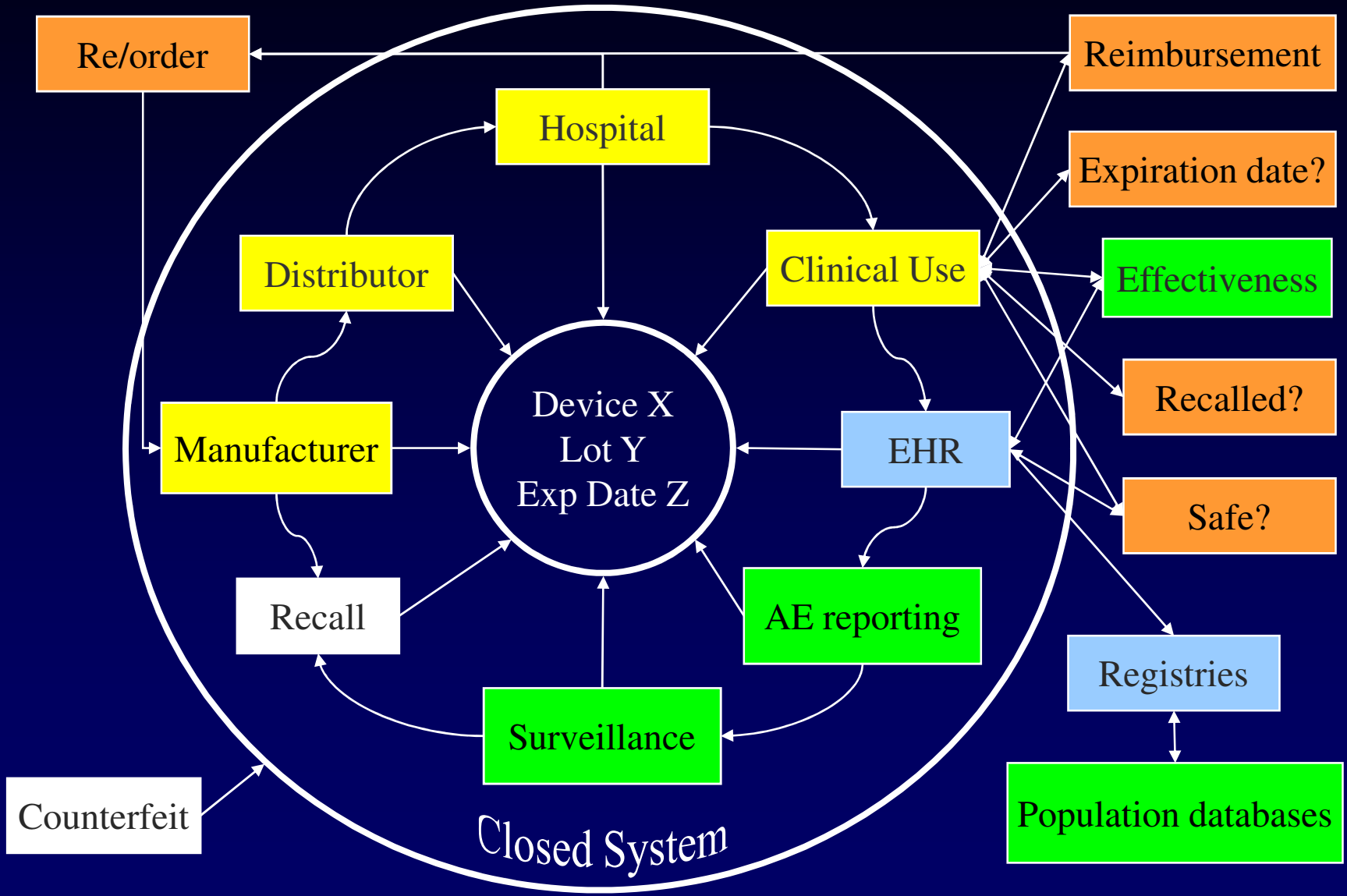
- Developed to identify drugs for reimbursement
- Identifies the manufacturer, product and package size
- FDA took over in 1972 (The Drug Listing Act)
- Pharmaceutical barcode rule – NDC in linear barcode
- Ubiquitous use has facilitated…
  - Analysis of claims in a large database
  - Retrospective chart review
  - Drug interaction checking and decision support
  - Identifying inappropriate prescribing and dispensing
  - Avoiding confusion with look/sound-alike drugs
  - Reporting adverse events

Medical Device Identification

Develop a system to identify medical devices, which is:

- Consistent
- Unambiguous
- Standardized
- Differentiates along all identification dimensions
- Unique at all levels of packaging
- Harmonized internationally

Future Information Lifecycle



UDI Can Improve…

- Medical device recalls
- Adverse event reporting and postmarket surveillance
- Tracking and tracing, supply chain security; and anti-counterfeiting/diversion
- Disaster/terror preparation and shortages/substitutions
- Systems to reduce medical errors
- Assisting clinicians in identifying appropriate device
- 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

Medical Device Adverse Events

For 2007, we received ~ 66k reports

- ~ 15% lacked model or catalogue number
- ~ 50% lacked lot or other identifier
- ~ 10% lacked both

The face of things to come…

(01)00802526255410(17)080531(10)6062151

Medical Device Recalls (2007)

- 41 Class I recalls
- 931 Class II recalls
- 78 Class III recalls
- Class I – 28M units (devices by lots, kits, etc)
  Range 4-27M (Moistureplus Solution)
- For March 2007 – 142 Class II recalls
  35M individual units (just one month)
  Range 1-33M (Lifescan one touch test strips)

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.

FDA Amendments Act of 2007

Establish a unique device identification system:

- Requires that the label of devices bear a unique identifier ["Label" is defined as "…a display of written, printed, or graphic matter upon the immediate container of any article."];
- Allows FDA to describe an alternative placement (e.g., on the device itself or its packaging) for a particular device or device type;

FDAAA of 2007 (continued)

Establish a unique device identification system:

- Allows FDA to exempt a particular device or type of device from the UDI requirements;
- The UDI must adequately identify the device through distribution and use; and
- The UDI includes information on the lot or serial number.

UDI Public Workshop

300 people attended/4000 on webcast

4 Panels addressed issues related to:

- Developing standardized unique device identifiers (UDI)
- Placing the UDI in human readable and/or AutoID on a device, its label, or both
- Creating and maintaining the UDI Database
- Promoting adoption and implementation

Establishing a UDI System

Combination of 3 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

1st – Developing the UDI

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

UDI Application Example

ENDOPATH®

dextrus™

Finger-Mounted Locking Forceps

REF	FMF02	LOT	1Q34
	080100	QTY	4

(01) 2 081019001 002 4

(17)080100(10)1Q34

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CE 0344

Manufacturer
T.A.G. Medical Products
Kibbutz Gaaton 25130 Israel
Tel: 972-4-9858400, Fax: 972-4-9858404

EC REP

EU representative
MEDNET GmbH
Borkstrasse 10 48163 Muenster, Germany
Tel: +49 (251) 32266-0
Fax: +49 (251) 32266-22

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Finger-Mounted Locking Forceps

REF	FMF02

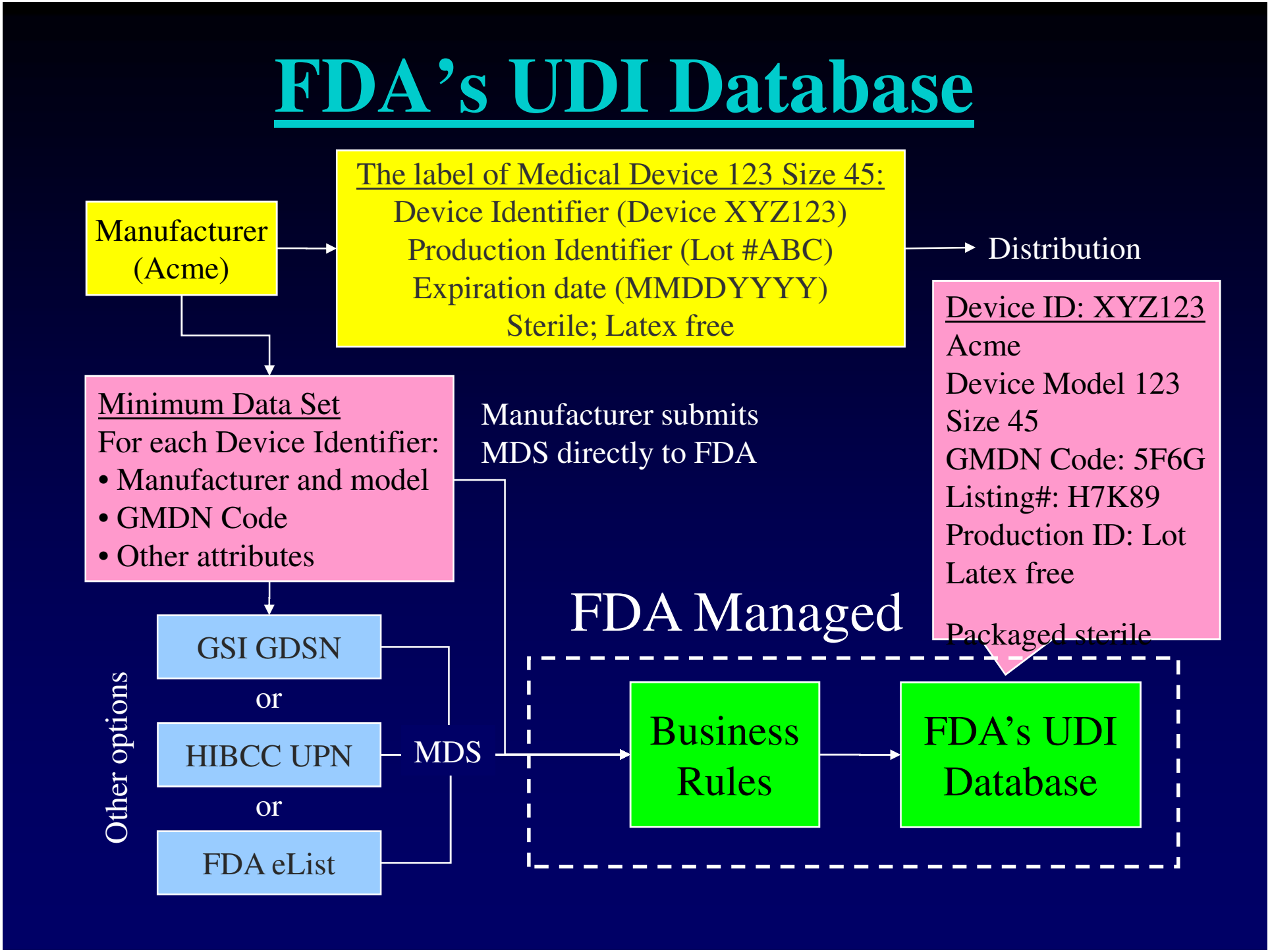
UDI Application Example

3rd – UDI Database

Minimum Data Set for each **Device Identifier**:

- Manufacturer, make/model (catalogue number)
- Description
- GMDN/UNSPCS Category/code
- Control mechanism
- Packaging level/number of items
- Country of origin/manufacture
- Labeled as single use or reusable
- Sterility
- Contains known, labeled allergen (e.g., latex)
- Storage conditions (e.g., needs to be refrigerated)

FDA's UDI Database



Other UDI Issues

- AutoID technology issues
- Kits; combination products; legacy devices
- Re/marking (legally) reprocessed SUDs
- Hospital and other healthcare facility uptake
- Remanufactured and refurbished devices
- Triggers requiring a new UDI
- Complex, multi-system (“capital”) devices
- Harmonized/international database

Unique Device Identification

www.fda.gov/cdrh/ocd/udi/

Email: cdrhudi@fda.hhs.gov