



**California State Board of Pharmacy**

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
PUBLIC BOARD MEETING  
MINUTES**

**DATE:** December 6, 2011

**LOCATION:** Department of Consumer Affairs  
First Floor Hearing Room  
1625 N. Market Boulevard  
Sacramento, CA 95834

**BOARD MEMBERS**

**PRESENT:** Stanley C. Weisser, President  
Randy Kajioka, PharmD, Vice President  
Greg Lippe, Public Member, Treasurer  
Anil Badlani, RPh  
Ryan Brooks, Public Member  
Rosalyn Hackworth, Public Member  
Deborah Veale, RPh  
Tappan Zee, Public Member

**BOARD MEMBERS**

**NOT PRESENT:** Ramón Castellblanch, Public Member  
Shirley Wheat, Public Member

**STAFF**

**PRESENT:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Robert Ratcliff, Supervising Inspector  
Judi Nurse, Supervising Inspector  
Joshua Room, Deputy Attorney General  
Kristy Shellans, DCA Staff Counsel  
Tessa Miller, Staff Analyst

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**I. Closed Session**

Pursuant to Government Code section 11126(c)(3), the board convened in closed session to deliberate on administrative disciplinary decisions at 9:00 a.m.

The closed session adjourned at 10:30 a.m.

## **General Session**

President Stan Weisser called the general session meeting to order at 10:51 a.m.

President Weisser conducted a roll call. Board Members Hackworth, Veale, Lippe, Badlani, Brooks, Kajioka, and Zee were present.

## **II. Announcements**

President Weisser recognized former Board Member Bob Graul who was in attendance in the audience.

## **III. Public Comment on Items Not on the Agenda/Agenda Items For Future Meetings**

Bob Gordon, representing the California LGBT Tobacco Education Partnership, requested the board's consideration to support a resolution to prohibit pharmacies from selling tobacco products.

Ron McGuff discussed the requirement pursuant to Business and Professions Code section 4162 wherein a wholesaler must submit a surety bond of one hundred thousand dollars upon the issuance or renewal of a wholesaler license. He stated that the McGuff Company submitted a request to the board to obtain the amount of funds the board has obtained pursuant to this requirement and received a response indicating that no funds have been collected as a result of enforcement action since January 1, 2006 thru May 31, 2011. Mr. McGuff requested that the board consider the removal of this requirement.

Board Member Ryan Brooks suggested that the board review its contact with Maximus, Inc., the current administrator of the Pharmacists Recovery Program. He requested that the board create a policy and a standard to allow for other potential companies to participate in this program.

President Weisser suggested that Maximus provide a presentation to the board.

Mr. Brooks requested that Executive Officer Virginia Herold send a notification to other companies that provide similar services to be provided with an opportunity to also provide a presentation.

Board Member Rosalyn Hackworth requested that the board be provided with a copy of the board's current contract with Maximus.

Mr. Brooks requested that staff review and report back to the board on the board's current surety bond requirements as well as any other requirements for fees that are being collected but are not currently being used.

President Weisser suggested that surety bond requirements be discussed at a future Licensing Committee Meeting.

#### **IV. Discussion on the Implementation of California's Electronic Pedigree Requirements for Prescription Drugs**

##### **a. Presentation by Connie T. Jung, RPh, PhD, Acting Associate Director for Policy and Communications, Center for Drug Evaluation and Research, US Food and Drug Administration**

Dr. Jung provided a presentation on the FDA's activities regarding a track and trace system for prescription medication. A copy of this presentation is attached, following this meeting summary.

Dr. Jung provided an overview of the supply chain and the many entities involved. She discussed that diversion of prescription medication can occur at any point within the chain and typically involves solid oral dosage forms.

Dr. Jung discussed risks to the drug supply including stolen and counterfeit products and provided an example of stolen insulin in June 2009. She reviewed the increase in counterfeit drug cases opened by the FDA's Office of Criminal Investigation from 1997 to 2010.

Dr. Jung discussed efforts by the FDA to develop supply chain security standards including serialization, authentication, tracking and tracing of product and transaction data, and potential models for this system. She discussed a guidance developed by the FDA and a workshop that was held in February 2011. (A summary of this workshop is available on the FDA's Web site.)

Mr. Brooks left the meeting room at 11:41 a.m. and returned at 11:55 a.m.

#### **Discussion**

The board discussed the role of the serial number identifier (SNI) in this process. It was suggested that guidelines for SNIs be developed.

Ms. Herold discussed that the FDA's guidance in this area is more specific than California's pedigree laws. She stated that effective July 1, 2017, California law will require pharmacies to have an authenticated pedigree for all drug stock. Ms. Herold indicated that the board may want to define SNI and address at what point an SNI will be retired, either at the point a drug enters a pharmacy or at the point of dispensing.

Mr. Brooks discussed that industry will need to ensure compatibility and development of standards within this system and provided an example of the cell phone industry that came together in development of Bluetooth technology.

#### Public Comment

George Pennebaker provided that the National Council for Prescription Drug Programs (NCPDP) is developing standards for data transmission communication in this area.

Mr. Brooks recommended that this issue be further discussed at a future board meeting.

Deputy Attorney General Joshua Room asked whether Mr. Brooks is seeking a possible regulation to define communication standards and data standards that will be implemented for purposes of the pedigree statutes.

Mr. Brooks provided that he personally doesn't believe that government should make this definition. He stated that he wants to ensure there is a standard for data transmission communication.

Mr. Pennebaker discussed that the new systems discussed during Dr. Jung's presentation will present a challenging transition for the 6,000 pharmacies in California. He suggested that there be a phased implementation for new requirements in this area.

Dr. Jung discussed that the FDA is cognizant and will be mindful of the challenges that these systems will present for pharmacies as well as for all parties involved in the supply chain.

Mr. Pennebaker asked whether batch numbers and expiration dates will be incorporated into SNIs.

Dr. Jung discussed that the FDA is recommending that the SNI be limited to the National Drug Code (NDC) and the serial number. She stated that considering the capabilities of data carriers, these additional elements could be incorporated.

Bryce Docherty asked whether there will be a uniform federal standard implemented by the FDA that would exempt the California ePedigree requirements.

Dr. Jung provided that the FDA is aware of California's deadline for ePedigree and will make their standards available as soon as they are finalized.

Gayle Shields, representing the California Department of Corrections and Rehabilitation, sought clarification regarding the tracking of repackaged bingo cards that will be dispensed directly to the patient.

Ms. Herold provided that the pharmacy is required to track the medication when it enters the pharmacy but does not need to serialize the bingo card when it is dispensed

to the patient. She stated that however, manufacturers must create a new serialized number for repackaged products.

Dr. Jung provided that this is consistent with the FDA guidance for repackagers.

Ron McGuff provided comment on data integrity and duplicate SNIs and possible problems in these areas.

Dr. Jung provided that the FDA is addressing these issues.

The board recessed for a lunch break at 12:37 p.m. and reconvened at 2:12 p.m.

## **b. Presentations and Questions from the Pharmaceutical Supply Chain**

### Presentation

Supervising Inspector Judi Nurse discussed that complex drug distribution makes investigation involving diversion and counterfeiting difficult. She provided an example based on a board investigation in which a patient received a drug containing two different HIV medications that originated from an unlicensed California wholesaler broker entity that disperses drugs through many different wholesalers and pharmacies. Dr. Nurse stated that epedigree will drastically benefit the board's investigation of such cases and will help to ensure patient safety.

### Discussion

Ms. Herold discussed that pharmacies are not permitted to sell back drugs to any wholesaler other than the wholesaler in which the drugs were purchased. She stated that the wholesaler surety bond requirement was enacted in the first epedigree law, and is another such safeguard which allows the board to claim against the bond if a licensee fails to pay a fine issued for failure to pass a pedigree.

Mr. Brooks asked for information regarding the types of drugs that are counterfeited.

Dr. Nurse explained that all types of drugs are counterfeited

Ms. Herold discussed that price drives the entire counterfeit process.

Dr. Jung discussed that over-the-counter medication is also being counterfeited.

### Presentation

Elizabeth Gallenagh, representing the Healthcare Distribution Management Association (HDMA), provided a presentation on the distribution of healthcare products within the supply chain. A copy of this presentation is attached, following this meeting summary.

Ms. Gallenagh provided an overview on HDMA as well as background information regarding pedigree.

Mr. Brooks left the meeting room at 2:38 p.m. and returned at 2:41 p.m.

Ms. Gallenagh reviewed other states that have adopted pedigree legislation or have pending legislation. She stated that California is the only state that starts the pedigree requirements at the manufacturer and explicitly includes the serialization requirement.

Ms. Gallenagh encouraged the board to participate in a tour of a distribution center.

Ms. Gallenagh reviewed results from a track and trace survey conducted by HDMA in late 2010. She stated that the survey identified that manufacturers are fully aware of track and trace programs being implemented within the healthcare industry, but pharmaceutical dispensers, particularly hospitals and independents, are not.

Ms. Gallenagh reviewed California issues in this area including grandfathering, drop ship, inference, and decommissioning.

#### Discussion

Dr. Jung provided comment on the international tracking of prescription drugs. She stated that Turkey is currently working on implementation of a track and trace system.

Mr. Room asked whether there is a different context for implementation now compared to in 2008.

Ms. Gallenagh provided that there is a different context now as the industry is more educated about the capabilities and problems in this area. She discussed that there is an emphasis at both the process and technological level.

No public comment was provided.

#### **c. General Discussion**

There was no discussion on this item.

#### **d. Discussion about Future Rulemakings to Implement California's Requirement**

Ms. Herold requested direction from the board regarding development of regulations in this area.

Ms. Herold recommend that the board start this process now and focus on the more straightforward issues including grandfathering and what type of electronic signature will be appended to the pedigree.

Ms. Herold discussed that the board will have to promulgate regulations to implement some of the provisions in the law. Regulations will be required for:

- Inference  
Inference allows a unique identifier to be applied to a case, pallet or other “aggregate” without individually reading each serialized unit. The law specifies that manufacturers, wholesalers and pharmacies distribute and receive electronic pedigrees, and verify and validate pedigrees at the unit level except where efficiency and safety can be secured through inference.
- Decommissioning  
When the medication within a serialized container has been dispensed, there needs to be a process to close out the e-pedigree. Also involved in this is outdated medication or recalled medication that cannot be dispensed.
- Drop Shipment Pedigree  
Drop shipping occurs when products are shipped from manufacturer directly to the pharmacy; however, ownership (and hence the need to append the pedigree) needs to track and certify ownership as it moves from the manufacturer to wholesaler to pharmacy, even though the wholesaler never possesses the medication. There will need to be a rule to describe what must occur in these situations.
- Linkage between invoice and shipping notice  
Invoices are typically sent after drugs are delivered. Shipping notices accompany the shipment. The pedigree requires annotation to the pedigree before the product is sold to another entity – this could occur before the invoice arrives. However, documenting the sale is an important part of the chain of custody created with the e-pedigree system.
- Grandfathering Lists  
The board is required to establish a process for manufacturers, wholesalers and pharmacies to designate drugs already in their possession when pedigree requirements kick in, and exempts these listed drugs from pedigree requirements. The law requires that the drugs be described in written lists submitted to board and specifies that these lists are confidential.

Ms. Herold suggested that the board direct staff to draft an order for these issues to help guide the board at a future meeting. She discussed that it will take some time in order for the board to address these issues and solicit input from the industry to develop adequate language.

Mr. Brooks discussed that input from both the industry and advocates will be needed during this process.

No public comment was provided.

**e. Future Meeting Dates to Discuss Electronic Pedigree**

Ms. Herold reviewed the following meeting dates for 2012:

- March 13
- June 12
- Sept. 11
- Dec. 4

Ms. Herold stated that the March 13 meeting will be rescheduled due to a conflict with an HDMA conference (representing large drug wholesalers) conference on the East Coast. The confirmed dated will be posted on the board's Web site.

There was no board discussion or public comment.

**V. Discussion Regarding the Board's 2011 Sunset Report**

Mr. Herold stated that the Board's 2011 Sunset Report is complete. She indicated that there will be a hearing for this review in February or March 2012.

There was no board discussion or public comment.

**VI. Executive Officer's Report**

Ms. Herold reviewed the following upcoming meeting dates:

- Board Meeting – October 16 and 17, 2012 (TO BE RECHEDULED for October 25 and 26, 2012)
- Communication and Public Education Committee Meeting – January 19, 2012
- Compounding Subcommittee Meeting – January 4, 2012

Ms. Herold provided that the board has secured additional office space across from the board's current suite. She stated that the board's licensing staff will be moving to this new space.

Ms. Herold provided that the board is no longer subject to the hiring freeze and reviewed the current vacancies and recent hires.

Ms. Herold provided that President Weisser and Vice President Kajioka met with the contracted consultant to finalize the board's Strategic Plan. She stated that the plan will be presented to the board at the January 2012 Board Meeting.

Ms. Herold provided that as requested by Board Member Zee, staff will begin reporting mail vote statistics to the board.

There was no board discussion or public comment.



**VII. Update on the Process for Evaluation of Board Executive Officers**

President Weisser provided that the evaluation form will be sent to the board members in the next few days. He requested that the forms be completed and returned to him by January 15, 2012. President Weisser stated that Executive Officer Herold will be completing an evaluation of herself and the board will review the evaluation at the January 2012 Board Meeting.

There was no board discussion or public comment.

The meeting was adjourned at 3:28 p.m.



# **FDA Track and Trace Efforts for finished drug products**

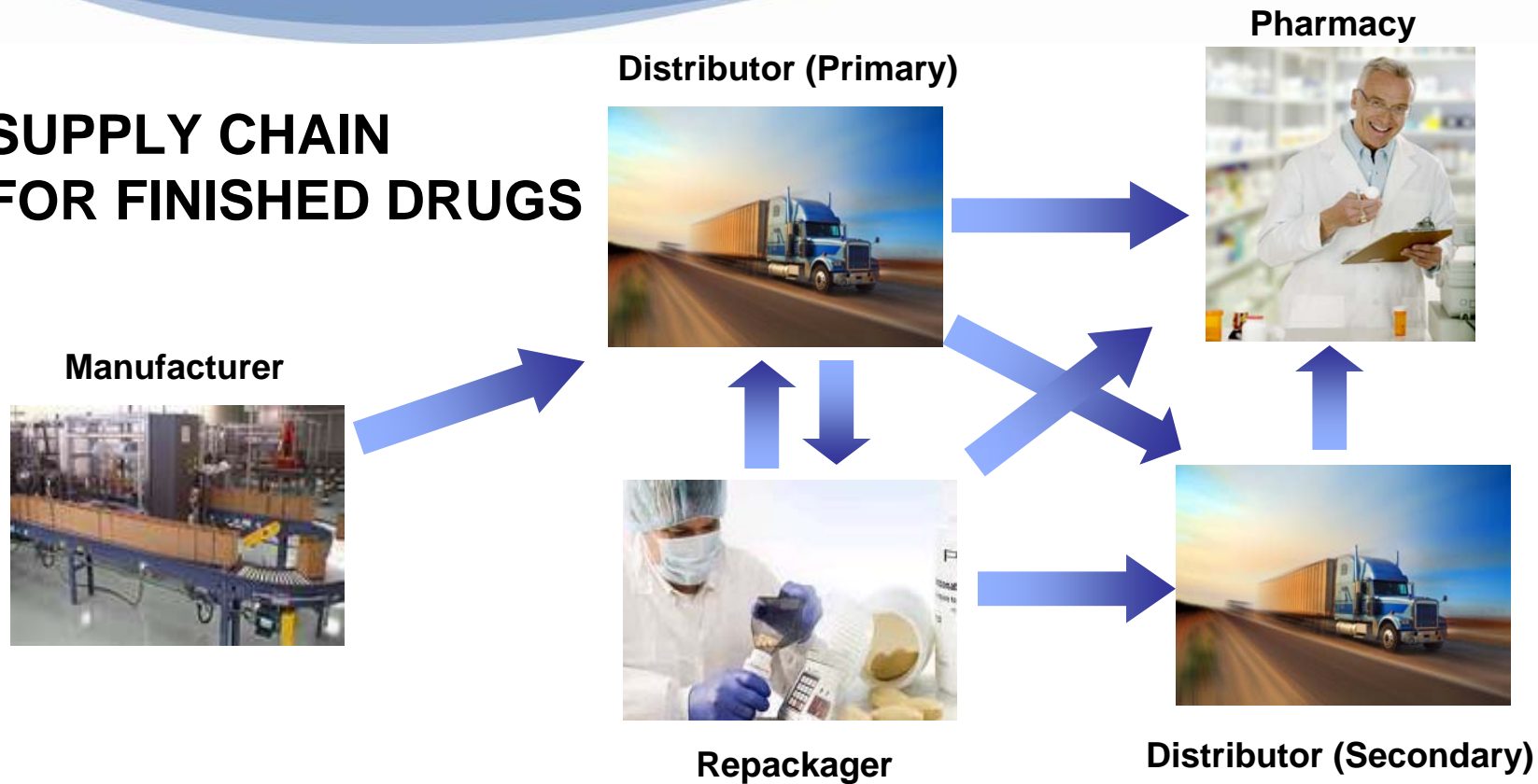
**Connie T. Jung, RPh, PhD**

Acting Associate Director for Policy and Communications  
Office Drug Security, Integrity and Recalls  
Office of Compliance  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration

California State Board of Pharmacy Public Meeting  
December 6, 2011



## SUPPLY CHAIN FOR FINISHED DRUGS



### Complexity of the supply chain is increased by:

- Multiple participants
- Globalization of supply chains
- RulesCriminal activities such as diversion, cargo theft, and counterfeiting
- Rules that vary by state

### Example of vulnerabilities in the supply chain:

- Stolen products reintroduced
- Counterfeit/falsified drugs sold to suppliers
- Diverted drugs resold
- Other adulterated/misbranded drugs introduced



# Preliminary Review of OCI Cases

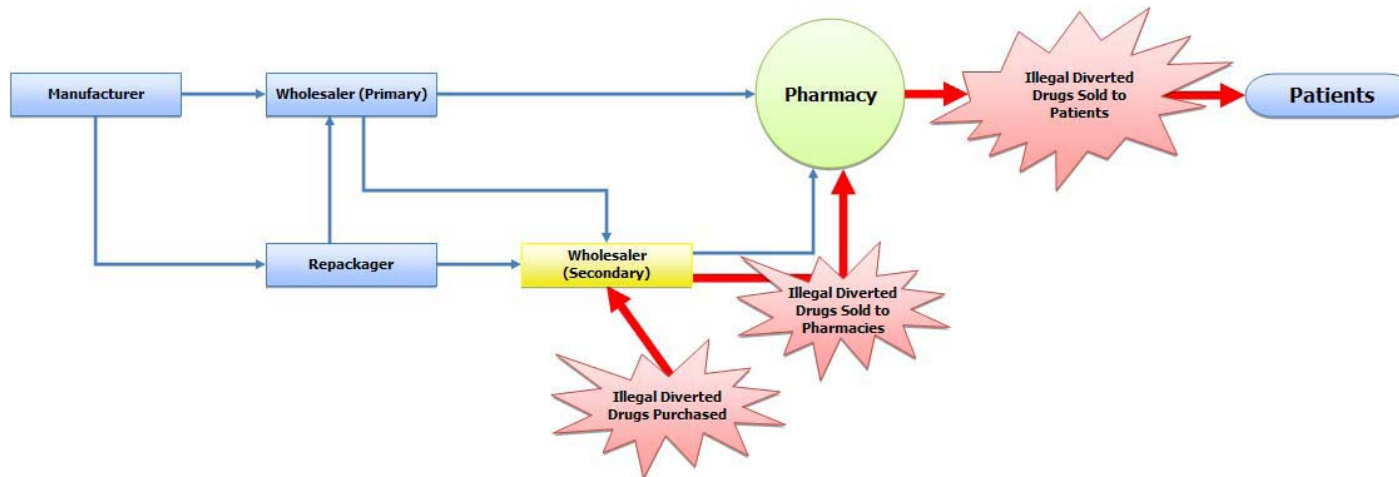
- **Review of case info of diversion and counterfeit judicial cases from 2003-2008\***
- **Purpose of review:**
  1. to describe potential threats to drug quality and integrity;
  2. to help identify where the U.S. drug supply may be vulnerable to diversion and counterfeiting; and
  3. to help identify the types of drugs that have been involved in these diversion and counterfeiting cases.
- **Having a better understanding of the types of schemes, products, and parties involved will help to prioritize risk management activities to protect the legitimate drug supply and help ensure drug quality and integrity.**

\* Since the information was limited to OCI judicial, diversion and counterfeit cases investigated from 2003-2008, the results should not be interpreted as a scientific representation of current drug supply chain trends or a comprehensive review of problems associated with the drug supply chain. Instead, these results should be viewed as an illustrative representation of certain problems and vulnerabilities that we have observed in the drug supply chain.

# Preliminary Review of OCI Cases

## Report Highlights

- **Examples of diversion and counterfeit schemes**



- **Drug products involved (solid oral dosage forms)**
- **Type of entities involved (wholesalers, pharmacist, doctor etc.)**

# Adverse events linked to stolen product




## For Consumers

Home > For Consumers > Consumer Updates

### Consumer Updates

Consumer Updates: Animal & Veterinary

Consumer Updates: Cosmetics

Consumer Updates: Dietary Supplements

Consumer Updates: Drugs

Consumer Updates: Food

Consumer Updates: Medical Devices

Consumer Updates: Radiation-Emitting Products

Consumer Updates: Vaccines, Blood & Biologics

### Resources for You

- Sign up for Consumer Updates by E-mail
- Consumer Updates RSS Feed

## Update to FDA Alert About Stolen Insulin

Search Consumer Updates

The Food and Drug Administration (FDA) is reminding the public that stolen vials of the long-acting insulin Levemir made by Novo Nordisk Inc. still may be on the market. FDA first alerted the public to the theft in June 2009.

Evidence gathered to date suggests that the stolen insulin was not stored and handled properly and may be dangerous for people to use. The agency has received multiple reports of patients who suffered an adverse event due to poor control of glucose levels after using a vial from one of the stolen lots.

In June 2009, FDA reported that three lots of Levemir totaling 129,000 vials had been stolen in North Carolina. So far only about 2 percent of the total amount stolen has been recovered.

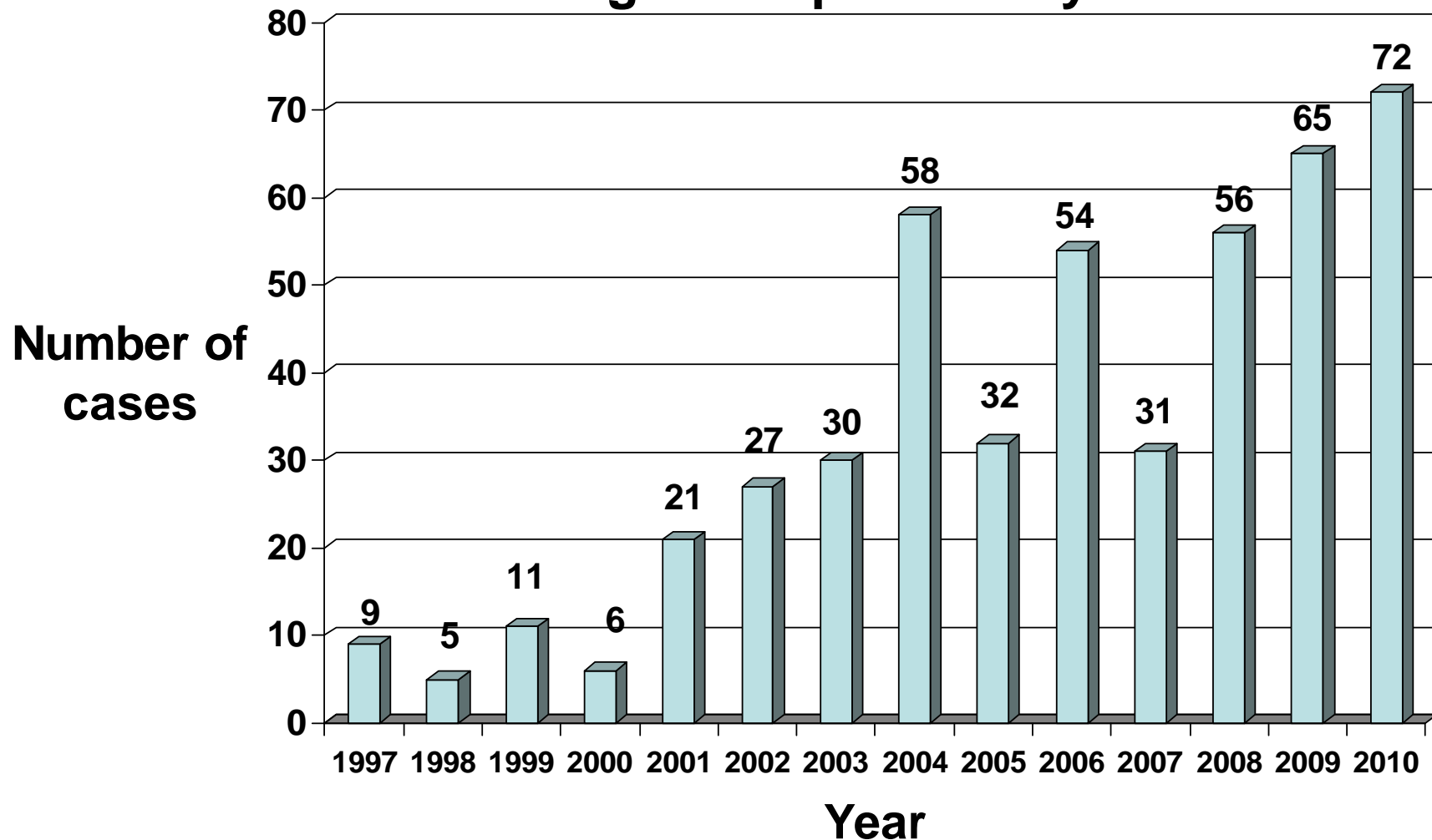
The agency continues to aggressively investigate this matter and is asking for the public's help in reporting any information regarding these vials to FDA's Office of Criminal Investigations (OCI) by calling 800-551-3989 or by visiting the OCI Web site.

### Advice for Patients

- Check your personal supply of insulin to determine if you have Levemir insulin from one of the following lots: XZF0036; XZF0037; XZF0038. You can locate the lot number on the side of the box of insulin and also on the side of the vial.
- Do not use your Levemir insulin if it is from one of these lots. Replace it with a vial of Levemir insulin from another lot. If you must switch to another brand of insulin for any reason, first contact your health care provider because another insulin product may require adjustments in dosing.
- Always look at your insulin carefully before using it. Levemir is a clear and colorless solution.

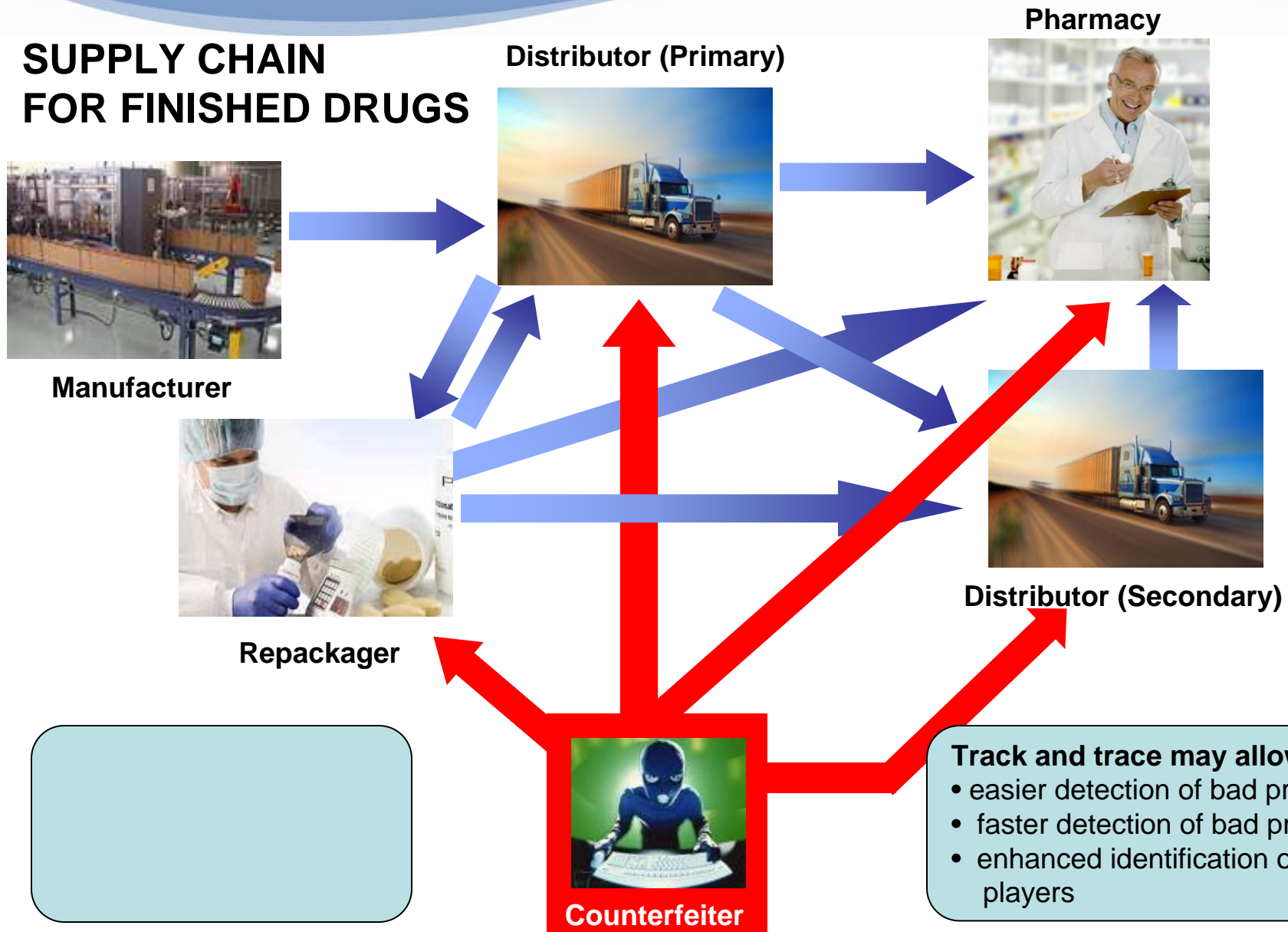


## Counterfeit drug cases opened by FDA's Office of Criminal Investigations per fiscal year





# SUPPLY CHAIN FOR FINISHED DRUGS



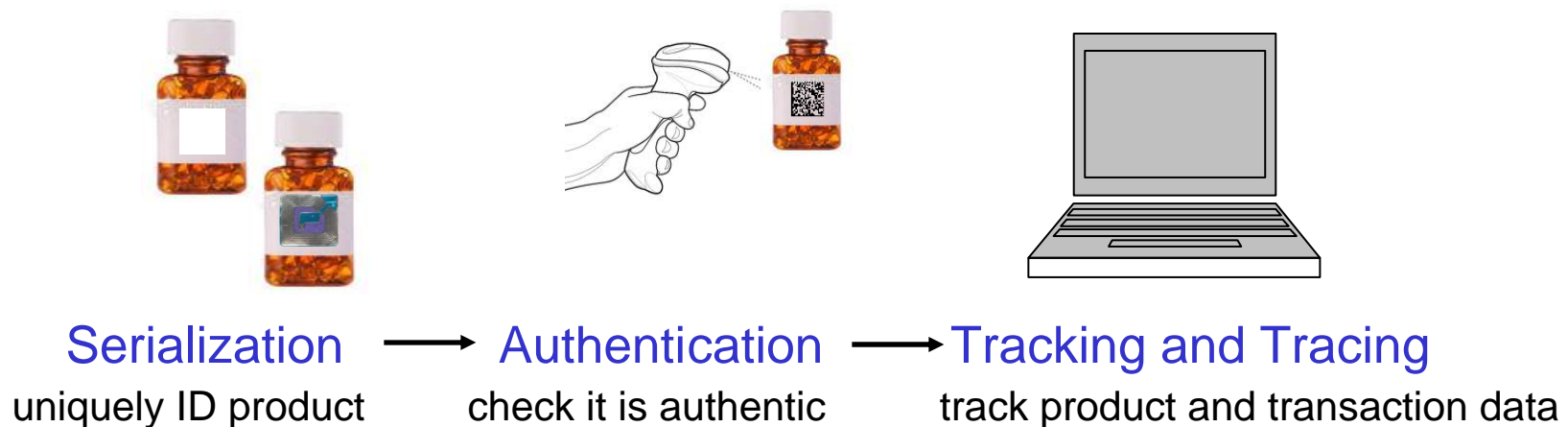
**Track and trace may allow**

- easier detection of bad products
- faster detection of bad products
- enhanced identification of rogue players



# What is FDA doing to develop supply chain security standards?

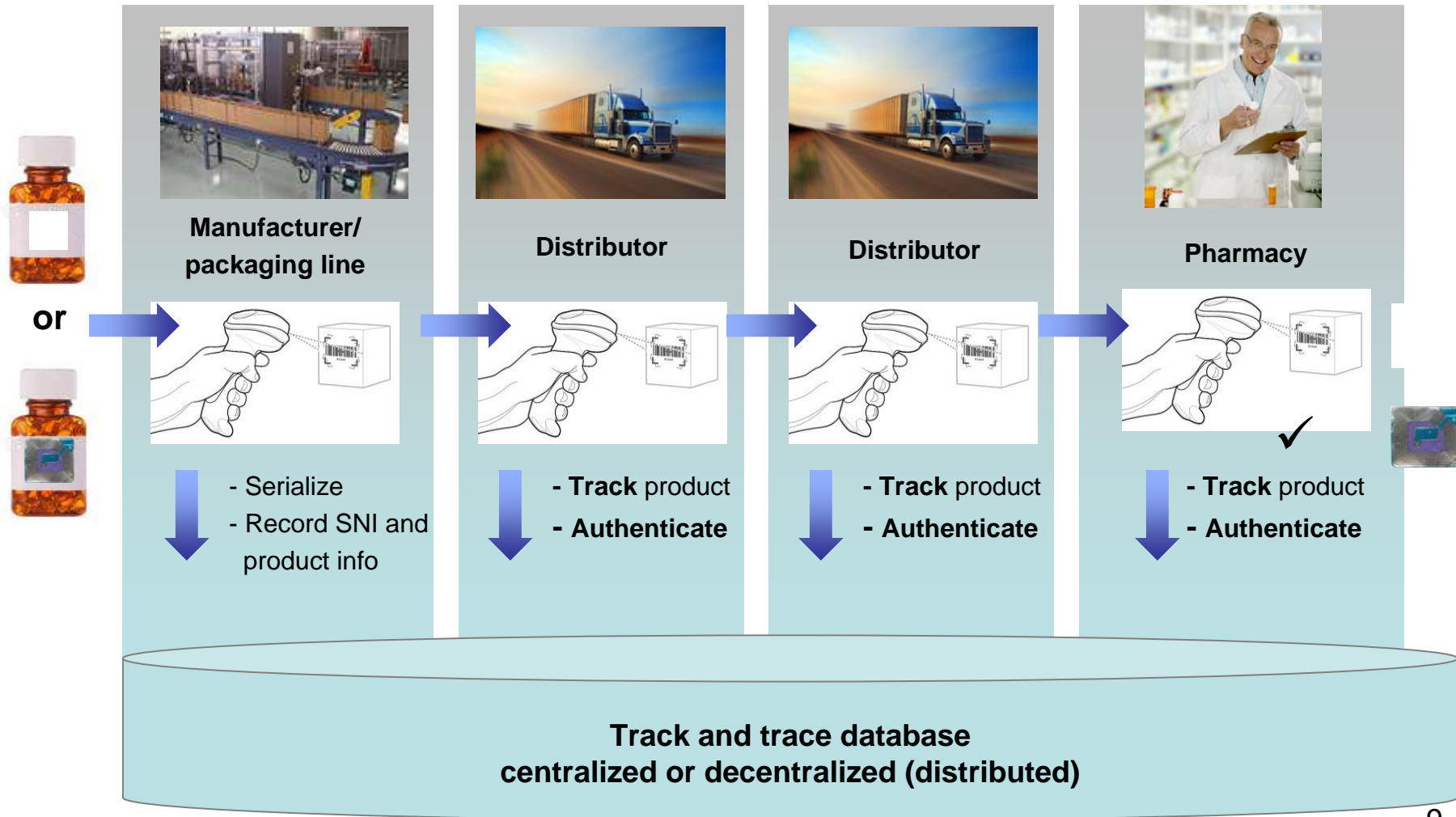
- Section 505D of the Federal Food Drug Cosmetic Act
- developing standards for tracking and tracing of Rx drug through the supply chain (who handled the product from the point of manufacture to point of dispense)





# Overview of a Track and Trace System

ILLUSTRATIVE





## FDA Track and Trace Efforts

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### Guidance for Industry Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages

*FINAL GUIDANCE*

U.S. Department of Health and Human Services  
Food and Drug Administration  
Office of the Commissioner (OC)  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)  
Office of Regulatory Affairs (ORA)  
March 2010

- package-level serialization
- SNI for most prescription products: Serialized NDC (sNDC)

#### Example of a serialized National Drug Code (sNDC)

NDC	SERIAL NUMBER
55555 666 77	+ 11111111111111111111

labeler code + product code + package code      unique, up to 20 characters

- Serial numbers : numeric or alphanumeric, no more than 20 characters
- Machine- and Human-Readable
- Harmonized with internationally recognized standards



# FDA Track and Trace Efforts

## Determination of System Attributes for the Tracking and Tracing of Prescription Drugs; Public Workshop

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Determination of System Attributes for the Tracking and Tracing of Prescription Drugs." This public workshop is intended to provide a forum for discussing potential approaches toward a track and trace system and obtaining input from supply chain partners on attributes and standards for the identification, authentication, and tracking and tracing of prescription drug packages, and to further the Agency's goal of protecting public health by securing the drug supply chain against the introduction of counterfeit and other substandard drugs.

**Date(s):** February 15-16, 2011

**Time:** 9:00 a.m. to 5:00 p.m.

**Location:** FDA White Oak Complex  
10903 New Hampshire Avenue  
Bldg. 31, Room 1503  
Silver Spring, Maryland 20993-0002

- [Federal Register Notice \(PDF - 55KB\)](#)
- [Agenda \(PDF - 22KB\)](#)
- [Discussion Topics \(PDF - 34KB\)](#)
- [Workshop Summary \(PDF - 63KB\)](#)
- [Federal Register Notice - Reopening of Comment Period](#)

### Submitting Comments to the Docket

Comments can be submitted electronically to the docket at <http://www.regulations.gov>. The docket number is FDA-2010-N-0633. Written comments can be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number. Written or

<http://www.fda.gov/Drugs/NewsEvents/ucm239382.htm>



## Track and Trace System Goals

1. Preventing the introduction of counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs
2. Facilitating the identification of counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs
3. Providing accountability for the movement of drugs by supply chain participants
4. Improving efficiency and effectiveness of recalls



## Potential System Attributes

- Capable of capturing the unique identification of a product and status of the number
- Ensure interoperability to enable supply chain participants to securely capture, store, and exchange track-and-trace data accurately and efficiently
- Authenticates the standardized numerical identifier (SNI) and the distribution history of each package
- Enable appropriate access to track-and-trace data necessary to achieve system goals
- Ensure security of data and systems from falsification, malicious attacks, and breaches
- Ensure confidential commercial information is protected
- Ensure patient privacy is maintained, if applicable

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*For discussion purposes only. Developed for use at FDA's public workshop.  
The information should not be interpreted as a final decision or position of the FDA.*



## DISCUSSION TOPICS for purposes of the workshop



establishes compatible data and process standards to enable system participants to have the capability of sharing data by integrating into the same system



- verifying that an SNI is a valid number for the package with which it is associated
- verifying that the package was sold, purchased, traded, delivered, handled, stored, brokered by, or otherwise transferred from legitimate supply chain participants, and confirming that there are no discrepancies in the distribution history



provides standardized mechanisms that supply chain participants use to capture, store, protect, and utilize track and trace data to facilitate authentication and interoperability



## Interoperability needs several elements of technology to be compatible

### Data Format

All inputs into the data system should be of the same format and structure to ensure compatibility of data when transmitted or exchanged

### Data Communication

All system participants should use the same communication protocol/standard to help ensure reliable and secure data exchange among participants (standard language)

### Data Interpretation

All data systems should refer to a common information interpretation standard which ensures that messages are understood by recipients in the way intended by senders

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## Authentication

### Authenticating an SNI

- The verification that the SNI is a valid number for that product with which it is associated

### Authenticating a distribution history

- The verification that the product was sold, purchased, traded, delivered, handled, stored, brokered by, or otherwise transferred from legitimate supply chain participants before reaching the person who is authenticating, and
- That there are no discrepancies in the information on the distribution history

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ILLUSTRATIVE EXAMPLE

# Example: Authentication of an SNI at a distributor warehouse

1

Serialized Product arrives at distributor warehouse



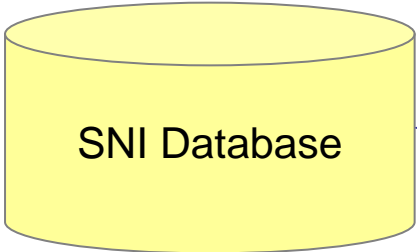
**NDC**  
55555 666 77  
labeler code + product code + package code

+

**SERIAL NUMBER**  
11111111111111111111  
unique, up to 20 characters

2

Package data carrier is read and SNI is authenticated



3



Computer display

Matches the SNI database ✓

Or

Does not match the SNI database ✗



ILLUSTRATIVE EXAMPLE

# Example: Authentication of distribution history at a pharmacy warehouse

**1** Serialized product arrives at Pharmacy warehouse



**NDC**  
55555 666 77  
labeler code + product code + package code

+

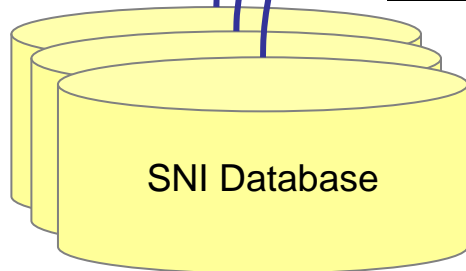
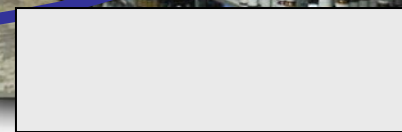
**SERIAL NUMBER**  
11111111111111111111  
unique, up to 20 characters

Computer display  
(oversimplified example)

<b>SNI: NDC + SERIAL NUMBER</b>	
<b>Product name</b>	
<b>Product dosage</b>	
2/6/11 11:00AM	Montville, NJ
Manufacturer	
2/7/11 12:03PM	Newark, NJ
Distributor 1	
2/9/11 1:20PM	New York, NY
Pharmacy	



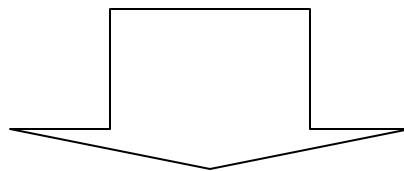
**2**



**3** Distribution history is retrieved about that SNI and recipient can review and verify

## Data Management

- Determining where and how data should be stored
- Identifying and upholding procedures that protect and secure data
- Defining and permitting access to participants' data in a secure, confidential manner
- Determining accountability and corrective action in certain circumstances (e.g., compliance)



## Models for system design



## Overview of system options

### Decentralized

- A system where data is stored in many databases
- Each participant would keep their own records
- Many choices in data storage (each participant stores their own data or outsources to a service provider)

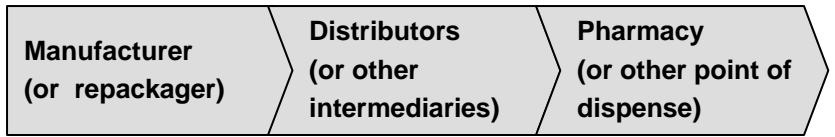
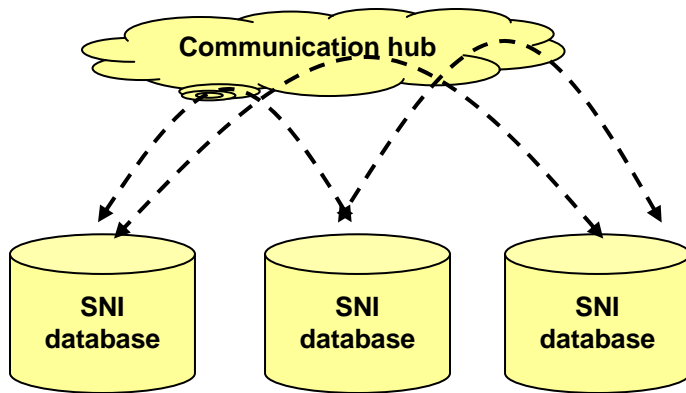
### Semi-centralized

- A system where data is stored in a few select databases
- Each participant would upload their records to one of these databases
- May have limited choice in data storage (choose one of several databases)

### Centralized

- A system where data is stored in only a single database
- Each participant would upload their records to one centralized database
- No choice in data storage (upload to national database)

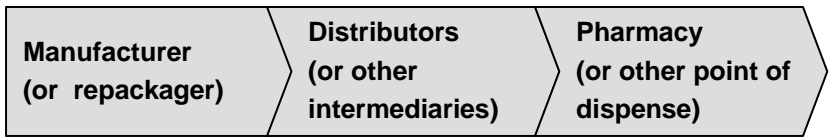
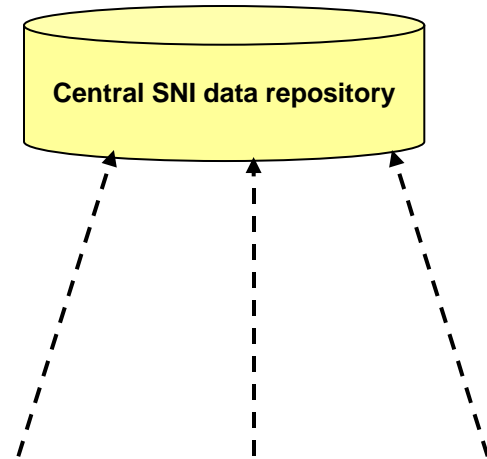
**Decentralized (Distributed) Model**



**Description**

- Participants record data into their own local database or data storage provider database
- Authentication and verification is performed by querying the each databases
- A communications hub connects different databases

**Centralized Model**



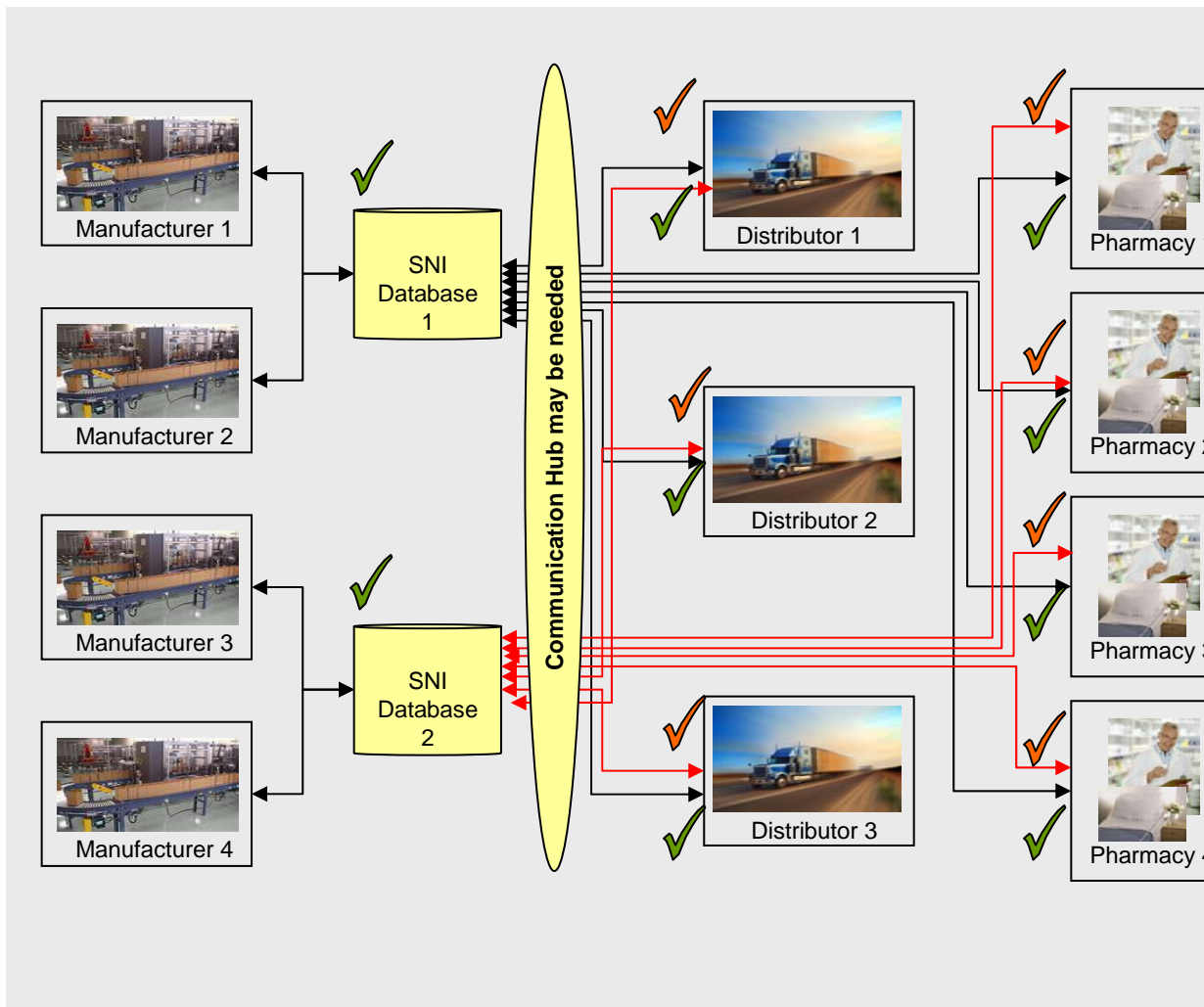
**Description**

- Participants record data into a central repository (database)
- Authentication and verification is performed by querying the central repository



## Semi-Centralized Model

• ILLUSTRATIVE EXAMPLE



- ✓ Verification of SNI
- ✓ Verification of distribution history

### Pros

- Introduces options for companies of where to store their data; may lead to competitive service and pricing
- Enables interoperability by using one data format and communication across several main databases
- Enables full and rapid pedigree – all records for SNI are in one database

### Cons

- Creates a large amount of data that should be expertly managed and stored
- Business intelligence submitted by each participant would be stored in the same database – would need good security



## Summary of points to consider

### Interoperability

- Use and build upon current standards
- Create system compatibility
- Ensure interoperability compliance
- Minimize impact on small businesses
- Define standard operating procedures for exceptions handling

### Authentication

- Define authentication and its requirements
- Manage identification and validation of participants centrally
- Need additional direction on inference, aggregation and exceptions handling

### Data Management

- **System design** (Centralized, Decentralized, Semi-centralized system - pros and cons of each)
- **Pilot and rollout perspectives** – pilots vs. no pilots
- **Data visibility concerns**
- **Definition needed for**  
Product status, Alerts, Recalls
- **Leadership in system harmonization for a single unified system**





## What FDA heard at the public workshop from participants

- 1. FDA should focus on developing the functional requirements of the track and trace system**
- 2. FDA has the opportunity to take a leadership role in standards development and implementation**
  - Harmonization of track and trace standards
  - Product scope
  - Participant validation
- 3. Explain the public health and public policy case for track and trace**
- 4. Incentivize adoption**
- 5. Need for timely action**



# **FDA mission: to promote and protect the public health**

Drug safety....is our priority

Drug quality...is our priority

Patient safety....is our priority

***These must be your priorities too!!!***



# THANK YOU!

## **Office of Drug Security, Integrity and Recalls**

<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/default.htm>

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**U.S. Food and Drug Administration**

# HDMA

# Distribution Overview

California Board of Pharmacy  
December 6, 2011  
Sacramento, CA

Elizabeth A. Gallenagh, Esq.  
VP, Government Affairs & General Counsel

# HDMA – Who We Represent

- Active members include 34 primary healthcare distributors – national, regional, specialty
- HDMA's members offer value-added services that help ensure safe and timely delivery of healthcare products to nearly 200,000 healthcare settings
- HDMA members operate 157 distribution centers serving all 50 states
- Nearly 87 percent of all U.S. pharmaceutical sales go through distributors – \$268 billion
- Distributors save the healthcare system nearly \$42 billion each year

**Slide 2**

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**FQ1**

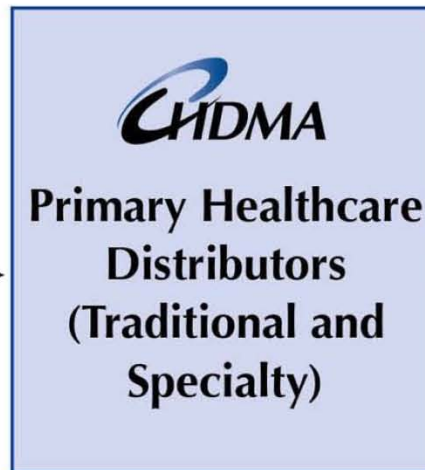
Reached out to LG about this number. Database number.

Farah Qureshi, 10/25/2011

# The Vital Link in a Sophisticated Supply Chain

## MANUFACTURERS

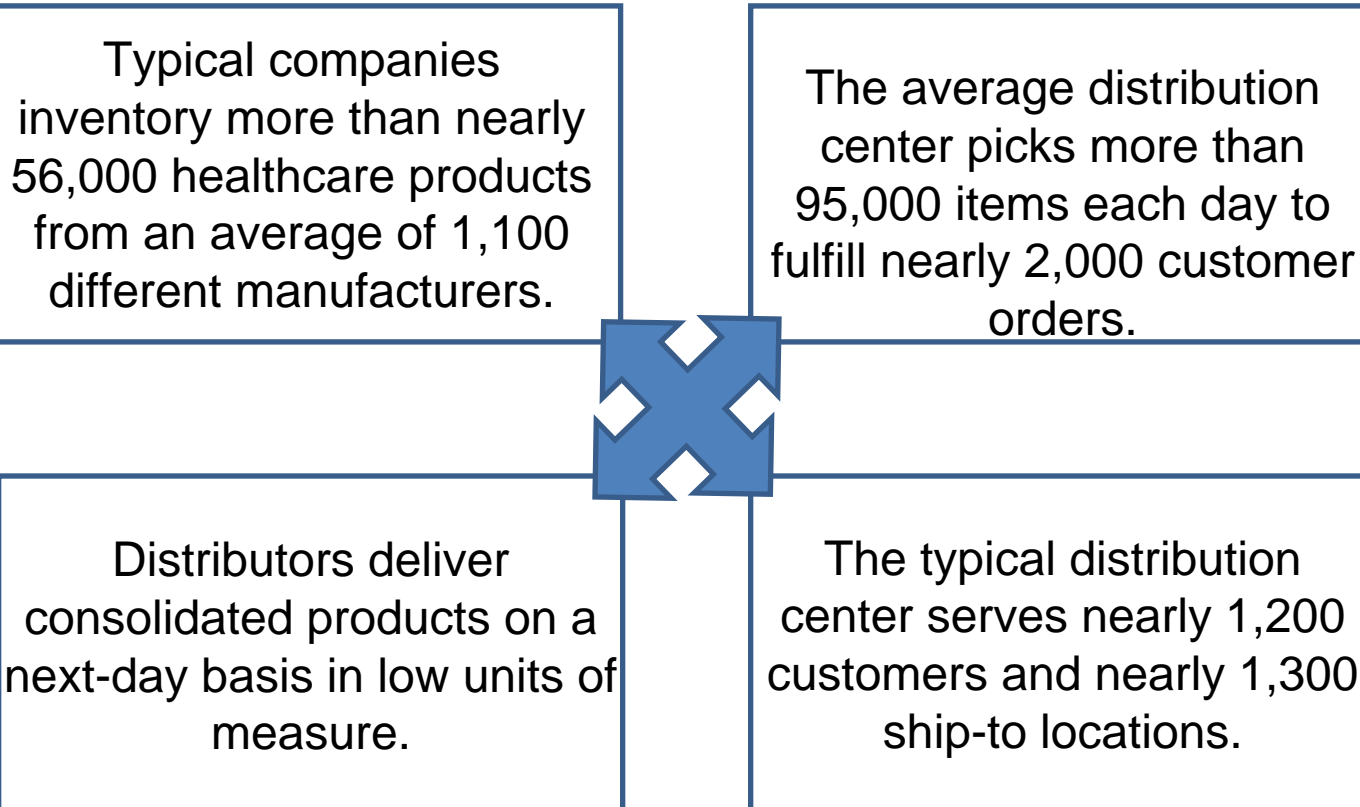
- Branded
- Generic
- Biologic
- Specialty
- OTC
- Medical and Surgical Device



- Hospitals, HMOs, Clinics and Nursing Homes
- Chain Pharmacies and Food Stores
- Chain Warehouses
- Independent Pharmacies
- Mail Order
- Physicians Offices
- Specialty Pharmacies
- Others

Source: *The Role of Distributors in the U.S. Healthcare Industry (2011)*

# Healthcare Distributors





# HDMA in California

- California Customers: HDMA members deliver lifesaving medicines to approximately **32,012 customers** in California.
- Jobs in California: HDMA member companies directly **employ 6,634** California residents and contract for transportation and other services that support hundreds of additional jobs.

# HDMA in California

## HDMA Member Locations in California

- **AmerisourceBergen Corporation** - Corona, Orange, Sacramento, San Bruno, Valencia
- **Cardinal Health, Inc.** - Elk Grove, Valencia
- **H. D. Smith** – Carson
- **McKesson Corporation** - City of Industry, Ontario, San Francisco, Santa Fe Springs, West Sacramento, Visalia,
- **Valley Wholesale Drug Company** - Stockton

# HDMA Strategic Objectives

- Protect patient safety and access to medicines through the safe and efficient distribution of healthcare products and services
- Create and exchange industry knowledge and best practices to enhance the value of the healthcare supply chain
- Advocate for standards, public policies and business processes that produce safe, innovative and cost-effective healthcare solutions

# Elements of Safe and Secure Supply Chain

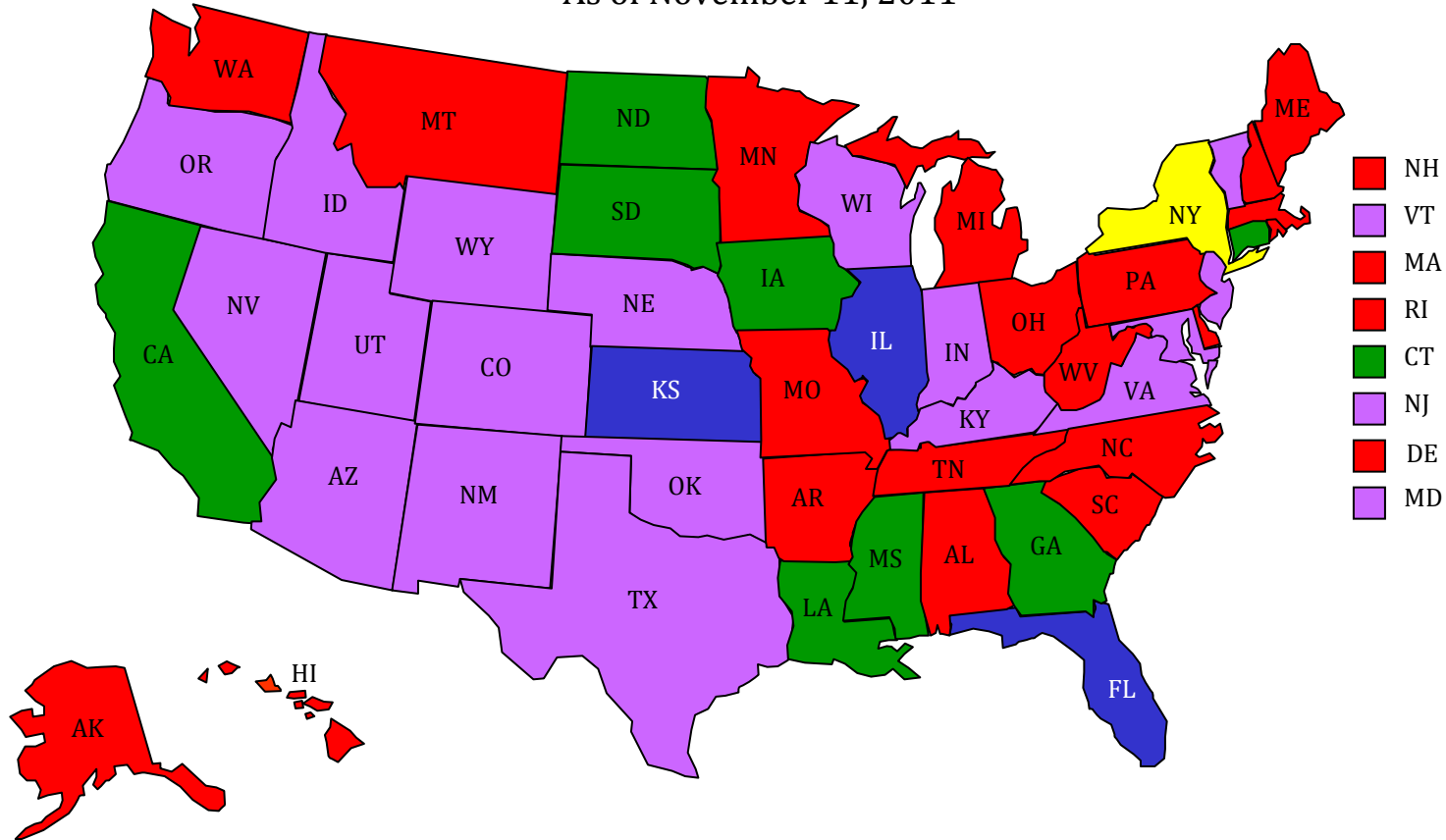
- Distributors perform a unique role in the healthcare supply chain
- Product safety and integrity are the responsibility of all partners
- Strengthen government agency abilities for oversight and enforcement
- Adopt new technologies and maintain integrity and efficiency
- Support industry best practices and vigilance

# Pedigree - Background

- Pedigree is the “statement of distribution history”
- 1988 Prescription Drug Marketing Act (PDMA) established first Rx pedigree requirement
  - Response to diverted, not counterfeit drugs
  - Applied only to “non-ADRs”
- Paper vs. electronic
- Federal and state requirements

# 2011 HDMA Map of State Pedigree Legislation/Regulations

As of November 11, 2011



20 No Legislation or Regulations

1 Proposed Legislation

8 Enacted Legislation

3 Enacted Legislation, Rules In Development

18 Final Rules Adopted

# Pedigree Status – December 2011

- FDAAA Serialized Numerical Identifier (SNI) guidance from FDA
- State activity - regulatory implementation
- States considering new pedigree legislation – NY
- Congressional action / Discussions on pedigree
- Preparation for California – 2015

# HDMA Federal Pedigree Policy

To improve patient safety and supply chain efficiency, HDMA supports federal legislation to establish a uniform, national pedigree requirement in place of conflicting and/or additional state requirements. This legislation should establish a federal pedigree requirement (based on “modified normal distribution”) until such time as a standard is available to facilitate the implementation of cost-effective electronic systems by all supply chain participants.



# Track and Trace Survey – Late 2010

- Manufacturers are fully aware of track-and-trace programs being implemented within the healthcare industry, but pharmaceutical dispensers, particularly hospitals and independents, are not
- All manufacturers indicated that they plan to use 2D barcode technology at the item level; pharmacies would implement a program if technology is standardized across the industry
- The primary driver of track-and-trace implementation is regulatory requirements, but risk management, specifically reducing counterfeit and diversion risk, is also important
- Pharmaceutical dispensers want leadership and guidance from their upstream channel partners

# California Issues

- Grandfathering
- Drop ship
- Inference
- Decommissioning

# California Issues

## Grandfathering

- Does it apply to all supply chain participants?
- With phased implementation, how does it work?
- What about serialized non-pedigree product?  
e.g., serialized inventory for pilots in supply chain now
- Pharmacy returns of non-serialized product?
- What information will need to be submitted?

# California Issues

## Drop Shipments

- Distributor is responsible for pedigree information but will never touch the product in a drop ship situation.
- The serialized, pedigreed product will go directly to the end customer (i.e., pharmacy). Is there a need for additional “pedigree” or should there be some differentiation/exception for this type of transaction?

# Thank You

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