

# Agenda Item XIV

## ENFORCEMENT COMMITTEE REPORT



**California State Board of Pharmacy**

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

## **Enforcement Committee**

**Randy Kajioka, PharmD, Chair**

**Greg Lippe, Public Board Member**

**Neil Badlani, Pharmacist Member**

**Tappan Zee, Esq., Public Board Member**

## **ENFORCEMENT COMMITTEE REPORT AND ACTION**

### **Report of the Meeting Held March 21, 2012**

*Note: at the Enforcement Committee Meeting, there was discussion about off shore entities inputting patient treatment and refill authorizations for California pharmacies. This item was not agendaized for this meeting, but will be added to the next board meeting agenda.*

### **Discussion and Proposed Action on the Implementation of California's E-Pedigree Requirements for Prescription Medication**

**a. FOR DISCUSSION: Counterfeit Avastin Identified in California Physician Offices**

In January, the FDA notified the board and the Medical Board of California about the identification of counterfeit Avastin discovered in California. Avastin is a cancer-treatment medication that is typically administered to patients (rather than dispensed to them) and high priced. The counterfeit Avastin contained no active ingredient.

The counterfeit drugs been traced from a Tennessee wholesaler who sold the product to 19 physician offices through the US; 16 of these physician offices are located in California.

Executive Officer Herold provided a brief presentation to Enforcement Committee on the matter, and she will provide the presentation at this Board Meeting.

**b. FOR INFORMATION AND DISCUSSION: Presentations on Pharmaceutical Supply Chain Security Models**

**During the Enforcement Committee Meeting, the committee heard presentations on various proposals for pharmaceutical supply chain security.** The committee heard the presentation, asked some questions, but made no recommendations for action or amendments on any presentation.

Copies of the presentations are provided in **ATTACHMENT 1** at the end of the committee's meeting minutes.

1. **Summary of a Presentation Made to the Committee by the Pharmaceutical Distribution Security Alliance on a Proposed Federal Model**

The PDSA is a coalition of various members of the pharmaceutical distribution chain: manufacturers, wholesalers and pharmacies. This proposal would call for a different, and less extensive tracking model for prescription medication for the US than those required by California's e-pedigree model. If enacted, these requirements would pre-empt California's requirements. A copy of the presentation is provided in **Attachment 1** behind the minutes.

The PDSA proposal would require manufacturers to add a serialized number to each saleable unit of medication produced; however, this number would NOT be required to be used by wholesalers or pharmacies. Instead the lot number, which can apply to hundreds of thousands of saleable units of medication, would be tracked by wholesalers. Pharmacies would be exempt from reading or tracking any information about the drug product they purchase or dispense. The proposal also would establish federal requirements for licensure and the operations of wholesalers that would preempt all other state laws regarding wholesalers. The proposal would push back full implementation of these and other requirements until mid 2020. And because the proposal would prohibit aggregation from being a requirement of the federal drug distribution system, serialized tracking of each saleable unit of medication – as required by California – would not be achieved.

2. **Summary of the Presentation Made by Connie Jung, RPh, PhD, Acting Associate Director for Policy and Communications, US Food and Drug Administration**

Dr. Jung provided information on the FDA's proposal for pharmaceutical supply chain safety. This proposal calls for a track and trace model with serialization at the unit level, a model very similar to California's requirements.

Dr. Jung provided information about the growing number of counterfeit drug cases the FDA has opened in the last few years. She provided specific details about what components are needed in a tracking system to protect the US drug supply, how some of the data sharing and storage could be accomplished, what type of tracking numbers are needed, and the role of each entity in the manufacturing and distribution of prescription drugs.

A copy of the presentation is provided in **Attachment 1** at the back of the minutes.

3. **Summary of a Presentation by Kimberly Fleming, Senior Manager, Product Security, EMD Serono, Inc,**

Ms. Fleming provided an overview of EMD Serono and the company's efforts to combat

diversion and counterfeiting of their products in the US and worldwide. This is first manufacturer to describe publicly the details and challenges of serializing their product lines for California's requirements.

Ms. Fleming described the need for product security that can be assured with components that include track and trace, authentication, specialized packaging, collaboration and communication. She shared that one of their products had been counterfeited and provided to patients within four months of market introduction. EMD Serono has serialized several of its product lines, and will be ready to meet California's deadlines for e-pedigree requirements.

A copy of the presentation is provided in **Attachment 1** at the back of the minutes.

4. Robert Celeste, Director, Healthcare, GS1 US

Mr. Celeste provided an overview on GS1 and efforts to implement global standards to improve the safety, efficiency and visibility of supply chains globally and across countries.

Mr. Celeste discussed the use of the global trade identification number (GTIN) and other standards worldwide. He announced that GS1 will be releasing an implementation guideline for applying GS1 standards to U.S. pharmaceutical supply chain business processes. The guideline is tentatively scheduled to be released on the GS1 Web site in April 2012.

A copy of the presentation is provided in **Attachment 1** at the back of the minutes.

5. Gabrielle Cosel, PEW Charitable Trust

Ms. Cosel reviewed findings from a report released by PEW on protecting the public from the risks of substandard and counterfeit drugs. She stated that many stakeholders support a strong national standard rather than separate state requirements.

Ms. Cosel discussed the Pharmaceutical Distribution Security Alliance (PDSA) proposal (described above) and stated that this proposals fall short as it calls for tracking of drug product at the lot level. It also would prohibit aggregation which would result in no tracking at the package level. Also, the PDSA proposal does not require the pharmacy or any other party to verify the authenticity of the drugs.

Ms. Cosel stated that PEW supports a national serialization and authentication standard. Ms. Cosel indicated that PEW is currently working on efforts to strengthen oversight and controlled systems for the manufacturing and distributing of drugs.

6. Marjorie Powell, Pharmaceutical Research and Manufacturers of America (PhRMA)

Ms. Powell stated that the California Board of Pharmacy has been the catalyst to bring all the parties within the pharmaceutical supply chain together to enact an interoperable electronic pedigree system. She stated that PhRMA member companies are in the

process of implementing unit level serialization numbers on products and developing data systems to manage and share unit level information. Ms. Powell stated that pilot projects are underway in this area and emphasized the need for a uniform national system.

Ms. Powell stated that PhRMA will continue to work with PDSA on the draft legislation for federal introduction. She encouraged the board to consider increased licensing standards nationwide and increased penalties for violations in this area.

Ms. Powell also offered support to the board in drafting regulations in this area.

**c. FOR POSSIBLE ACTION: Proposal to Initiate a Rulemaking to Adopt Requirements Specifying an Unique Identification Number for Prescription Medication Pursuant to California's E-Pedigree Requirement**

Over the coming few years, California will need to promulgate regulations to implement e-pedigree requirements. Regulations will be needed to clarify a number of requirements, including:

- Inference (relating a single number affixed to a pallet or case, to all serialized products contained within the pallet or case so that each product does not need to be hand-scanned and read)
- Closure of a Pedigree (when all product has been sold and the pedigree needs to be "ended")
- Pedigrees to remain compliant when product is drop shipped (where the product is shipped directly to the pharmacy, but the wholesaler that never possesses product still is an owner of the product, and thus must be listed on the pedigree)
- Pedigree annotation to link shipping information to that which occurs on an invoice (the invoice is required to be tracked as part of the pedigree, but arrives typically after the product does, to prevent delays in distributing product)

There will likely be other regulations required. Staff suggests that the board prepare the language for initiation of a rulemaking, but not actually initiate the process until multiple proposed requirements have been readied for public release.

One of the first proposals being brought to the board as a proposed regulation is to establish the parameters for the unique, serialized number that must be affixed to each saleable product. The origins of these requirements are in the FDA's requirements for a unique identifier for a single product.

Unique Identification Number

Pursuant to Business and Professions Code section 4034, the "unique identification number" established and applied to the smallest package or immediate container by the manufacturer or repackager shall conform to the Standardized Numerical Identifier (SNI) set forth in the Guidance for Industry published by the U.S. Food and Drug Administration (FDA) in March 2010, consisting of a serialized National Drug Code (NDC) identifier (or equivalent

product identifier for dangerous drugs for which no NDC has been assigned) combined with a unique numeric or alphanumeric serial number that is no more than twenty (20) digits or characters in length.

Motion: Enforcement Committee: Recommend that the board hold the proposed language to specify a unique identification number for prescription medication pursuant to California's e-pedigree requirements to be pursued with other e-pedigree regulations as part of a regulation package.

**d. FOR POSSIBLE ACTION: Discussion and Possible Action to Develop "Grandfathering" Provisions**

The Business and Professions Code directs that the board establish requirements for any conditions under which the continued used of non-pedigreed drug products in California commerce can occur after implementation of the e-pedigree requirements. The following proposal has been drafted to establish such requirements:

Specification of Non-Pedigreed Dangerous Drugs

Pursuant to Business and Professions Code sections 4163.2, 4163.4, and 4163.5, manufacturers, wholesalers, repackagers, and pharmacies may take the following actions to specify dangerous drugs that are not yet subject to the pedigree requirements set forth in sections 4034 and 4163 et seq. Other than as specified below, all dangerous drugs distributed in or through California are subject to the pedigree requirements set forth in those sections.

(a) By no later than December 1, 2014, any manufacturer seeking to limit application of the pedigree requirements to 50 percent of its drugs pursuant to Business and Professions Code section 4163.5 shall submit to the board a declaration, signed under penalty of perjury by an owner, officer, or employee of the manufacturer with the legal capacity to bind the manufacturer, that specifies the dangerous drugs by name and product package (SKU) type representing 50 percent of its total as of January 1, 2015, as measured pursuant to section 4163.5, subdivision (d), that is ready for implementation of pedigree requirements as of January 1, 2015. The declaration shall identify the measurement from section 4163.5, subdivision (d) used to measure the 50 percent, shall illustrate the calculation(s) used to arrive at the 50 percent figure, shall identify those drugs by name and product package (SKU) type that are in the remaining 50 percent not yet subject to pedigree requirements, and shall specify the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed. Any manufacturer submitting a declaration to identify the 50 percent of its drugs that are subject to the pedigree requirements as of January 1, 2015 shall also, by no later than December 1, 2015, submit a declaration, signed under penalty of perjury by an owner, officer, or employee of the manufacturer with the legal capacity to bind the manufacturer, that specifies the remaining 50 percent of its dangerous drugs by

name and product package (SKU) type ready for implementation as of January 1, 2016. The declaration shall identify the measurement from section 4163.5, subdivision (d) used to measure the 50 percent, shall illustrate the calculation(s) used to arrive at the 50 percent figure, shall identify all drugs by name and product package (SKU) type that are ready for implementation, and shall specify the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed. The Board or its designee shall have discretion to determine whether any submitted declaration is compliant, and to reject and require re-submission of any non-compliant declaration(s) until fully compliant. Information contained in these declarations shall be considered trade secrets and kept confidential by the board. Any failure to submit a first or second declaration conforming to these requirements by December 1, 2014 or December 1, 2015, or any failure to submit a fully compliant first or second declaration by January 31, 2015 or January 31, 2016, shall automatically make the entire drug stock of any manufacturer failing to do so subject to the pedigree requirements as of January 1, 2015, and no exemption shall be applied to any drugs owned or distributed by that manufacturer.

(b) By no later than August 1, 2016, any wholesaler or repackager seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the pedigree requirements pursuant to Business and Professions Code sections 4163.2 and 4163.4, shall submit to the Board a declaration, signed under penalty of perjury by an owner, officer, or employee of the wholesaler or repackager with the legal capacity to bind the wholesaler or repackager, that specifies the dangerous drugs by name and product package (SKU) type in the possession, ownership, or control of the wholesaler or repackager that were acquired prior to July 1, 2016, specifies the means and source of acquisition, and specifies the anticipated means of any subsequent distribution or disposition. The Board or its designee shall have discretion to determine whether any submitted declaration is compliant, and to reject and require resubmission of any non-compliant declaration(s) until fully compliant. Information contained in these declarations shall be considered trade secrets and kept confidential by the Board. Failure to submit a declaration conforming to these requirements by August 1, 2016, or failure to submit a fully compliant declaration by September 31, 2016, shall automatically make the entire drug stock of any wholesaler or repackager failing to do so subject to the pedigree requirements as of July 1, 2016, and no exemption shall be applied to any drugs owned or distributed by that wholesaler or repackager.

(c) By no later than August 1, 2017, any pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the pedigree requirements pursuant to Business and Professions Code sections 4163.2 and 4163.4, shall submit to the Board a declaration, signed under penalty of perjury by an owner, officer, or employee of the pharmacy or pharmacy warehouse with the legal capacity to bind the pharmacy or pharmacy warehouse, that specifies the dangerous drugs by name and product package (SKU) type in the possession,

ownership, or control of the pharmacy or pharmacy warehouse that were acquired prior to July 1, 2017, specifies the means and source of acquisition, and specifies the anticipated means of any subsequent distribution or disposition. The Board or its designee shall have discretion to determine whether any submitted declaration is compliant, and to reject and require re-submission of any non-compliant declaration(s) until fully compliant. Information contained in these declarations shall be considered trade secrets and kept confidential by the Board. Failure to submit a declaration conforming to these requirements by August 1, 2017, or failure to submit a fully compliant declaration by September 31, 2017, shall automatically make the entire drug stock of any pharmacy or pharmacy warehouse failing to do so subject to the pedigree requirements as of July 1, 2017, and no exemption shall be applied to any drugs owned or distributed by that pharmacy or pharmacy warehouse.

**MOTION:** Enforcement Committee: Recommend that the board hold the proposed language to develop “grandfathering” provisions for non-pedigreed dangerous drugs pursuant to Business and Professions Code section 4163.2 to be pursued with other e-pedigree regulations as part of a regulation package.

e. **FOR INFORMATION: Minutes of the Enforcement Committee Meeting Held March 21, 2012**

**Attachment 1** contains the minutes of the March 21, 2012 Enforcement Committee, and copies of any presentations made during the meeting.

f. **FOR INFORMATION: Review of Enforcement Statistics and Performance Standards of the Board**

**Attachment 2** contains the board’s third quarter enforcement statistics.

g. **FOR INFORMATION: Third Quarterly Report on the Committee’s Goals for 2011/12**

**Attachment 3** contains the third quarter’s update report on the committee’s strategic plan.

# Attachment 1



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GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
ENFORCEMENT COMMITTEE AND E-PEDIGREE PUBLIC MEETING  
MINUTES**

**DATE:** March 21, 2012

**LOCATION:** Hilton San Francisco Airport  
600 Airport Boulevard  
Burlingame, CA 94010

**COMMITTEE MEMBERS**

**PRESENT:** Randy Kajioka, PharmD, Chair  
Greg Lippe, Public Member, Treasurer  
Anil Badlani, RPh  
Tappan Zee, Public Member

**STAFF**

**PRESENT:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Janice Dang, Supervising Inspector  
Joshua Room, Deputy Attorney General  
Carolyn Klein, Legislation and Regulation Manager  
Tessa Miller, Staff Analyst

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**NOTE:** The webcast for this meeting is available at:

[http://www.dca.ca.gov/publications/multimedia/pharm\\_20120321.wmv](http://www.dca.ca.gov/publications/multimedia/pharm_20120321.wmv)

**Call to Order**

Chair Randy Kajioka called the meeting to order at 9:36 a.m.

Chair Kajioka conducted a roll call. Board Members Anil Badlani, Tappan Zee, and Greg Lippe were present.

Board Member Ryan Brooks was in attendance in the audience for part of the meeting.

I. **PRESENTATION AND DISCUSSION ON THE USE OF OFF-SHORE ENTITIES TO INPUT PATIENT TREATMENT AND REFILL AUTHORIZATIONS FOR CALIFORNIA PHARMACIES**

Background

Last year, the board directed a pharmacy to stop using an off-shore data entry service to input patient data.

After this order, the board received a request from an attorney representing the pharmacy and requested an appearance before the board to more fully discuss this matter.

Presentation

An Vong, Pharmacist-in-Charge, Skilled Nursing Pharmacy (SNP) provided a presentation on the benefits of remote data entry of refill prescription orders.

Dr. Vong discussed the benefits that SNP believes it gains from using offsite services for non-clinical clerical data entry.

Stacie Neroni, Hooper, Lundy and Bookman, P.C., confirmed that SNP is not currently using off shore entry, but would like to in the future.

Discussion

Joshua Room, Deputy Attorney General, advised that the committee to focus its discussion on the general topic of off-shore data entry.

The committee discussed the information presented and indicated that, as advised by Mr. Room, no action can be taken at this time.

Chair Kajioka stated that the issue of remote data entry may be brought to the full board for further discussion and consideration in the future.

No public comment was provided.

The board recessed for a break at 10:06 a.m. and reconvened at 10:15 a.m.

## **II. DISCUSSION ON THE IMPLEMENTATION OF CALIFORNIA'S ELECTRONIC PEDIGREE REQUIREMENTS FOR PRESCRIPTION MEDICATION**

### **a. Discussion about the Presence of Counterfeit Avastin in California Physician Offices**

#### Presentation

Executive Officer Virginia Herold provided a presentation on counterfeit drugs. A copy of this presentation is attached, following this meeting summary.

Ms. Herold reviewed the appearance of counterfeit drugs in the supply chain and discussed a recent incident involving Avastin.

Ms. Herold stated that pursuant to Business and Professions Code section 4034(h), a manufacturer, wholesaler or pharmacy that has reasonable cause to believe it is in possession of counterfeit drugs must notify the board within 72 hours of discovery.

There was no committee discussion or public comment.

### **b. Presentation and Discussion of a Proposal for Federal Legislation by the Pharmaceutical Distribution Security Alliance**

#### Presentation

Vince Ventimiglia, representing the Pharmaceutical Distribution Security Alliance (PDSA), provided a presentation to propose the development and enactment of the Pharmaceutical Traceability Enhancement Code (RxTEC) Act of 2012, a federal policy proposal for the domestic pharmaceutical distribution system. A copy of this presentation is attached, following this meeting summary.

Mr. Ventimiglia introduced other PDSA representatives in attendance and provided an overview of PDSA. He discussed that RxTEC is a federal approach that replaces the patchwork of state laws to improve the security and efficiency of the pharmaceutical distribution chain.

#### Discussion

Chair Kajioka provided comment on California's e-pedigree requirements and implementation schedule.

Mr. Room provided comment on the discussion draft of the RxTEC Act and sought clarification regarding the tracking and identification of product throughout the system.

Mr. Ventimiglia discussed that the RxTEC system would use lot-level reference systems, while a serialized code would be placed but not read or tracked at the unit-level. This would improve the safety of the supply chain today.

Discussion continued regarding the RxTEC system. The committee evaluated the system's enactment and the implementation of e-pedigree requirements.

No public comment was provided.

**c. 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**

Presentation

Dr. Jung provided a presentation on the need for protection of products in the drug supply chain. A copy of this presentation is attached, following this meeting summary.

Dr. Jung provided an overview of the supply chain and reviewed efforts by the FDA to protect the integrity of the supply chain to ensure patient safety. She indicated that the FDA has established the new Office of Drug Security, Integrity and Recalls (ODSIR) to address this issue.

Dr. Jung discussed attributes of the track and trace system and reviewed possible system models. She advocated for a national, uniform track and trace model, with an authentication system with tracking at the unit level. This would be a far more beneficial system than one which does not require tracking at the unit level.

Discussion

Chair Kajioka sought additional information regarding whether authentication should be done at the ownership level or the possession level.

Dr. Jung stated that this has not yet been determined as the requirement in this area has not been finalized. She provided comment on the importance of chain of custody for all products in U.S. distribution and discussed that pharmacies should know where product has been shipped and stored before it reaches the pharmacies.

No public comment was provided.

The board recessed for a break at 12:15 p.m. and resumed at 12:28 p.m.

**d. Presentations and Questions from the Pharmaceutical Supply Chain on Their Readiness to Meet California's Staggered E-Pedigree Implementation Schedule**

Kimberly Fleming, Senior Manager, Product Security, EMD Serono, Inc.

Ms. Fleming provided an overview on EMD Serono and the company's efforts to combat diversion and counterfeit product in the U.S. She reviewed "must have's" for product security including track and trace, authentication and packaging, collaboration and communication, and supply chain security. She indicated that EMD Serono had serialized several of its product lines, and will be ready to meet California's deadlines for e-pedigree requirements.

Ms. Fleming discussed the Secured Distribution Program that EMD Serono has developed to maintain the integrity of EMD Serono's products that are at risk for diversion and/or counterfeit. She indicated that the ultimate goal is patient safety and stated that products are tracked via unique box serial numbers from the point of manufacture to the point of final dispensation. Ms. Fleming stated that these steps are necessary because their products have been counterfeited. In one case, within four months of bringing a new product onto the market patients were discovered with counterfeit product.

Discussion

Mr. Lippe referenced the \$5.8 billion Euros in revenue earned by EMD Serono in 2010 and asked how much the serialization system costs.

Ms. Fleming indicated that although she is unsure of the exact number, the cost for the global process is several million Euros.

Mr. Room asked how much product is currently serialized.

Ms. Fleming indicated that the highest volume products are not serialized at this time.

No public comment was provided.

Robert Celeste, Director, Healthcare, GS1 US

Mr. Celeste provided an overview on GS1 and efforts to implement global standards to improve the efficiency and visibility of supply chains globally and across countries. A copy of this presentation is attached, following this meeting summary.

Mr. Celeste discussed the use of the global trade identification number (GTIN) and other standards and serialization worldwide. He announced that GS1 will be releasing an implementation guideline for applying GS1 standards to U.S. pharmaceutical supply chain business processes. The guideline is tentatively scheduled to be released on the GS1 Web site in April 2012.

There was no committee discussion or public comment.

### 3. Other Companies, Associations and Other Entities Wishing to Address the Committee on E-Pedigree Issues

#### Gabrielle Cosel, PEW Charitable Trust

Ms. Cosel reviewed findings from a report released by PEW on protecting consumers from the risks of substandard and counterfeit drugs. She stated that many stakeholders support a strong national standard rather than separate state requirements.

Ms. Cosel discussed the Pharmaceutical Distribution Security Alliance (PDSA) proposal currently being considered by Congress and stated that this proposals fall short as it calls for tracking of drug product at the lot level. It also would prohibit aggregation which would result in no tracking at the package level. Also, the PDSA proposal does not require the pharmacy or any other party to verify the authenticity of the drugs.

Ms. Cosel stated that PEW supports a national serialization and authentication standard.

Ms. Cosel indicated that PEW is currently working on efforts to strengthen oversight and controlled systems for the manufacturing of drugs.

#### Marjorie Powell, Pharmaceutical Research and Manufacturers of America (PhRMA)

Ms. Powell stated that the California Board of Pharmacy has been the catalyst to bring all the parties within the pharmaceutical supply chain together to enact an interoperable electronic pedigree system. She stated that PhRMA member companies are in the process of implementing unit level serialization numbers on products and developing data systems to manage and share unit level information. Ms. Powell provided an overview on other efforts and pilot tests in this area and emphasized the need for a uniform national system. She stated that PhRMA will continue to work with PDSA on the draft legislation.

Ms. Powell offered support to the board in drafting regulations in this area. She encouraged the board to consider increased licensing standards nationwide and increased penalties for violations in this area.

Ms. Herold encouraged participation and input from industry during the regulation process for California's requirements.

The board recessed for a lunch break at 1:34 p.m. and reconvened at 2:37 p.m.

#### **e. General Discussion**

There was no additional discussion.

**f. Discussion and Possible Action to Develop Regulation Requirements Specifying a Unique Identification Number for Prescription Medication Pursuant to California's E-Pedigree Requirements**

Mr. Room reviewed the following language regarding the specification of a unique identification number.

Unique Identification Number

Pursuant to Business and Professions Code section 4034, the "unique identification number" established and applied to the smallest package or immediate container by the manufacturer or repackager shall conform to the Standardized Numerical Identifier (SNI) set forth in the Guidance for Industry published by the U.S. Food and Drug Administration (FDA) in March 2010, consisting of a serialized National Drug Code (NDC) identifier (or equivalent product identifier for dangerous drugs for which no NDC has been assigned) combined with a unique numeric or alphanumeric serial number that is no more than twenty (20) digits or characters in length.

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Ms. Herold recommended that the board promulgate this regulation as part of a regulation package.

No public comment was provided.

**MOTION:** Recommend that the board hold the proposed language to specify a unique identification number for prescription medication pursuant to California's e-pedigree requirements to be pursued with other e-pedigree regulations as part of a regulation package.

M/S: Lippe/Zee

Support: 4    Oppose: 0    Abstain: 0

**g. Discussion and Possible Action to Develop "Grandfathering" Provisions for Non-Pedigreed Dangerous Drugs Pursuant to Section 4163.2 of the Business and Professions**

Mr. Room reviewed proposed language to specify the methodology to be used by manufacturers, wholesalers, repackagers, and pharmacies to identify drugs already in the supply chain that are not serialized but could be sold after the e-pedigree requirements take effect. A copy of this language is attached, following this meeting summary.

### Public Comment

Diane Arico, representing Novartis Pharmaceuticals, sought clarification regarding the implementation requirements in subdivision (a) of the draft language.

Mr. Room reviewed the implementation requirements in Business and Professions Code section 4163.5(b). He clarified that before January 1, 2015, each manufacturer of a dangerous drug distributed in California must identify those dangerous drugs representing a minimum of 50 percent of its drugs that will be serialized and the remaining 50 percent must be serialized by January 1, 2016. Wholesalers have until July 1, 2016 to append the e-pedigree required information. Pharmacies and pharmacy warehouses have until July 1, 2017 to read and append pedigrees, making the system fully operational. He commented that this proposal deals with what happen to the non-serialized product that is in the supply chain when the requirements take effect, at each level, and thus could not be sold or distributed without an exemption.

**MOTION:** Recommend that the board hold the proposed language to develop “grandfathering” provisions for non-pedigreed dangerous drugs pursuant to Business and Professions Code section 4163.2 to be pursued with other e-pedigree regulations as part of a regulation package.

M/S: Lippe/Zee

Support: 4    Oppose: 0    Abstain: 0

### **h. Closing Comments**

Chair Kajioka discussed the importance of addressing the counterfeit and diversion problem. He stated that the board will hold additional meetings to solicit input and develop strong requirements and standards to protect the public.

Ms. Herold announced that the board will hold its next Enforcement Committee and E-Pedigree Meeting in June 2012. The exact date and location will be posted on the board’s Web site.

### **III. PUBLIC COMMENT ON ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS**

No public comment was provided.

The meeting was adjourned at 2:51 p.m.

### Specification of Non-Pedigreed Dangerous Drugs

Pursuant to Business and Professions Code sections 4163.2, 4163.4, and 4163.5, manufacturers, wholesalers, repackagers, and pharmacies may take the following actions to specify dangerous drugs that are not yet subject to the pedigree requirements set forth in sections 4034 and 4163 et seq. Other than as specified below, all dangerous drugs distributed in or through California are subject to the pedigree requirements set forth in those sections.

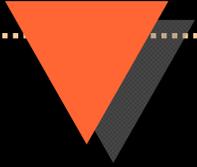
(a) By no later than December 1, 2014, any manufacturer seeking to limit application of the pedigree requirements to 50 percent of its drugs pursuant to Business and Professions Code section 4163.5 shall submit to the Board a declaration, signed under penalty of perjury by an owner, officer, or employee of the manufacturer with the legal capacity to bind the manufacturer, that specifies the dangerous drugs by name and product package (SKU) type representing 50 percent of its total as of January 1, 2015, as measured pursuant to section 4163.5, subdivision (d), that is ready for implementation of pedigree requirements as of January 1, 2015. The declaration shall identify the measurement from section 4163.5, subdivision (d) used to measure the 50 percent, shall illustrate the calculation(s) used to arrive at the 50 percent figure, shall identify those drugs by name and product package (SKU) type that are in the remaining 50 percent not yet subject to pedigree requirements, and shall specify the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed. Any manufacturer submitting a declaration to identify the 50 percent of its drugs that are subject to the pedigree requirements as of January 1, 2015 shall also, by no later than December 1, 2015, submit a declaration, signed under penalty of perjury by an owner, officer, or employee of the manufacturer with the legal capacity to bind the manufacturer, that specifies the remaining 50 percent of its dangerous drugs by name and product package (SKU) type ready for implementation as of January 1, 2016. The declaration shall identify the measurement from section 4163.5, subdivision (d) used to measure the 50 percent, shall illustrate the calculation(s) used to arrive at the 50 percent figure, shall

identify all drugs by name and product package (SKU) type that are ready for implementation, and shall specify the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed. The Board or its designee shall have discretion to determine whether any submitted declaration is compliant, and to reject and require re-submission of any non-compliant declaration(s) until fully compliant. Information contained in these declarations shall be considered trade secrets and kept confidential by the Board. Any failure to submit a first or second declaration conforming to these requirements by December 1, 2014 or December 1, 2015, or any failure to submit a fully compliant first or second declaration by January 31, 2015 or January 31, 2016, shall automatically make the entire drug stock of any manufacturer failing to do so subject to the pedigree requirements as of January 1, 2015, and no exemption shall be applied to any drugs owned or distributed by that manufacturer.

(b) By no later than August 1, 2016, any wholesaler or repackager seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the pedigree requirements pursuant to Business and Professions Code sections 4163.2 and 4163.4, shall submit to the Board a declaration, signed under penalty of perjury by an owner, officer, or employee of the wholesaler or repackager with the legal capacity to bind the wholesaler or repackager, that specifies the dangerous drugs by name and product package (SKU) type in the possession, ownership, or control of the wholesaler or repackager that were acquired prior to July 1, 2016, specifies the means and source of acquisition, and specifies the anticipated means of any subsequent distribution or disposition. The Board or its designee shall have discretion to determine whether any submitted declaration is compliant, and to reject and require re-submission of any non-compliant declaration(s) until fully compliant. Information contained in these declarations shall be considered trade secrets and kept confidential by the Board. Failure to submit a declaration conforming to these requirements by August 1, 2016, or failure to submit a fully compliant declaration by September 31, 2016, shall automatically make the entire drug

stock of any wholesaler or repackager failing to do so subject to the pedigree requirements as of July 1, 2016, and no exemption shall be applied to any drugs owned or distributed by that wholesaler or repackager.

(c) By no later than August 1, 2017, any pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the pedigree requirements pursuant to Business and Professions Code sections 4163.2 and 4163.4, shall submit to the Board a declaration, signed under penalty of perjury by an owner, officer, or employee of the pharmacy or pharmacy warehouse with the legal capacity to bind the pharmacy or pharmacy warehouse, that specifies the dangerous drugs by name and product package (SKU) type in the possession, ownership, or control of the pharmacy or pharmacy warehouse that were acquired prior to July 1, 2017, specifies the means and source of acquisition, and specifies the anticipated means of any subsequent distribution or disposition. The Board or its designee shall have discretion to determine whether any submitted declaration is compliant, and to reject and require re-submission of any non-compliant declaration(s) until fully compliant. Information contained in these declarations shall be considered trade secrets and kept confidential by the Board. Failure to submit a declaration conforming to these requirements by August 1, 2017, or failure to submit a fully compliant declaration by September 31, 2017, shall automatically make the entire drug stock of any pharmacy or pharmacy warehouse failing to do so subject to the pedigree requirements as of July 1, 2017, and no exemption shall be applied to any drugs owned or distributed by that pharmacy or pharmacy warehouse.

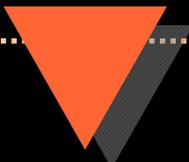


# Counterfeit Drugs

California State Board of Pharmacy

Enforcement Committee

March 21, 2012

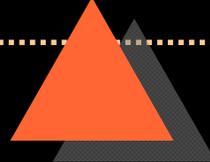


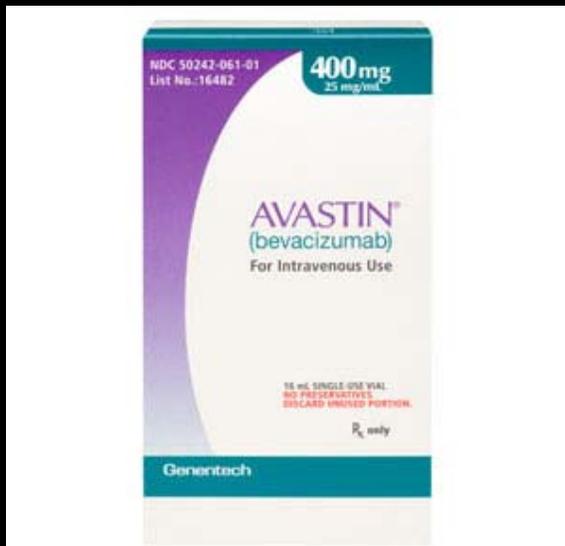
# Statutory Mandate

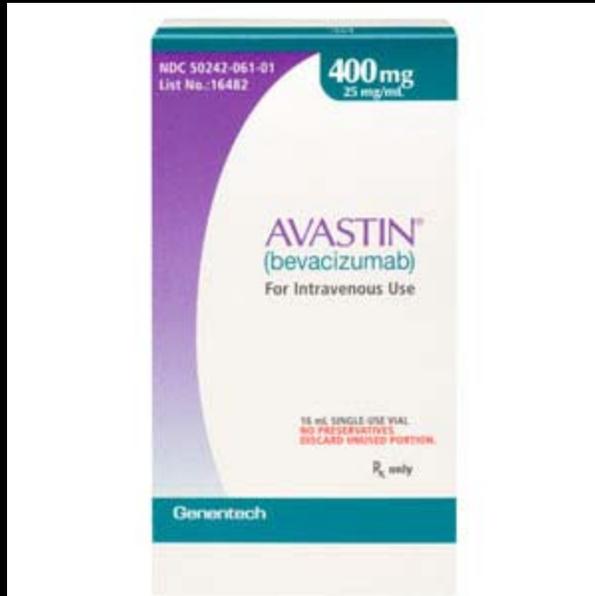
Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions.

Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

*CA Business and Professions Code 4001.1*







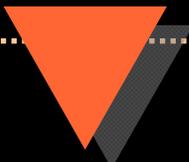






Counterfeit

Genuine



# Reporting Counterfeits in CA

- If a manufacturer, wholesaler or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler or pharmacy shall notify the Board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or throughout CA

*CA Business & Prof Code 4034(h)*



# ***California Board of Pharmacy***

***Presentation by  
The Pharmaceutical Distribution  
Security Alliance (PDSA)***

**March 21, 2012**

## ***The Mission***

- PDSA's mission is to develop and help enact a federal policy proposal that enhances the security and integrity of the domestic pharmaceutical distribution system for patients, and to articulate a technical migratory pathway to implement such a policy
- Our primary goal is ensuring patients have uninterrupted access to safe, authentic, FDA-approved medicine

## ***Who We Are***

- Membership spans the entire spectrum of the U.S. pharmaceutical distribution system, including brand and generic manufacturers, large and small wholesale distributors, third-party logistics providers, and retail and community pharmacies
- More than 25 organizations are formal members of PDSA, while many other external stakeholders provide additional policy and technical support to the group

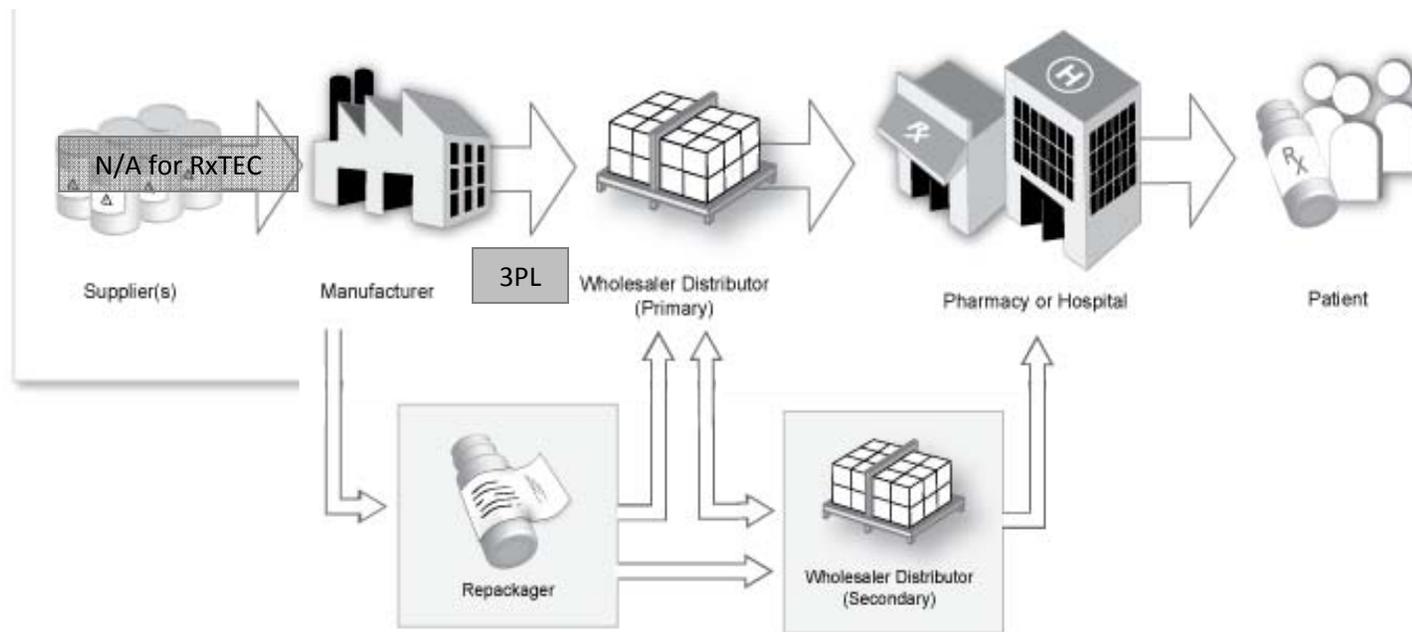
# PDSA: Who We Are



## ***PDSA: Why This Is Different***

- **First time** that all sector participants in the pharmaceutical distribution chain:
  - Have engaged in robust discussion regarding pathways and proposal to advance prescription drug distribution supply chain security through a national policy framework
  - Have prepared a consensus policy approach to enhance supply chain security and safety
  - Are fully engaging, collectively, with bipartisan and bicameral Congressional leaders in support of legislative action
  - Are *asking* for more regulation

# ***The Current Pharmaceutical Distribution Chain***



*The pharmaceutical distribution chain as adapted from a diagram by the U.S. Food and Drug Administration*

# ***Why a Federal Approach?***

- Public health experts agree that while incidents of counterfeiting and drug diversion are less common in the United States than in other parts of the world, they are a serious concern
- While California and a handful of other states have passed enhanced wholesale distribution requirements and/or pedigree legislation, currently there is no uniform national system to prevent or identify possible suspect products
- This state patchwork creates opportunities for bad actors to "shop" for states with the lowest safety requirements in order to enter the gray market or infiltrate the legitimate supply chain
- Illegal online "pharmacies" take advantage of loopholes in federal law to evade law enforcement
- A federal solution would raise the bar for industry participants in all 50 states, address current loopholes, and aide deterrence – all greatly enhancing supply chain safety and security worldwide
- Such a uniform national system would enable regulators, law enforcement and industry participants to harmonize their processes on a global basis, yielding costs savings and investment efficiencies for all parties

# ***The PDSA Proposed System***

## ***The Pharmaceutical Traceability Enhancement Code (RxTEC) Act of 2012***

- ✓ ***Prevention***
- ✓ ***Identification***
- ✓ ***Response***
- ✓ ***Assessment***

# ***The RxTEC Act***

## ***Prevention – Identification – Response - Assessment***

### **A Comprehensive Approach with Immediate Benefits**

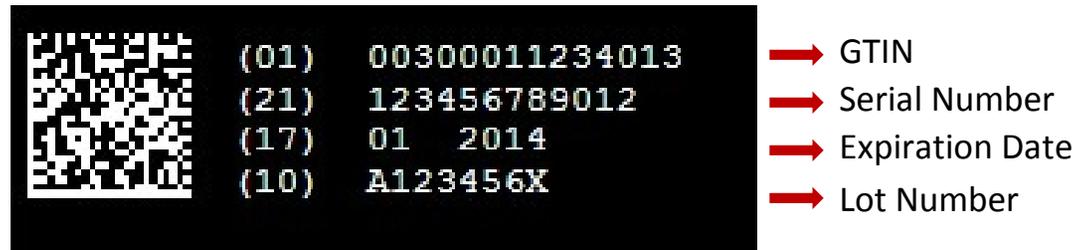
- |   |   |
|---|---|
| <ul style="list-style-type: none"><li>➤ <b>Establishes Strong National Standards:</b> Immediately sets strong federal standards for wholesale distributors with state licensure authorities, strong standards and a new federal license for third-party logistics providers, and streamlined licensure requirements for manufacturers</li></ul> | <ul style="list-style-type: none"><li>➤ <b>Raises the Bar for Wholesale Distribution:</b> Interim federal requirements for wholesale distribution during RxTEC system development to provide a strong, efficient, uniform system for product distribution in between states</li></ul> |
| <ul style="list-style-type: none"><li>➤ <b>Addresses Loopholes:</b> New laws to combat illegal online drug sellers (aka “online pharmacies”), including requiring a “valid prescription” prior to dispensing, and creating a registry of all safe online sources</li></ul>  | <ul style="list-style-type: none"><li>➤ <b>Aids Deterrence:</b> Increases penalties for prescription drug counterfeiters</li></ul>  |

# ***The RxTEC Act***

## ***Prevention – Identification – Response – Assessment***

- The cornerstone of the RxTEC Act of 2012 is the development of the RxTEC system through unit-level serialization and use of a new data carrier to improve product visibility throughout the pharmaceutical distribution chain
  
- The RxTEC system leverages lot-level business systems that may be in place today, while serializing at the unit-level and increasing the ability to identify suspect product at both the unit and lot level
  
- **Obligations under the Act:**
  - Requires manufacturers to apply the RxTEC data carrier that includes both unit level (SNI) and lot level data to individual saleable units of prescription drugs and to homogenous cases in both human and machine-readable formats
  - Requires manufacturers to maintain associations between serial numbers and lot numbers
  - Requires trading partners to have systems and process to support
    - verification of a suspect product as determined necessary by the Secretary for investigations
    - lot level tracing upon change of ownership
    - lot level recalls

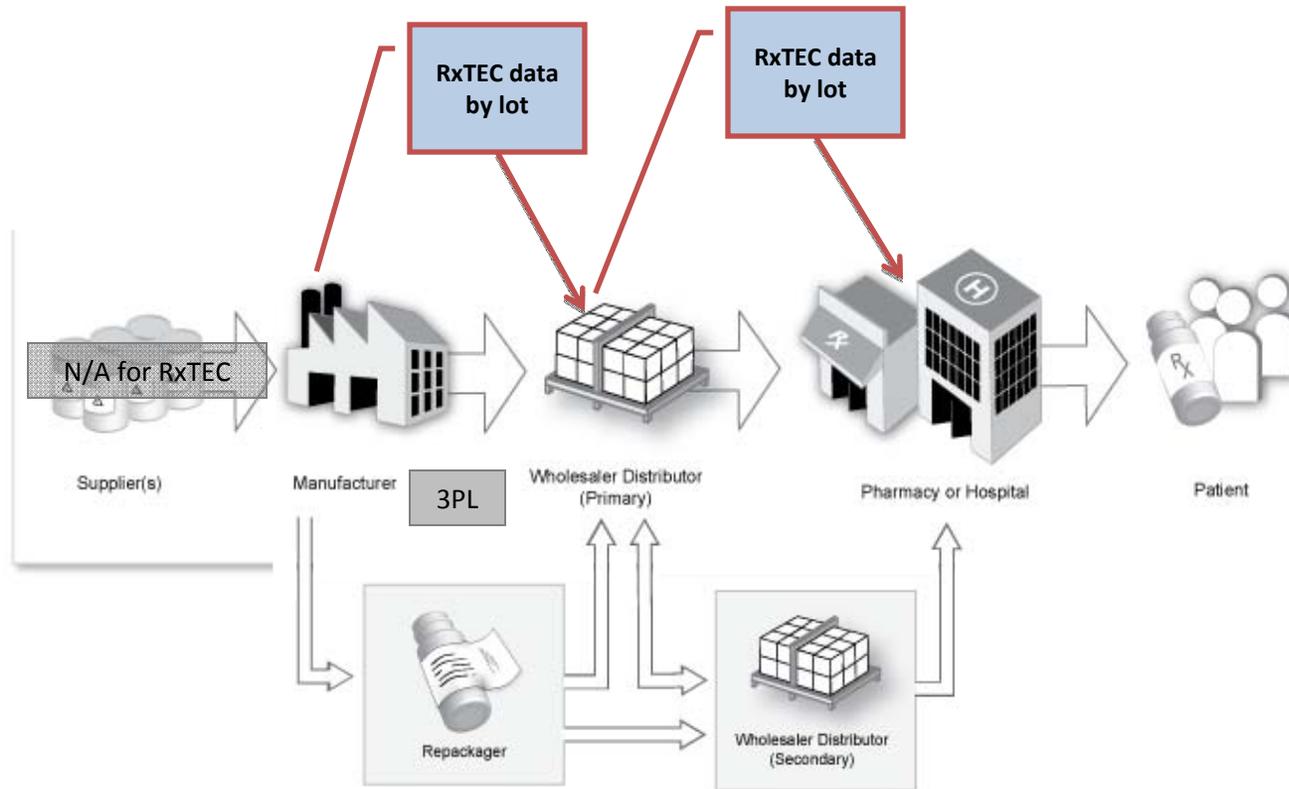
# ***The Data Carrier – A Closer Look at RxTEC***



- RxTEC is a data carrier that includes a Global Trade Item Number (GTIN), a serial number, expiration date and lot number
- This RxTEC data carrier would be applied on each individual saleable unit and homogenous case by manufacturers and repackagers
- Data will be in both human and machine-readable formats

# The RxTEC Act

**Prevention – Identification – Response – Assessment**



*The pharmaceutical distribution chain as adapted from a diagram by the U.S. Food and Drug Administration*

# ***The RxTEC Act***

## ***Prevention – Identification – Response – Assessment***

- Provides new tools for identifying possible counterfeit or diverted product in the supply chain
  - The Secretary, state regulators, and manufacturers may verify the serial number of an individual saleable unit against a manufacturer's database to investigate a suspect product
  - Trading partners would be able to trace drug shipments upon change of ownership at the lot level
  
- Enables additional opportunities to check the legitimacy of products
  - Trading partners could also leverage RxTEC data in combination with their own business systems and processes to detect, prevent, or respond to threats in the distribution chain
  - Trading partners could also verify the serial number of an individual saleable unit against a manufacturer's database

# ***The RxTEC Act***

## ***Prevention – Identification – Response – Assessment***

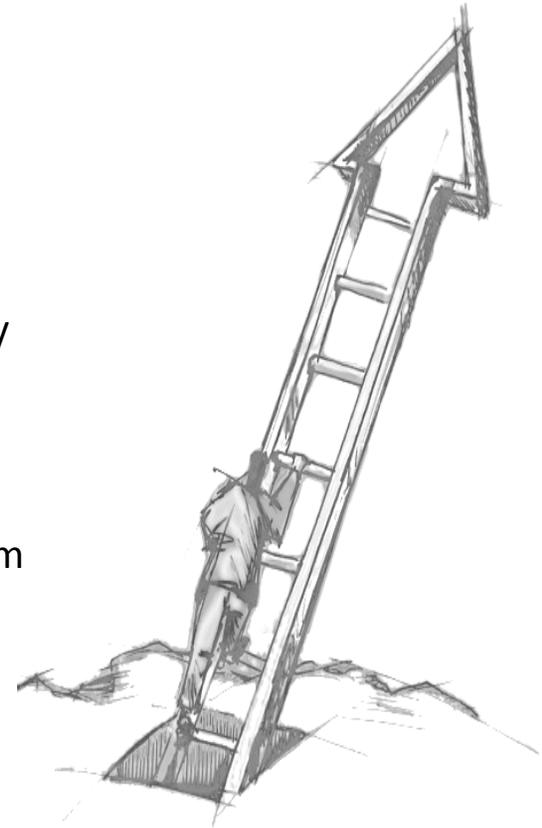
- Enables faster, more efficient response to identified counterfeit or diverted product
  - The Secretary and state regulators may obtain RxTEC data in the event of a recall or as determined necessary by the Secretary to investigate a suspect product
  - The Secretary and state regulators direct industry response to identified threats in the distribution chain
  - Trading partners would conduct a faster and more efficient recall by lot

# The RxTEC Act

## Prevention – Identification – Response – Assessment

### Opportunities for Assessment and Enhancement

- The RxTEC Act provides critical building blocks that can be expanded as public health threats, interoperability standards, and technologies evolve
- Establishes the Pharmaceutical Distribution Chain Community
  - 21 members appointed by the Comptroller General
  - Provides regular consultation and advice to the Federal Government on pharmaceutical chain safety and security issues, including RxTEC implementation, best practices, pilot projects, and other insights
- Requires the Secretary to evaluate and report to Congress on
  - The RxTEC system's impact on health care delivery system and patient access to medicines,
  - RxTEC system's capabilities and scalability, and
  - Findings on whether additional electronic traceability requirements are needed to protect the public health
- This evaluation and report will help determine if further electronic traceability components are needed to ensure patient safety and secure the supply chain



**ENACTMENT**

2012.5

**IMMEDIATE BENEFITS:** New Standards, Enhanced Internet Security and Penalties

2013.5

**COMMUNITY:**  
1<sup>st</sup> recommendation 12 months after enactment (annual thereafter)

2014

**RxTEC REGULATIONS:**  
Final regulations promulgated 18 months after enactment

2017

**MANUFACTURERS:**  
3 years after final regulations

FDA REQUEST AUTHORITY-  
Manufacturers

**REPACKAGERS:**  
4 years after final regulations

**WHOLESALERS:**  
5 years after final regulations

2019

2020

**DISPENSERS:**  
6 years after final regulations

2020

FDA REQUEST AUTHORITY- All participants

2020.5

FDA ASSESSMENT &  
REPORT TO CONGRESS

2021

**CONTINUED BENEFITS:**  
New Standards,  
Enhanced  
Internet Security  
and Penalties

# ***Overview of RxTEC Act Benefits***

- Increases patient access to safe medicines
- Improves security of the pharmaceutical distribution chain
- Replaces the patchwork of state laws
- Increases efficiency throughout the pharmaceutical distribution chain
- Establishes a foundational technology -- creates “building blocks” not “road blocks” – that can evolve or be expanded based on public health needs and technological capabilities
- Is consistent with existing and emerging international requirements
- Lowers costs and regulatory burdens for all sectors when compared to compliance with existing and proposed laws

# ***Thanks and Questions***

## **PDSA contacts**

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Phone: 202-312-7400



U.S. Food and Drug Administration  
Protecting and Promoting Public Health

[www.fda.gov](http://www.fda.gov)

# Protecting the Drug Supply Chain



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

Acting Associate Director for Policy and Communications

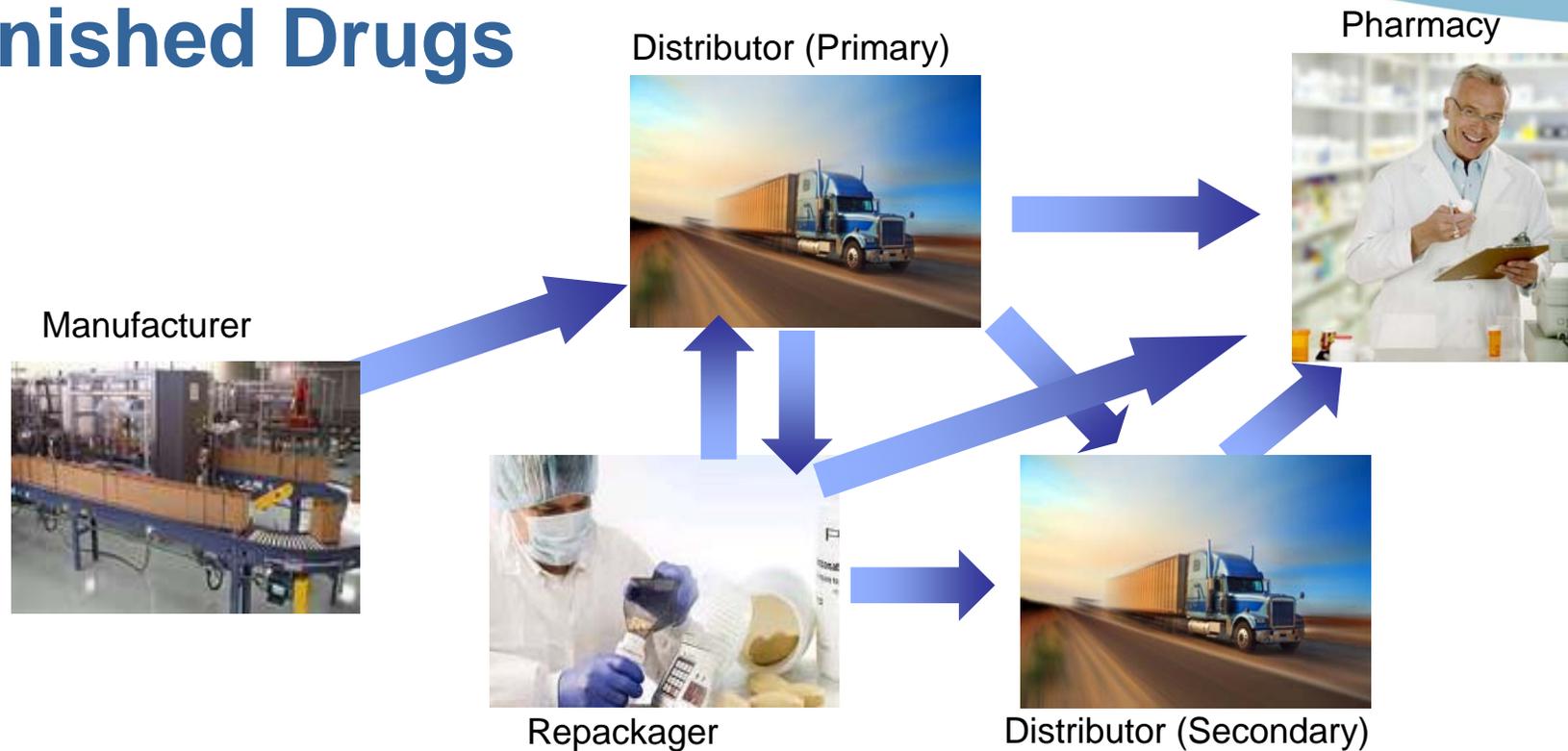
Office of Drug Security, Integrity, and Recalls

Office of Compliance/Center for Drug Evaluation and Research

U.S. Food and Drug Administration

CA State Board of Pharmacy - March 21, 2012

# Supply Chain for Finished Drugs



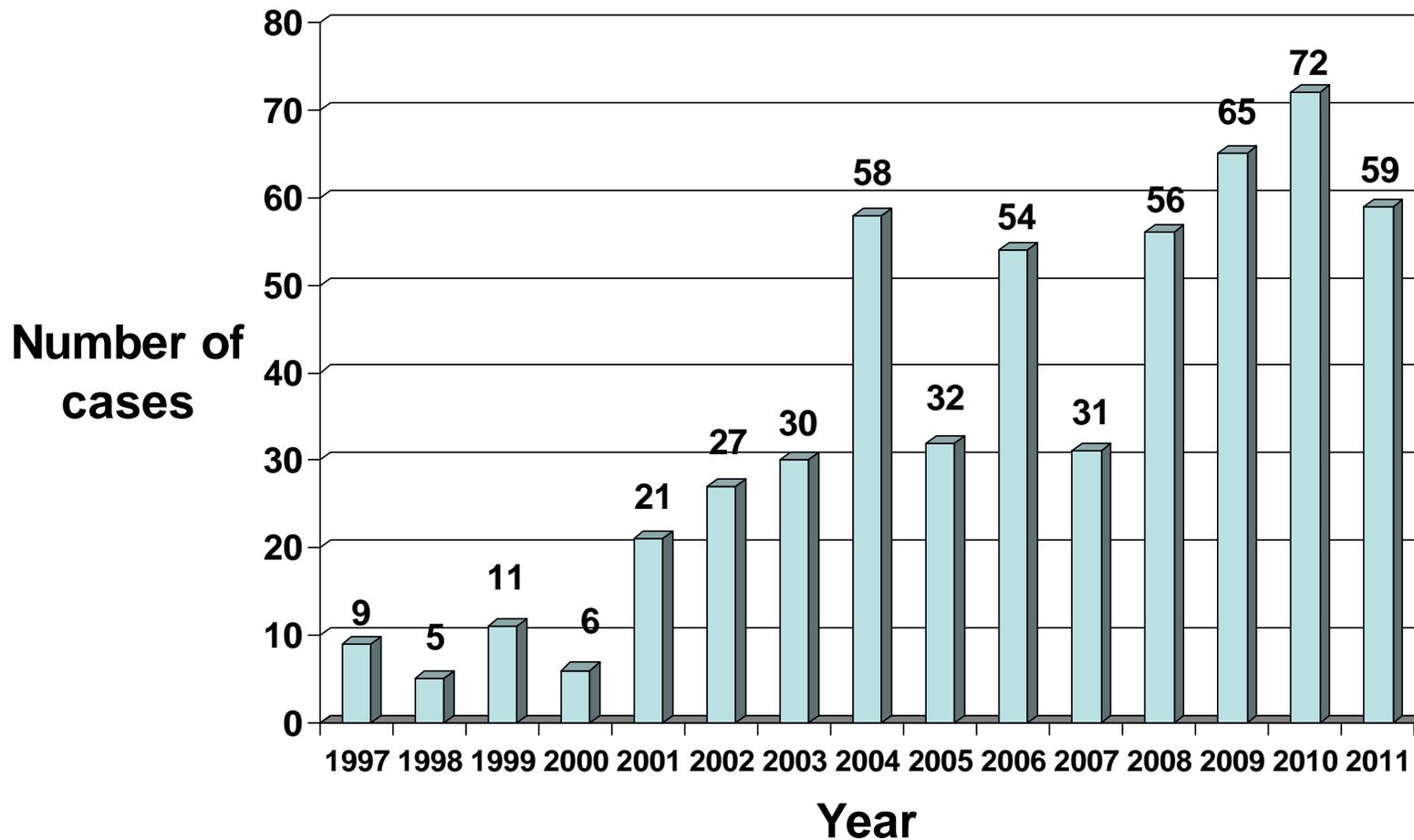
## Complexity of the supply chain is increased by:

- Multiple participants
- Globalization of supply chains
- Criminal 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

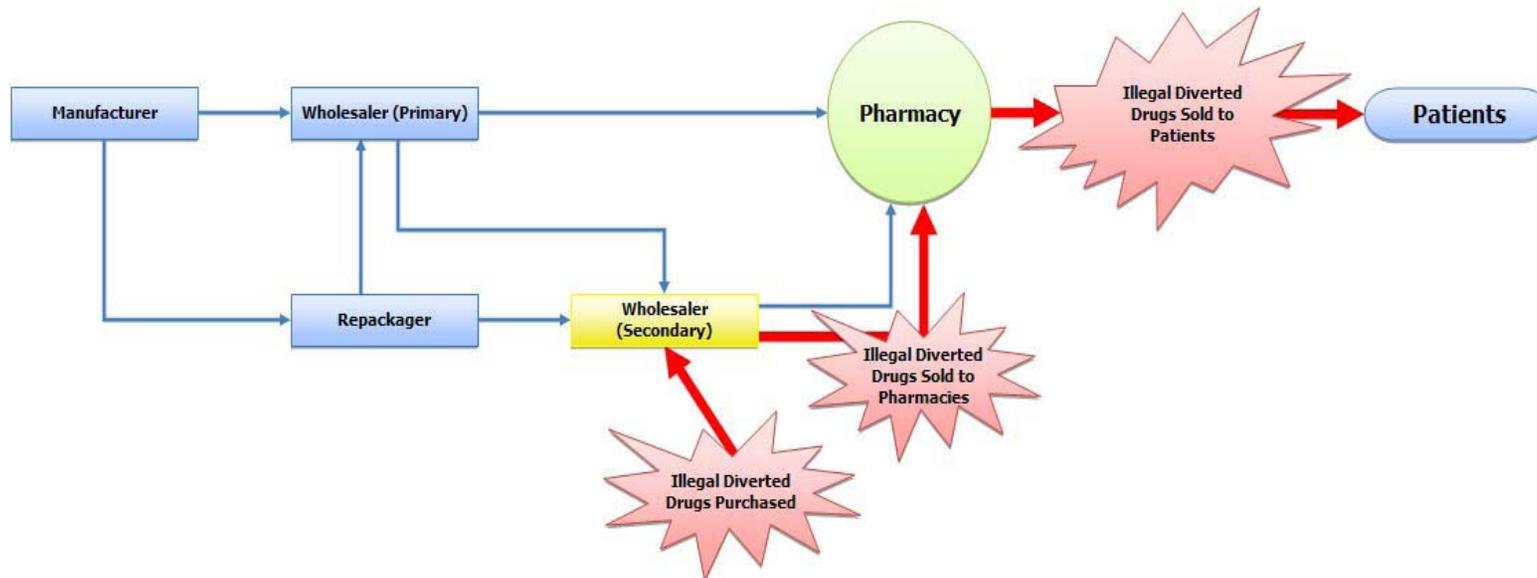
## Counterfeit Drug Cases Opened by FDA's Office of Criminal Investigations per Fiscal Year



# Preliminary Review of OCI Cases

## Report Highlights

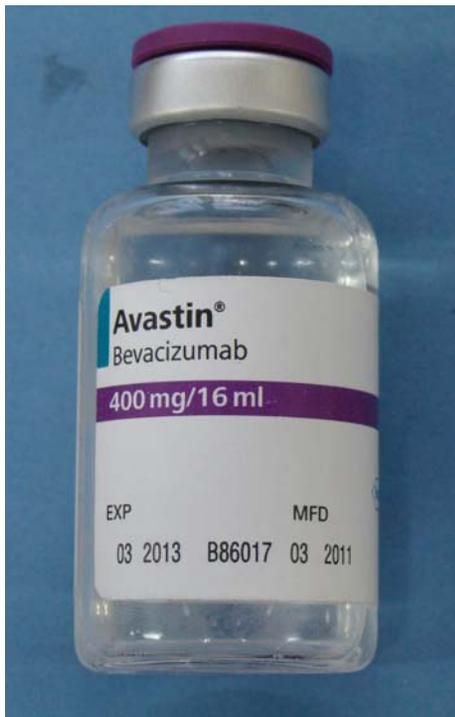
- Examples of diversion and counterfeit schemes



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

# Compromised Integrity: Recent Supply Chain Threats

## Counterfeit



- Counterfeit Roche Avastin
- No active ingredient
- Medical clinics notified
- Only Genentech Avastin is FDA-approved in U.S.
- Investigation ongoing

## Authentic



Images from  
Genentech, Inc.

## Counterfeit/Falsified, Diverted or Stolen or Unapproved Drugs may be Dangerous



- May contain harmful ingredients
- May be ineffective (contain no or little drug)
- May cause adverse events (due to ingredients or wrong strength)
- May have lost potency (due to improper storage)
- May be expired
- May be produced under filthy conditions...etc.

**= harm to public health**



***What's FDA doing to protect public health?***

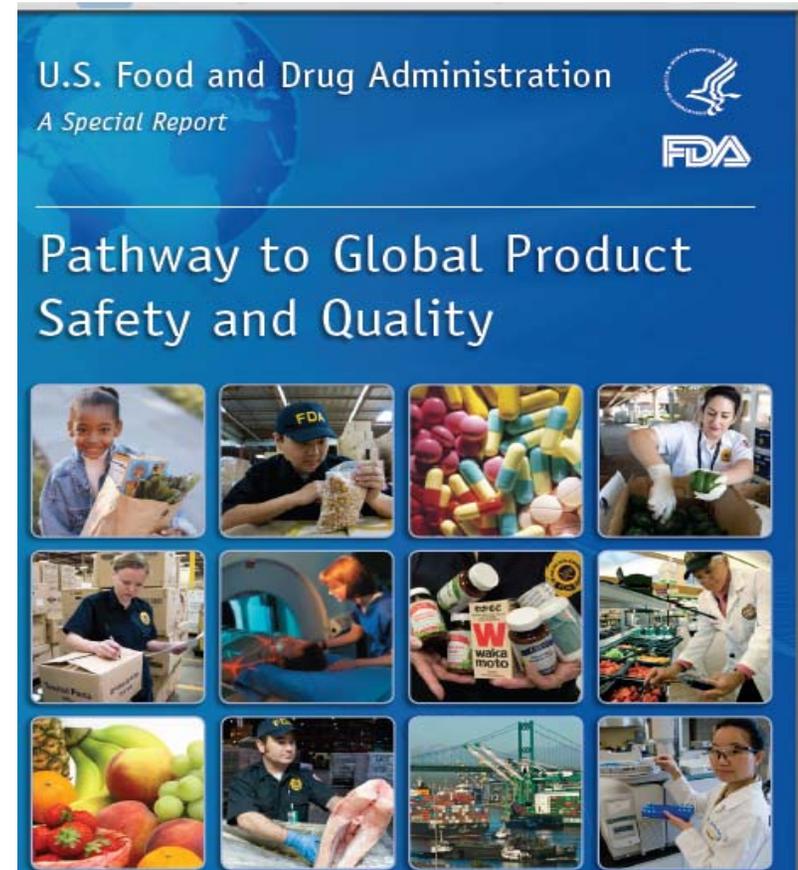
# Building Supply Chain Integrity to Ensure Patient Safety (1)

- Transparency and accountability in the supply chain – up and down
- Better enforcement and regulatory tools
- Stakeholder responsibility
- Surveillance/monitoring
- Increased vigilance and awareness
- Educate consumers

*(continued)*

# Building Supply Chain Integrity to Ensure Patient Safety (2)

- Collaboration/cooperation – domestic and international
- Harmonize/Converge internationally
- Share scientific and technical expertise with fellow foreign regulators
- Training programs in regulatory disciplines internationally
- Strengthen global detection, surveillance and assessment systems
- Support development of innovative information systems



# **New** Office of Drug Security, Integrity, and Recalls (ODSIR)

- Enhanced and targeted resources
- Address increasing supply chain threats
  - Intentional adulteration, cargo theft, counterfeiting, diversion, other
  - Focus on life-cycle of the product from drug components through to the finished dosage form delivered to the patient
- New and coordinated approaches, policies and enforcement strategies

**Recalls**  
**Drug Shortages**

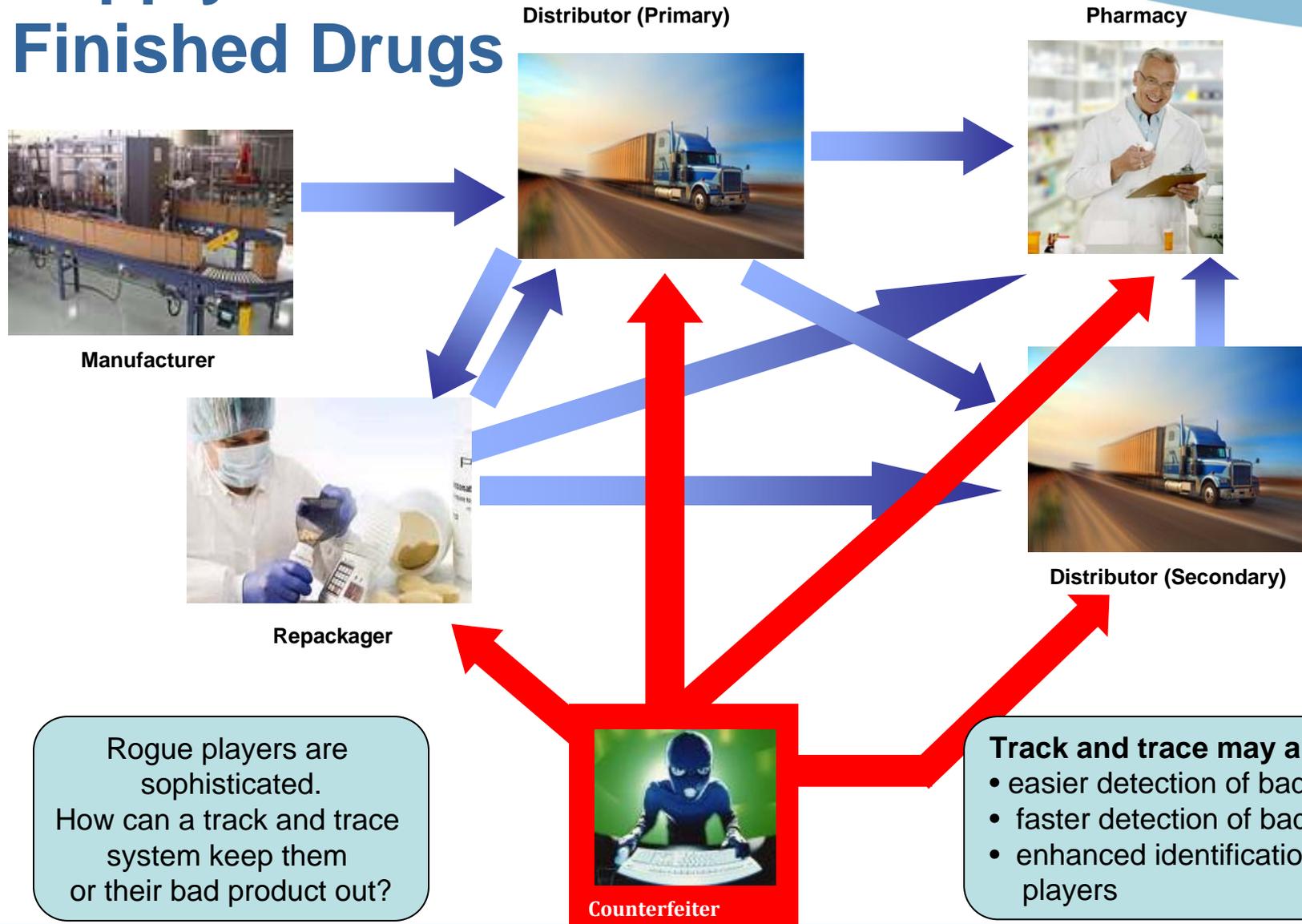
**Imports**  
**Exports**

**Drug Supply Chain Integrity**

# Transparency and Accountability

- **Know what is in the drug supply chain and who is handling the drugs**
- **Current: Pedigree**
  - documenting each sale or transaction of the product
  - knowledge of:
    - What drug? How much?
    - Who they bought it from and when
    - Who they sold it to and when
    - Other information
- **Future/Ideal: Track and Trace & Authentication**
  - National, uniform tracking and tracing & authentication at unit/package level
  - All supply chain stakeholders track and trace & authenticate
  - Authentication: Check unique serial number on each package & who sold it
  - Other possible security features ( e.g., hologram, color-shifting ink, taggants)

# Supply Chain for Finished Drugs



Rogue players are sophisticated. How can a track and trace system keep them or their bad product out?

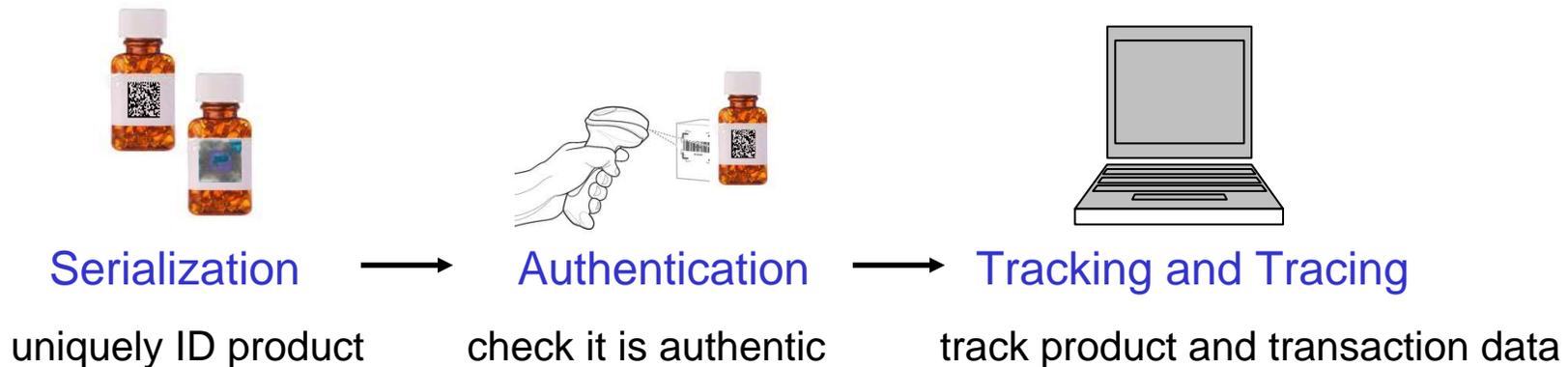
**Track and trace may allow**

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

Counterfeiter

# Development of Supply Chain Security Standards – Track and Trace

- Section 505D of the Federal Food Drug Cosmetic Act (2007)
- 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)
- Public Dockets (2008)
- SNI Guidance (2010) – standardized numerical identification, serialized NDC
- FDA Track and Trace Public Workshop (2011)



# Development of Supply Chain Security Standards – Track and Trace

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	+ 1111111111111111111111

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

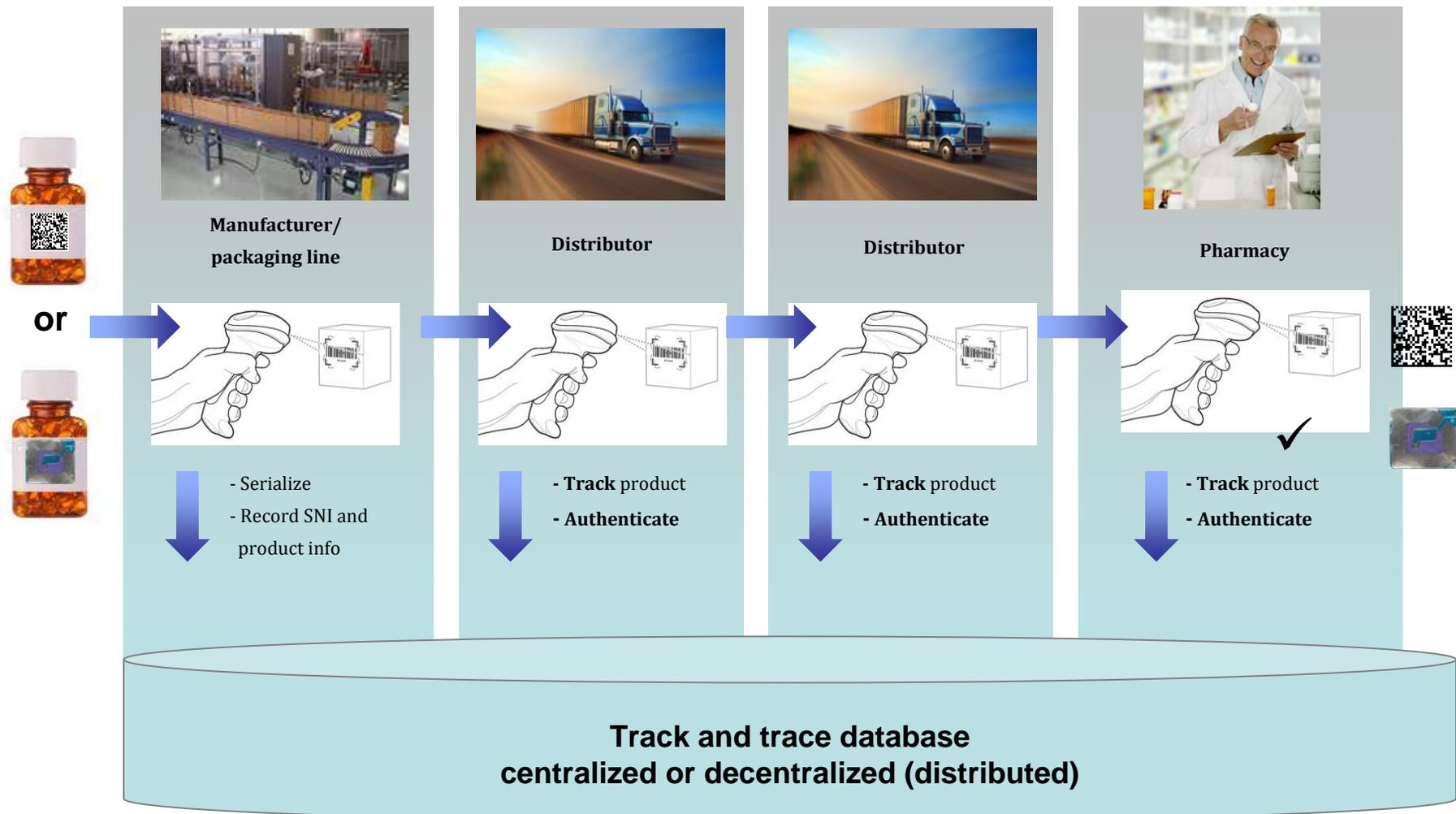
# Development of Supply Chain Security Standards – Track and Trace

## FDA Track and Trace Public Workshop (February 2011)

- Purpose of workshop – to obtain public input on the necessary elements to achieve effective authentication and the desirable attributes of a track and trace system
- 120 participants representing all stakeholders (manufacturers, distributors, pharmacy, carriers, standards organizations, solution providers)
- Workshop structure was very well-received by participants

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

# Overview of a Track and Trace System



## Track and Trace System Goals to Protect the Drug Supply Chain

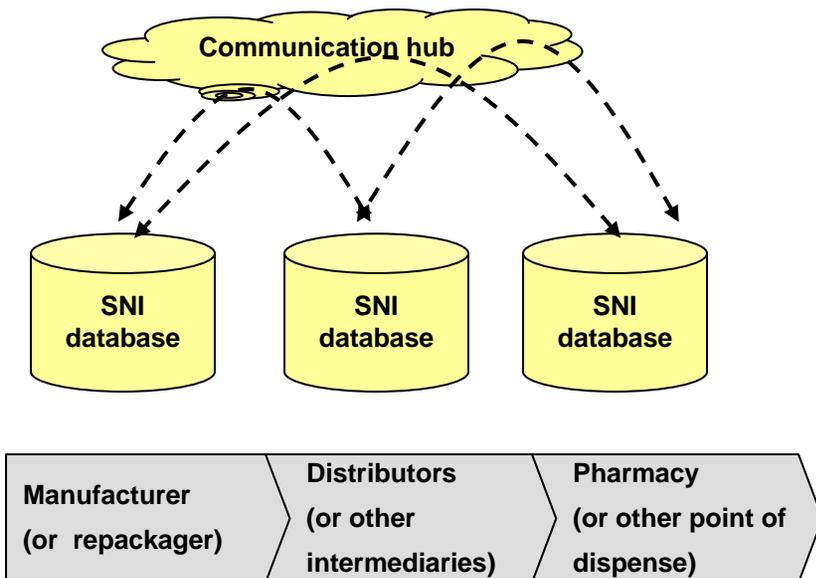
- Help to preventing the introduction of counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs
- Facilitating the identification of counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs
- Providing accountability for the movement of drugs by supply chain participants
- Improving efficiency and effectiveness of recalls

# Potential System Attributes

- Capable of capturing data (SNI and status of the number)
- Interoperability - to enable supply chain participants to securely capture, store, and exchange track-and-trace data accurately and efficiently
- Authentication - SNI and distribution history of each package
- Appropriate Data Access and Utilization
- Secure
- Protects confidential commercial information and patient privacy (if applicable)

# Possible System Models

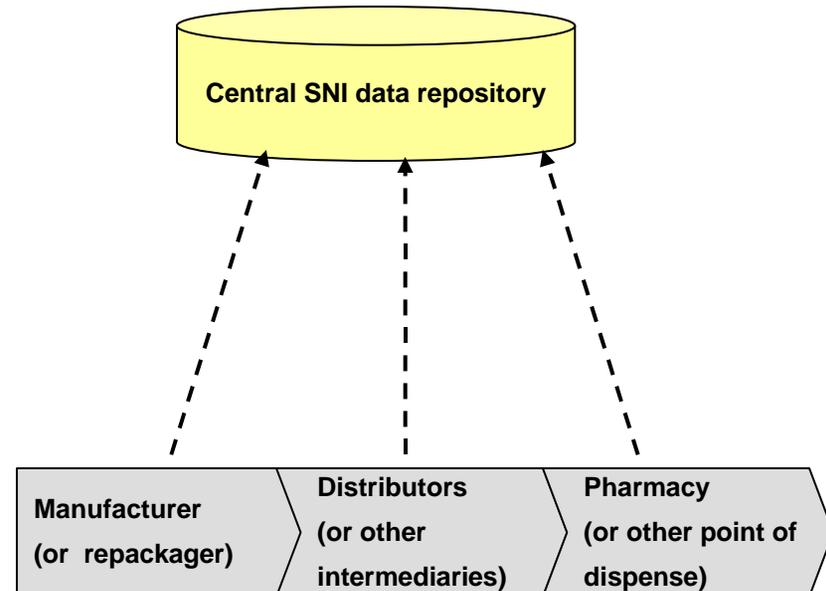
## Decentralized (Distributed) Model



### 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

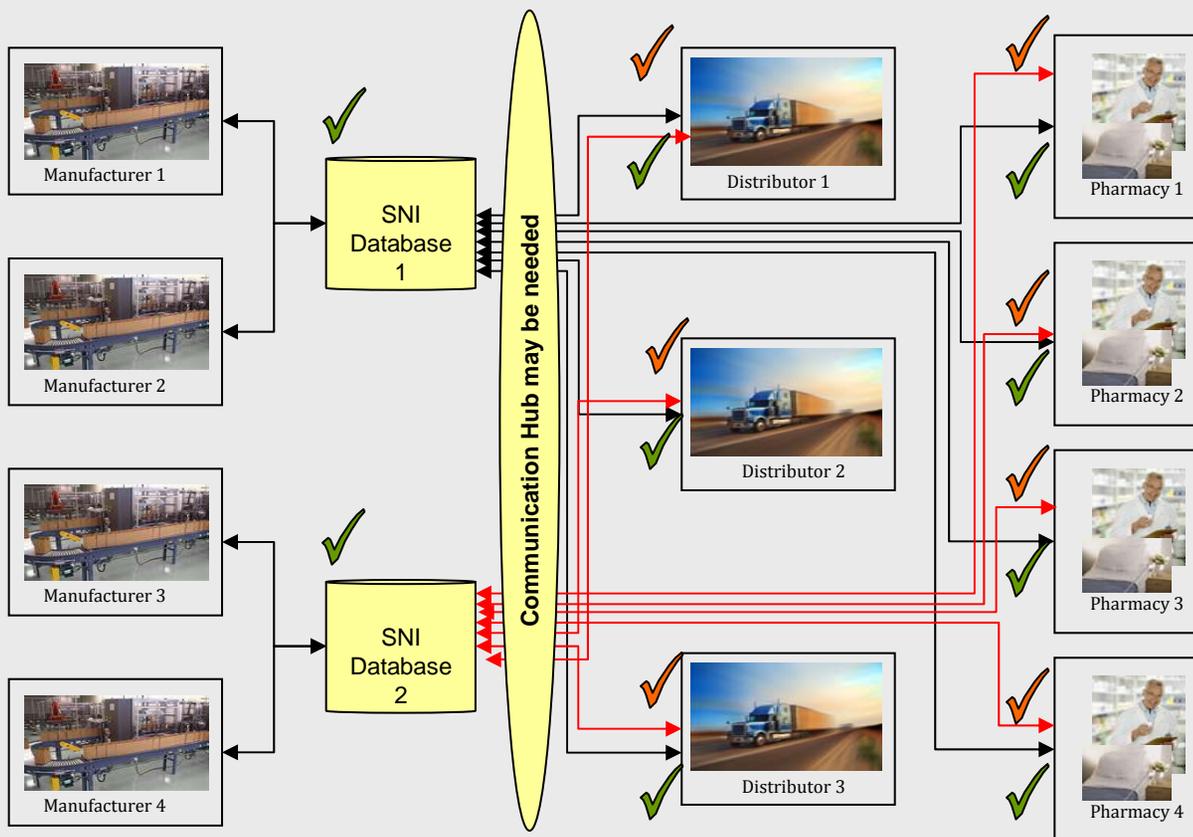


### Description

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

# Possible System Models

## Semi-Centralized Model



• ILLUSTRATIVE EXAMPLE

- ✓ Verification of SNI
- ✓ Verification of distribution history

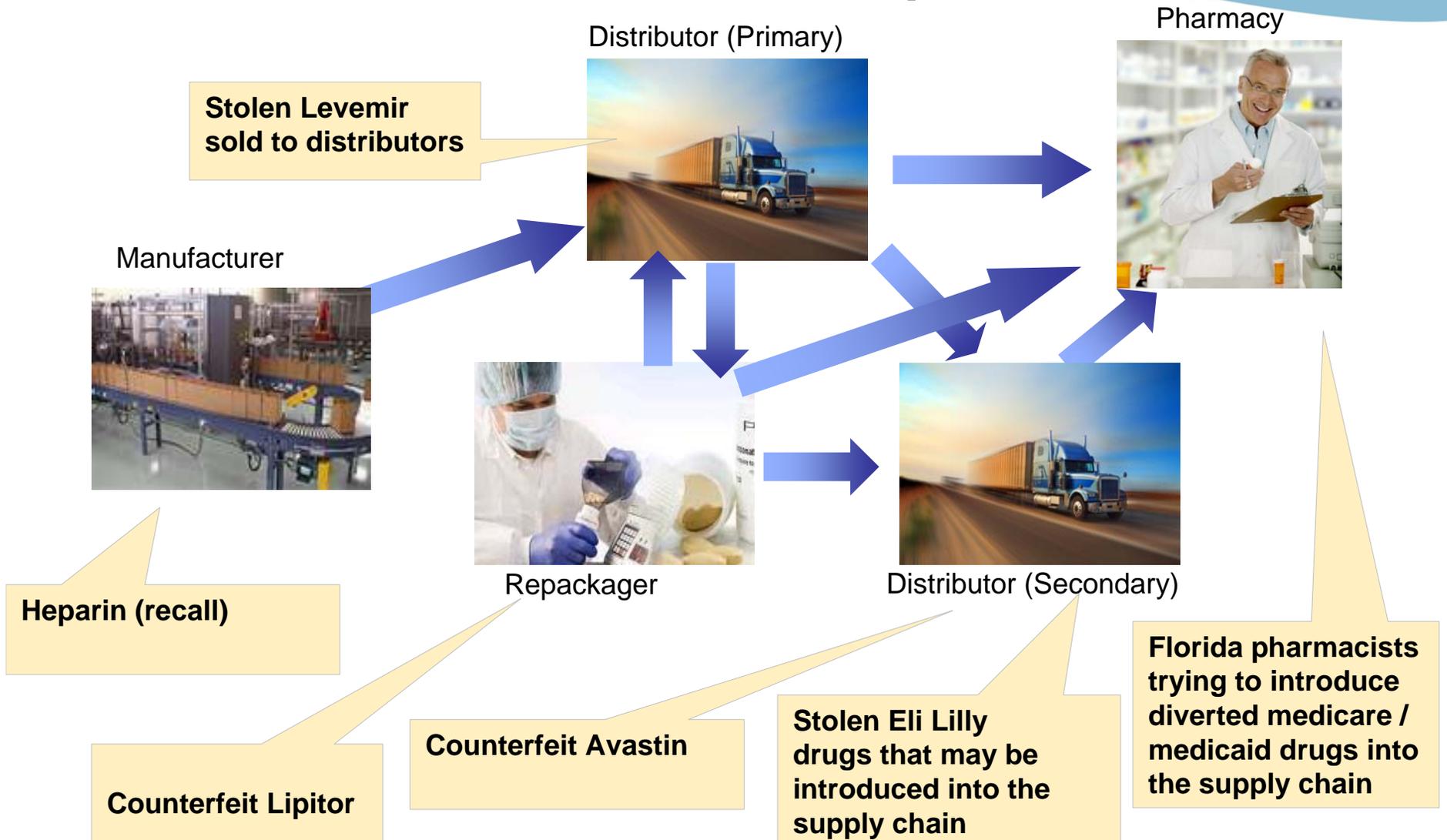
### Pros

- 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

# Where Track and Trace Can Help



## Summary Points to Consider to Protect the Drug Supply Chain

- What drugs should be tracked and traced?
- How should those drugs be identified?  
(SNI at the unit/package level)
- What info should be track and trace?  
(SNI at the unit/package level)
- What to authenticate? (SNI and who sold/received package)
- Who should be actively tracking and tracing/authenticating?  
(ALL members of the supply chain)

## Summary Points to Consider to Protect the Drug Supply Chain

- How does unit/package level traceability build quality and integrity into the system to detect potentially dangerous products from entering into the drug supply and prevent further distribution of these dangerous product?  
(a robust track and trace system would detect the problem product immediately when the product is introduced into the supply, assuming authentication at each step – is proactive, not just reactive to a problem)
- What would the system look like?  
(Centralized, Semi-Centralized or De-centralized?)
- What data standards should be used for language, format and communication, utilization?



# Thank you for your attention!

CDER/Office of Compliance/ODSIR Webpage

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

Counterfeit Medicines Webpage

<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/default.htm>

connie.jung@fda.hhs.gov





# THE ROLE OF GS1

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- **GS1** is a not-for-profit organisation dedicated to the design and implementation of **global standards** to improve the efficiency and visibility of **supply chains** globally and across sectors
- **111** member service organizations
- **35** years of experience
- **Neutral** platform for all supply chain stakeholders
- Over a **million** companies doing business across **150** countries
- Over **6 billion** transactions a day

GS1 is the most widely used supply chain standards system in the world



# WHY GLOBAL STANDARDS?



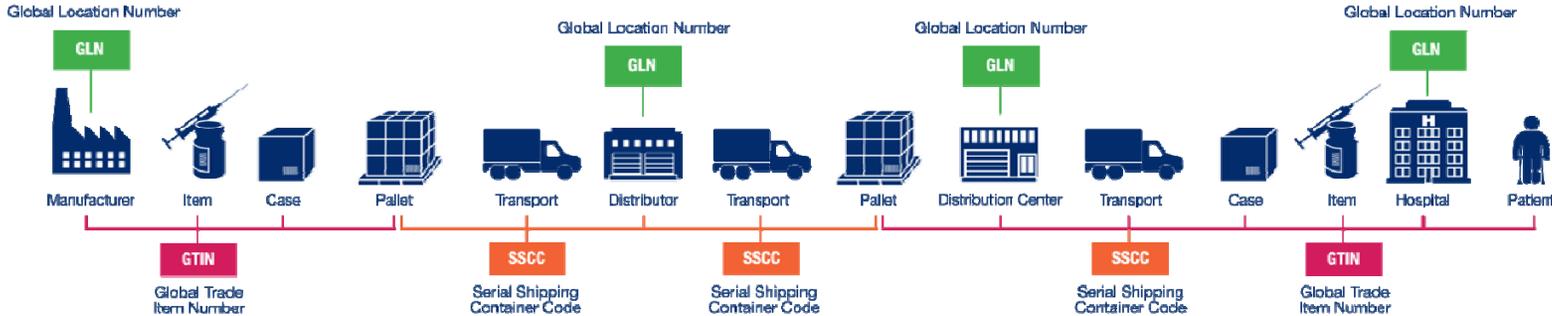
The package has:

- 6 machine readable codes (5 bar codes, 1 data matrix).
- 17 flags (UK, Ireland, Malta, Netherlands, Belgium, Germany, Austria, France, Spain, Portugal, Greece, Cyprus, Norway, Sweden, Denmark, Iceland, Finland) (not Italy)
- 12 different language texts (English, French and German are used in more than one country).

# GS1 STANDARDS IN HEALTHCARE

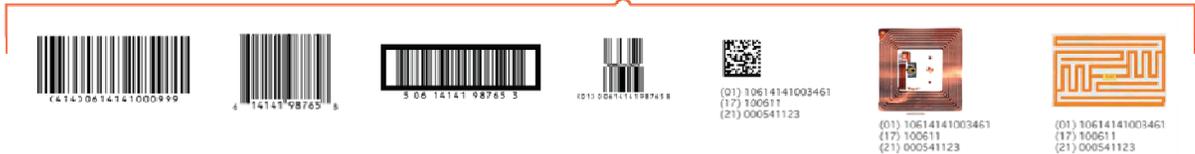
## Identify

GS1 System Identification Numbers



## Capture

GS1 System Data Carriers  
Barcodes and EPC-enabled RFID tags



## Share

Electronic Commerce Information Flow

Master Data (GLN Registry for Healthcare, GDSN) • Transactional Data (eCom) • Physical Event Data (EPCIS)

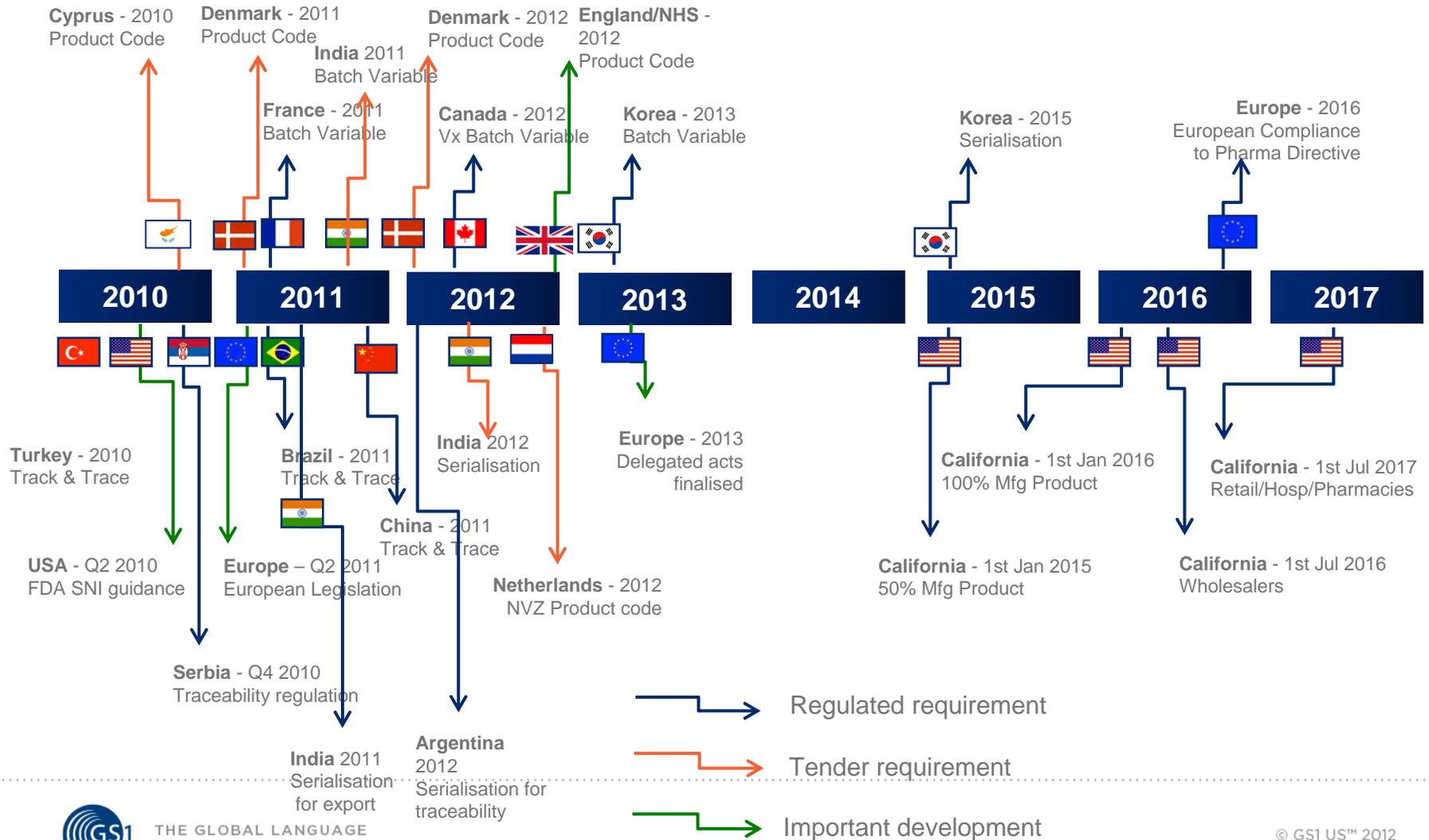




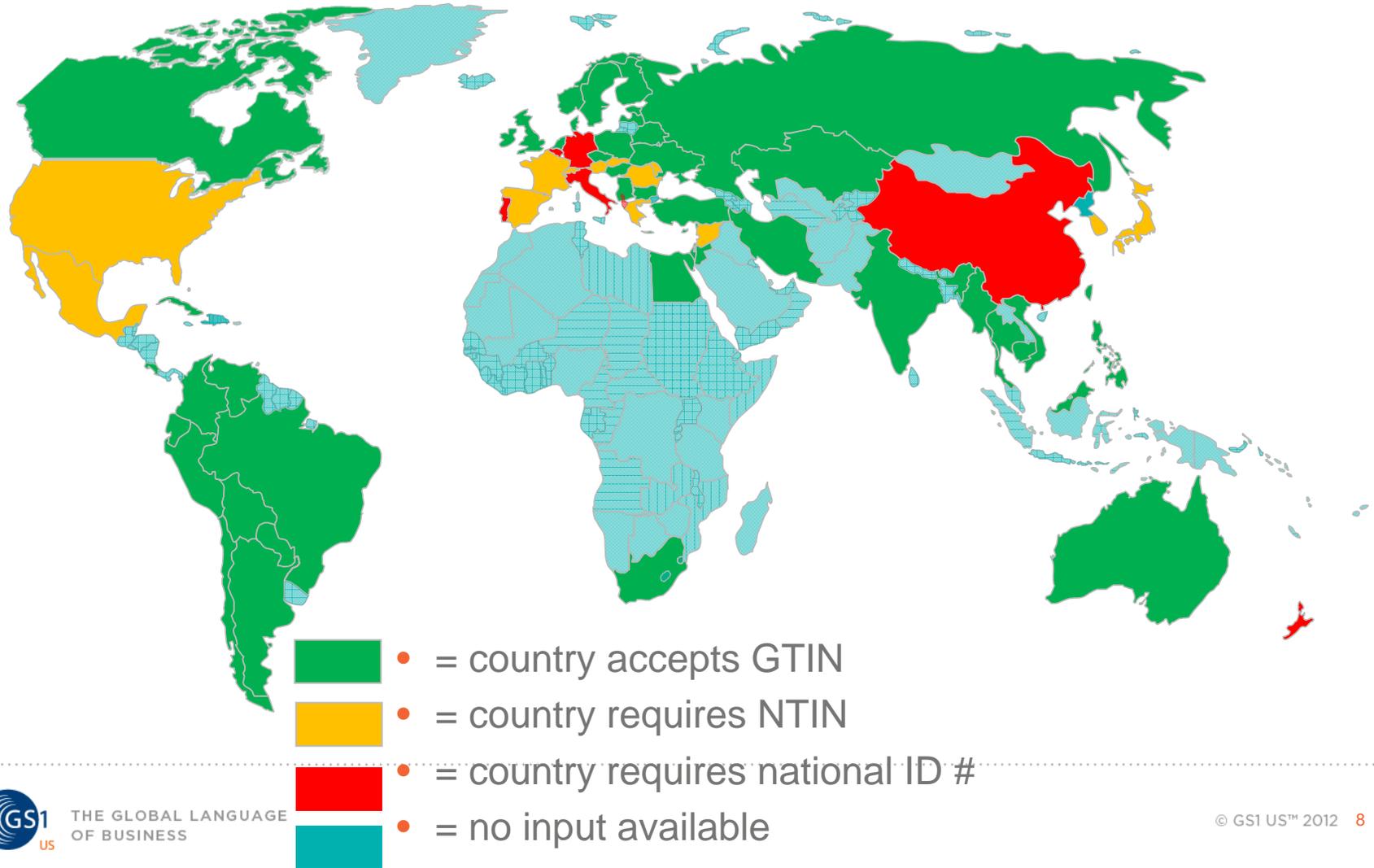
# GLOBAL IMPLICATIONS

# PHARMACEUTICALS

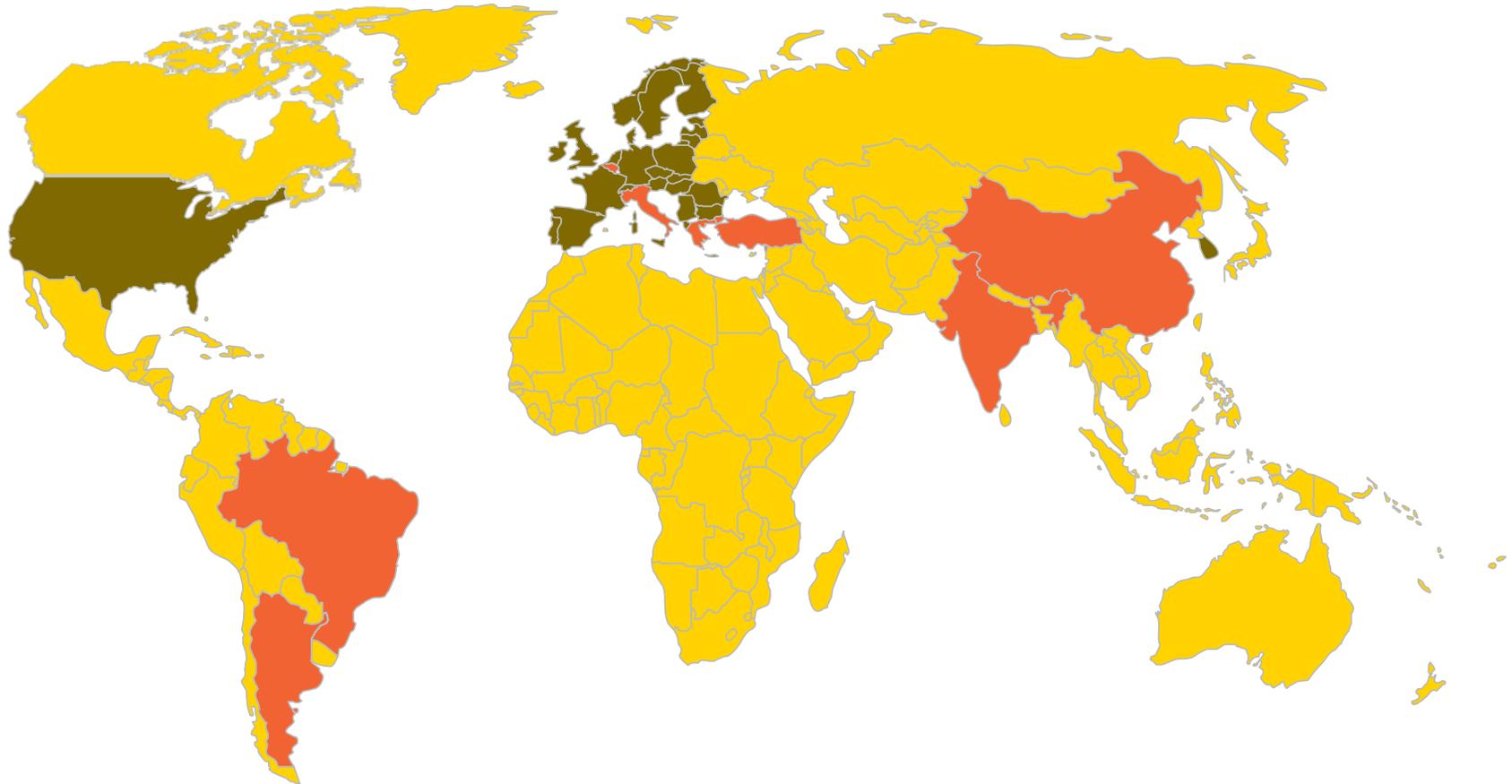
## NEW CODING & SERIALISATION REQUIREMENTS



# IDENTIFICATION OF PHARMACEUTICALS



# SERIALISATION OF PHARMACEUTICALS



• = country requires serial number

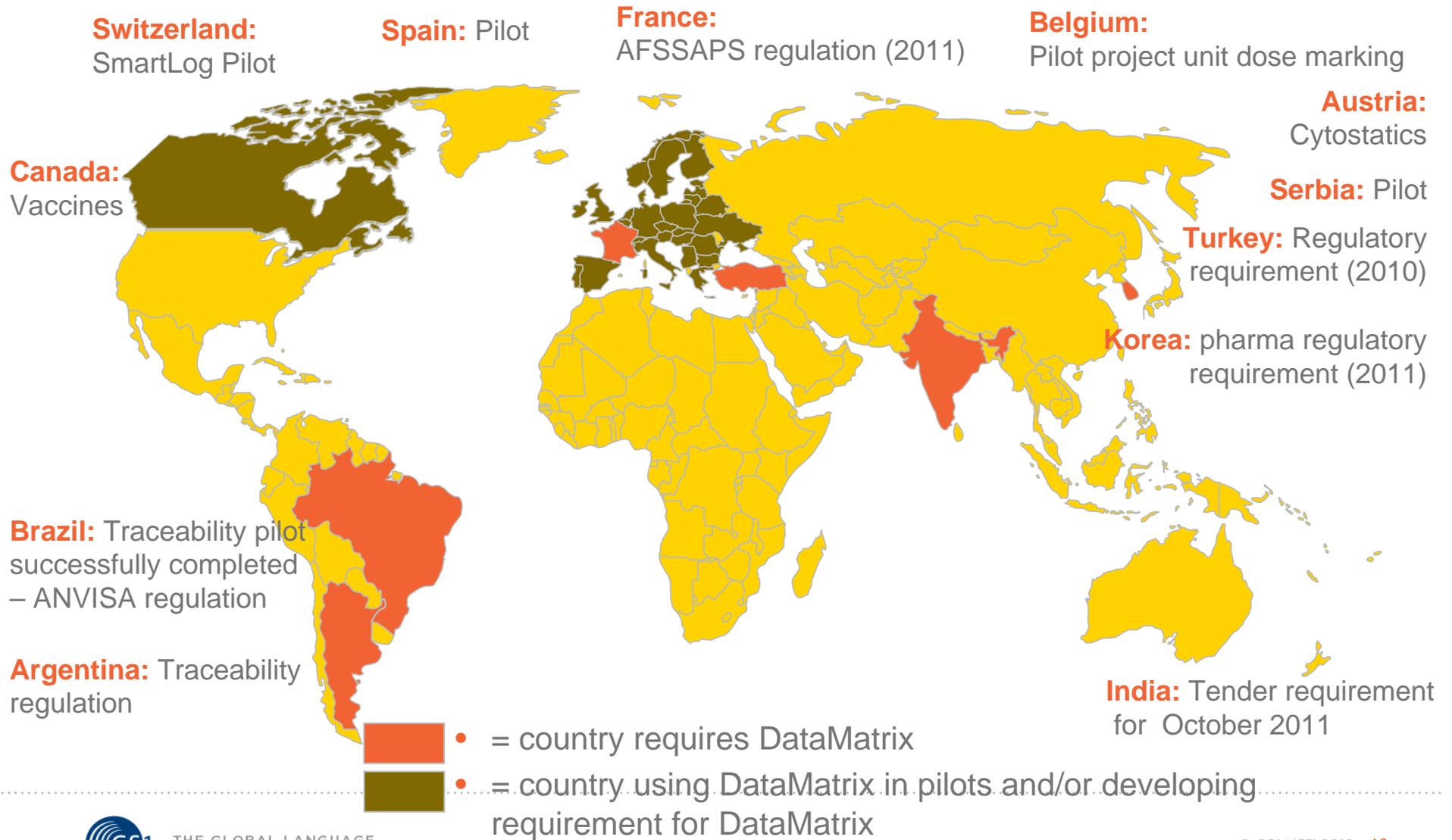


• = country developing requirement for serial number



THE GLOBAL  
LANGUAGE  
OF BUSINESS

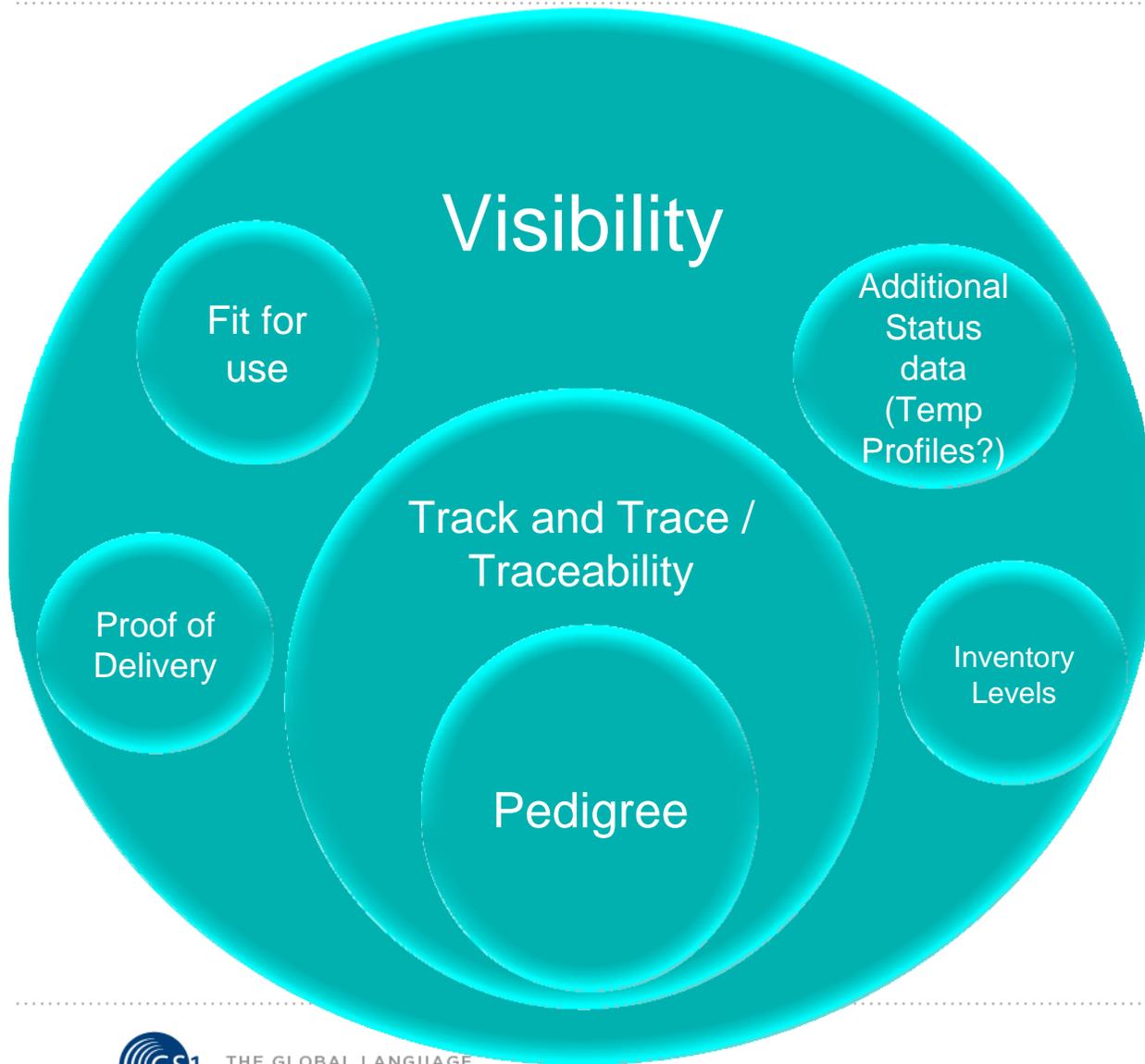
# DATAMATRIX ON PHARMACEUTICALS





# PEDIGREE, TRACK & TRACE, VISIBILITY

# VISIBILITY, TRACEABILITY, TRACK AND TRACE, PEDIGREE TERMS



## **Visibility:**

All of Track & Trace / Traceability. Can also provide status or disposition of item. May include other attributes that provide insight as to whether the item is fit for use. Leverages separate Master Data management.

## **Traceability / Track and Trace:**

Interchangeable terms. GS1 uses Traceability while others (FDA) use Track & Trace).

Provides ability to track forward to determine where the item currently is or trace back where it had been. Can leverage separate Master Data management.

## **Pedigree:**

Usually defined by U.S. State or Federal law. Information to “trace” the distribution history of an item. May include Chain of Custody and/or Chain of ownership.



# THE BALANCING ACT

THINGS TO CONSIDER, PERCEPTION ISSUES

# SERIALIZATION AND TRACK & TRACE

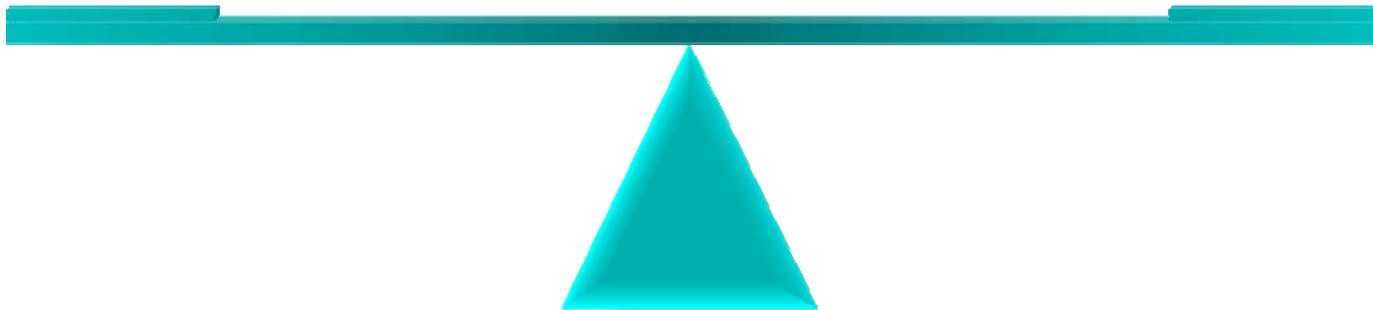
## THE BALANCING ACT

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Inference  
1 Up, 1 Down  
On Demand  
Single Architecture Models

**Decisions,  
Decisions,  
Decisions**

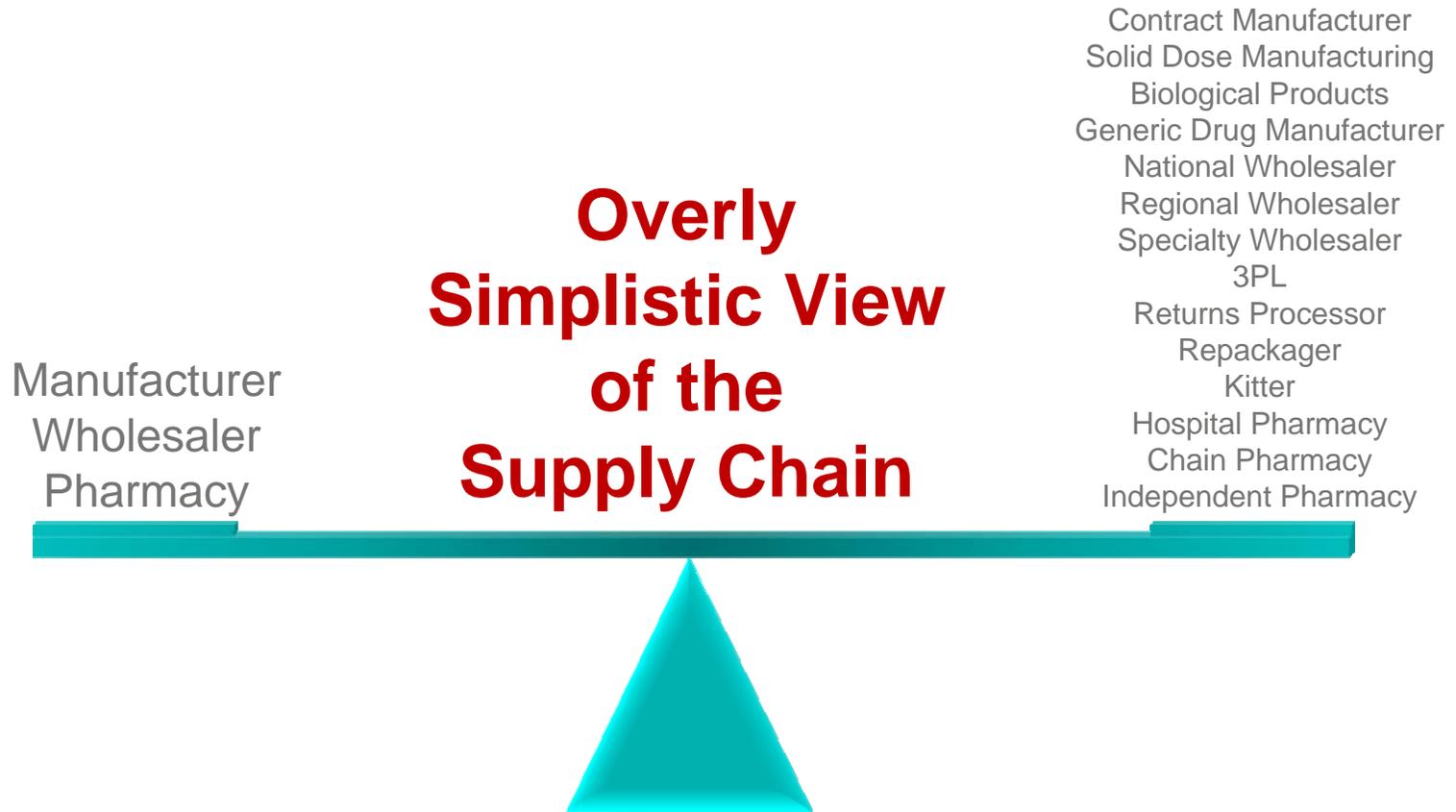
Decommissioning  
Track & Trace  
On Arrival  
Multi-Architectures



# SERIALIZATION AND TRACK & TRACE

## THE BALANCING ACT

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# SERIALIZATION AND TRACK & TRACE

## THE BALANCING ACT

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### Normal Processes

Basic Forward Logistics  
Drop Shipments  
Kitting  
Repackaging  
Recalls  
Returns  
Withdrawals  
Refusals

**Perception of  
the amount  
of Processes  
Impacted or  
Created**

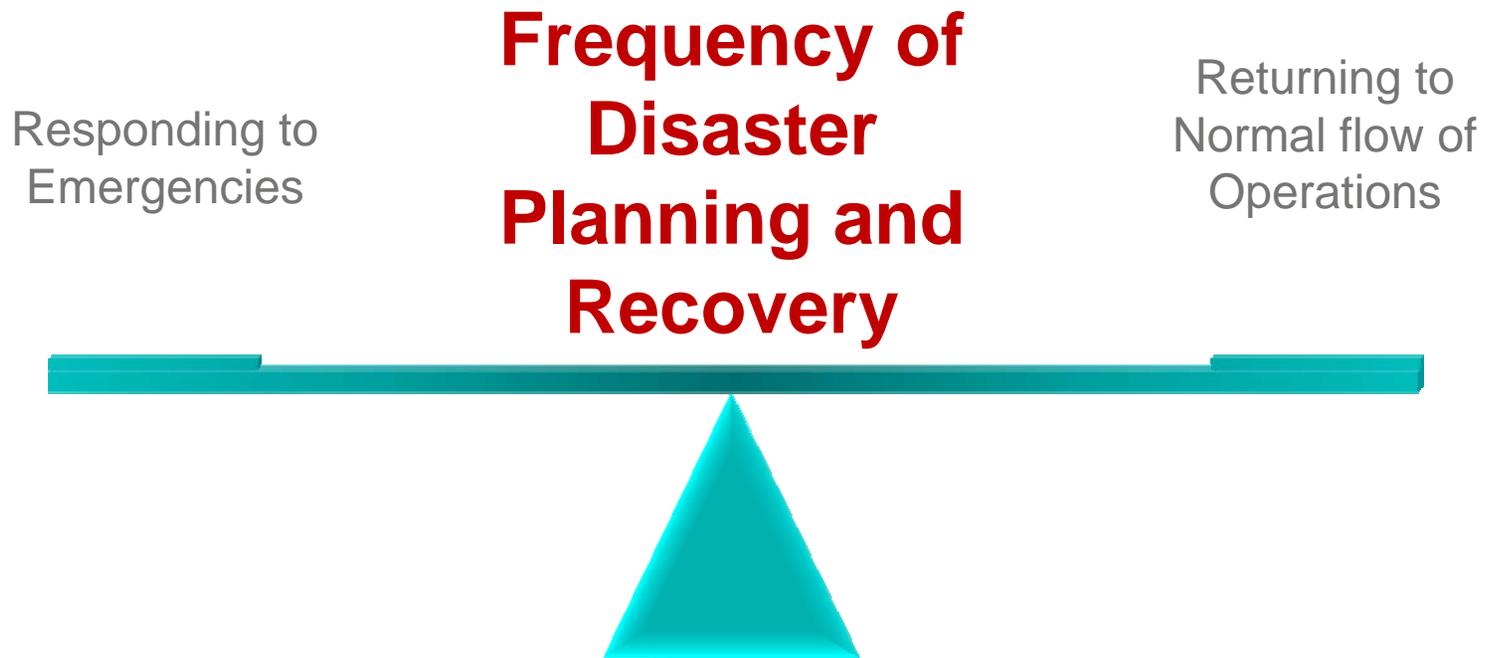
### Exception Processes

Visible Overage  
Visible Shortage  
Pedigree Serial # Discrepancy  
Pedigree Lot Discrepancy  
Product Inference Problem  
Concealed Discrepancy  
Physical Inventory - Visible Overage  
Physical Inventory - Concealed Overage  
Physical Inventory - Pure Shortage  
Physical Inventory - Concealed Shortage  
Pedigree Data Error  
Pedigree Data Not Received  
Undelivered Shipment  
Lost Shipment  
Unidentified Sender  
Pedigree Security Error  
Damaged Bar Code or RFID  
Damaged Product  
Damaged Shipment  
Product Damaged after Receipt  
Unauthorized Return

# SERIALIZATION AND TRACK & TRACE

## THE BALANCING ACT

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# STANDARDS ACTIVITIES IN THE U.S.

IMPLEMENTATION SUPPORT

# SECURE SUPPLY CHAIN TASK FORCE

## IMPLEMENTATION GUIDE UPDATE



**GS1 Healthcare<sup>®</sup>**  
US Improving Patient Safety and Supply Chain Efficiency

Implementation Guide

**Applying GS1 Standards to  
U.S. Pharmaceutical Supply Chain  
Business Processes**

To Support Pedigree and Track & Trace

**DRAFT**  
V0.13 (February 7, 2011)

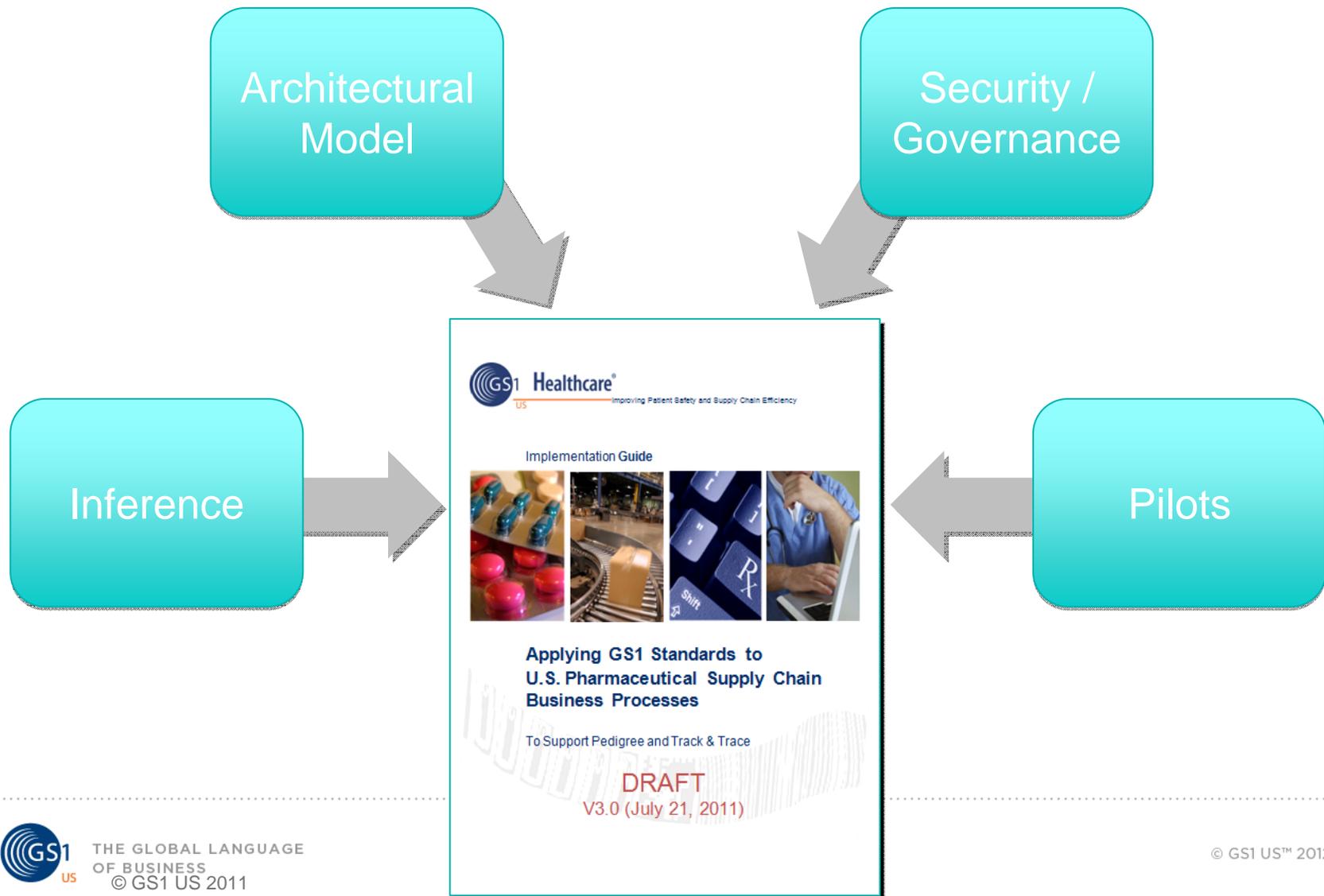
### Contents of the guideline:

- Identifying Trade Units (Products, Cases, and Kits):
- Identifying Logistics Units (Cases, Pallets, and Totes)
- Identifying Parties & Locations
- Encoding GS1 Data Carriers
- Translating Captured Data
- Master Data Management (product and location data)
- Applying GS1 Standards for Event Data
- Supply Chain Events to be Captured for Pedigree
- Additional Supply Chain Events for Track & Trace
- Exceptions Processing
- Pilot learnings / best practices
- Forward Logistics Examples
- Reverse Logistics Examples
- Potential Architectural Models

### Decisions that will affect final version:

- Track and Trace granularity (Lot, Item)
- Inference
- Architecture (Centralized, Decentralized, etc.)
- Data access governance

# STANDARDS ACTIVITIES WITHIN THE U.S. IMPLEMENTATION SUPPORT



# STANDARDS ACTIVITIES WITHIN THE U.S. IMPLEMENTATION SUPPORT - STATISTICAL SAMPLING MODEL



THE GLOBAL LANGUAGE  
OF BUSINESS



Statistical Sampling Plan										Quality Characteristics of the Selected Plan									
<b>Input required by users:</b>										<b>1. Operating characteristic (OC) curve</b>									
Size of shipment (in bottles): 1,000 bottles										Shows the ability of the plan to distinguish between good and bad shipments.									
Acceptable quality level (%): 1.000% please select from the drop down list										For any fraction nonconforming $p$ , the OC curve shows the probability $P_a$ that the shipment will be accepted.									
<b>Output:</b>										<b>Operating Characteristic (OC) Curve</b>									
Code letter: J																			
<b>Normal Inspection:</b>										<p><b>Reduced Inspection (1):</b> the probabilities of acceptance accompanied by continuation of reduced inspection.</p> <p><b>Reduced Inspection (2):</b> the probabilities of not rejecting a shipment. The difference between the two curves equals to the probability that a shipment will be accepted but normal inspection will be reinstated.</p>									
<b>Parameters of sampling plan:</b>										<b>2. Average Outgoing Quality (AOQ):</b>									
sample size (n): 80										Calculates the average percentage of nonconforming items after inspection, <u>in the long run</u> .									
Acceptance number (c): 2										Please check in the "Model assumptions" tab for more information on how the AOQ is calculated.									
<b>Sample plan instructions:</b>																			
1. Randomly select 80 bottles out of all bottles in the shipment, and inspect them.																			
2. If the total number of nonconforming items found in the inspection is less than or equal to 2, accept shipment. Otherwise reject shipment.																			
3. Record inspection results in the results form.																			
4. If shipment was rejected, conduct 100% inspection of all bottles in the shipment.																			
5. Follow company policy to determine how to deal with any nonconforming items found during inspection.																			
<b>Switch to tightened inspection:</b>																			
6. If 2 or more of the last 5 shipments from the same supplier have been rejected, switch to tightened inspection.																			
<b>Switch to reduced inspection:</b>																			
7. Switch to reduced inspection if <b>ALL</b> of the following conditions have been met:																			
- It seems likely that the product to be inspected under reduced inspection will be produced and delivered to the receiving party under the same conditions that gave rise to the recent good quality history; and																			
- <b>Reduced inspection is considered desirable</b> by the responsible authority; and																			
- The total number of nonconforming items found in the preceding 10 (or more) shipments is sufficiently low. To check																			

# 2015 READINESS PILOTS GET INVOLVED & LEARN FROM OTHERS



# 2015 READINESS PILOTS

## SAMPLE PILOT TRACKER

Pilots	Participants	Carrier Quality (Barcode, RFID)			Data Exchange			Operations			Functionality				EPCIS Events/Steps			Exceptions											
		Barcode Verification			HD/MA/EDI Guidelines	GDSN	Discovery	Shared Event Repositories	DPMS	Aggregation Accuracy			Basic Forward Logistics	Drop Shipment	Returns	Recalls	Withdrawals	Refusals	Item Commissioning	Case Commissioning	Aggregation	Shipping	Receiving	Overage	Underage	Serial # Discrepancy	Lot # Discrepancy	Concealed Shortage	Incorrect EPCIS data
Barcode Quality	Manufacturer X	X																											
	Pharmacy Z	X																											
Extended Trading Partners	Manufacturer X				X							X																	
	Wholesaler Y				X							X																	
	Pharmacy Z				X							X																	

# TRACEABILITY PILOTS TASK FORCE

## PILOT PANEL CALLS

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Date	Agenda Topics
2/29/2012	Main Topic: <b>Serialization on packaging lines (encoding,)</b>
3/14/2012	Main Topic: <b>Interoperability and exchange between partners</b>
3/28/2012	Main Topic: <b>Pilot Planning</b>
4/11/2012	Main Topic: <b>Managing traceability information and implementation across the enterprise (scaling, avoiding competing implementations inside your co)</b>
4/25/2012	Main Topic: <b>Labeling (AI (30), Item Count), labeling practices you might encounter</b>
5/9/2012	Main Topic: <b>Packaging level indicators</b>
5/16/2012	Main Topic: <b>Pharmacy/Clinic roundtable</b>
5/30/2012	Main Topic: <b>Master Data Management</b>

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# CONTACT INFORMATION

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**[www.GS1US.org](http://www.GS1US.org)**

Connect with the GS1 US community on



# Attachment 2

# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2011/2012

**Workload Statistics**                      **July-Sept**    **Oct-Dec**    **Jan-Mar**    **Apr-June**    **Total 11/12**

**Complaints/Investigations**

Received	611	610	633		1854
Closed	413	450	485		1348
Pending (at the end of quarter)	1772	1849	1944		1944

**Cases Assigned & Pending (by Team) at end of quarter\***

Compliance Team	537	584	449		449
Drug Diversion/Fraud	226	318	297		297
Probation/PRP	101	119	132		132
Routine Inspection	33	85	266		266
Mediation/Enforcement **	64	82	146		146
Criminal Conviction	561	661	613		613

**Application Investigations**

Received	217	379	286		882
Closed					
Approved	135	137	156		428
Denied	18	27	22		67
Total ***	243	224	269		736
Pending (at the end of quarter)	209	363	409		409

**Letter of Admonishment (LOA) / Citation & Fine**

LOAs Issued	20	21	29		70
Citations Issued	239	127	236		602
Citations Closed	273	190	215		678
Total Fines Collected ****	\$319,115.00	\$198,405.00	\$408,751.76		\$926,271.76

\* This figure include reports submitted to the supervisor.

\*\* This figure include reports submitted to the citation and fine unit, AG referral, EO referral, as well as cases assigned to enf. staff

\*\*\* This figure includes withdrawn applications.

\*\*\*\*Fines collected (through 3/31/2012 and reports in previous fiscal year.)

# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2011/2012

**Workload Statistics**                      **July-Sept**    **Oct-Dec**    **Jan-Mar**    **Apr-June**    **Total 11/12**

**Administrative Cases** (by effective date of decision)

Referred to AG's Office*	85	49	65		199
Pleadings Filed	61	56	48		165
<b>Pending</b>					
Pre-accusation	194	175	129		129
Post Accusation	279	265	248		248
Total*	533	515	438		515
<b>Closed</b>					
<b>Revocation</b>					
Pharmacist	2	4	2		8
Intern Pharmacist	0	1	0		1
Pharmacy Technician	16	28	27		71
Designated Representative	1	0	0		1
Pharmacy	0	0	0		0
<b>Revocation, stayed; suspension/probation</b>					
Pharmacist	2	3	4		9
Intern Pharmacist	0	0	0		0
Pharmacy Technician	1	0	1		2
Designated Representative	0	0	0		0
Pharmacy	0	0	0		0
<b>Revocation, stayed; probation</b>					
Pharmacist	3	5	3		11
Intern Pharmacist	0	0	1		1
Pharmacy Technician	6	5	6		17
Designated Representative	0	0	0		0
Pharmacy	3	3	2		8
<b>Surrender/Voluntary Surrender</b>					
Pharmacist	0	3	5		8
Intern Pharmacist	0	0	0		0
Pharmacy Technician	7	8	9		24
Designated Representative	0	0	1		1
Pharmacy	0	1	0		1

# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2011/2012

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 11/12
<b>Public Repeval/Reprimand</b>					
Pharmacist	0	1	0		1
Intern Pharmacist	0	0	0		0
Pharmacy Technician	0	0	0		0
Designated Representative	0	0	0		0
Pharmacy	0	0	0		0
Cost Recovery Requested**	\$88,208.00	\$285,189.20	\$222,740.50		\$596,137.70
Cost Recovery Collected**	\$77,917.99	\$65,379.59	\$133,920.99		\$277,218.57

\* This figure includes Citation Appeals

\*\* This figure includes administrative penalties

### Probation Statistics

#### Licenses on Probation

Pharmacist	111	110	130		130
Intern Pharmacist	5	3	5		5
Pharmacy Technician	31	35	42		42
Designated Representative	2	2	3		3
Pharmacy	18	20	25		25
Wholesaler	2	3	4		4
Probation Office Conferences	17	40	31		88
Probation Site Inspections	73	66	60		199
Probationers Referred to AG for non-compliance	2	1	0		3

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences.

These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset,

2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

As of March 31, 2012.

## SB 1441 – Program Statistics

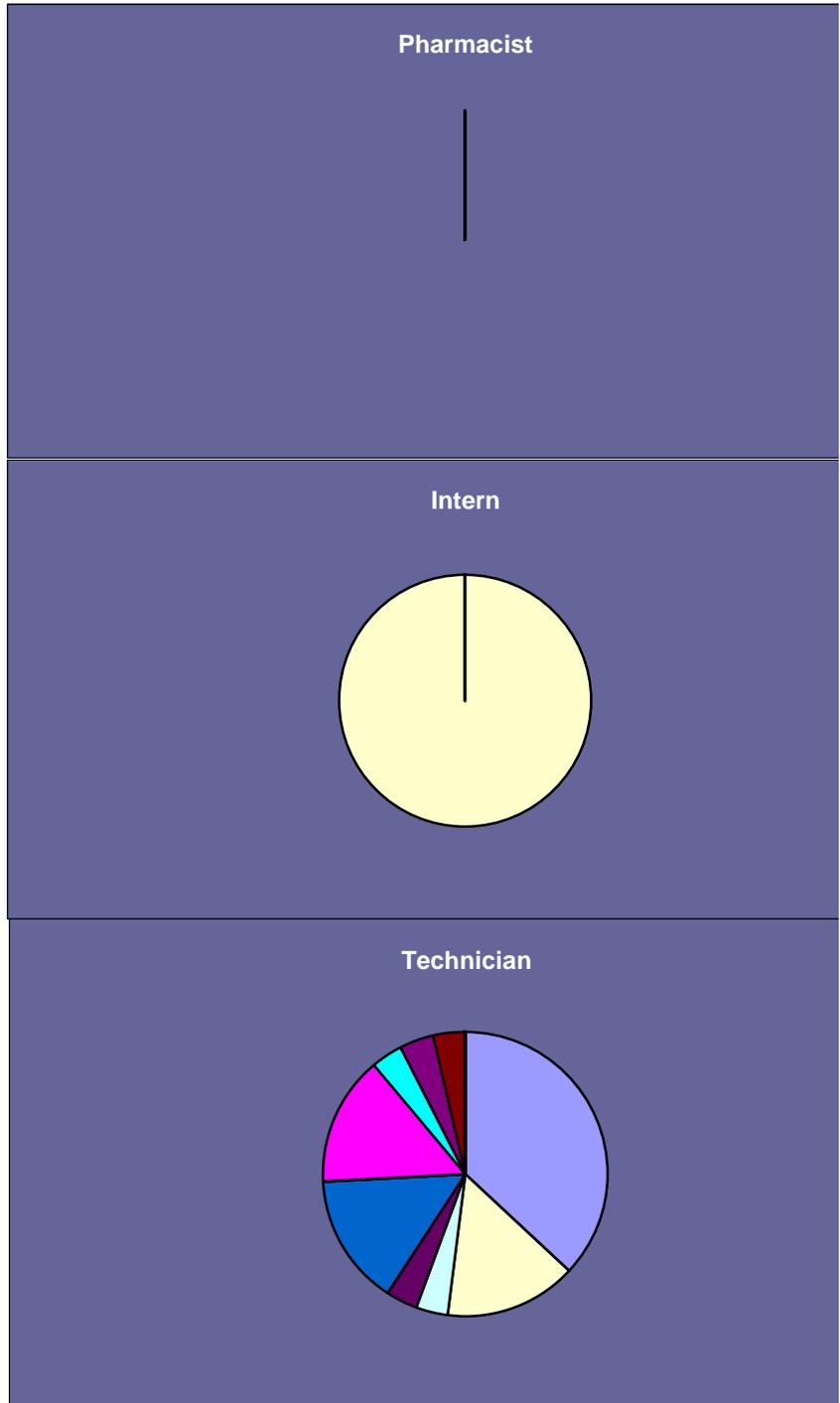
Pharmacist Recovery Program (PRP)

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 11/12
PRP Self-Referrals	3	0	1	0	4
PRP Board Referrals	3	0	2	0	5
PRP Under Investigation	3	5	1	0	9
PRP In Lieu Of	0	0	0	0	0
PRP Intakes	9	5	4	0	18
<b>New Probationers</b>	9	9	12	0	30
Pharmacists	2	3	5	0	10
Interns	0	0	1	0	1
Technicians	7	6	6	0	19
<b>Total PRP Participants</b>	76	80	76	0	N/A
Contracts Reviewed	70	76	72	0	218
	0	0	0	0	0
Total Probationers	100	95	110	0	305
Inspections Completed	97	106	91	0	294
<b>Referrals to Treatment</b>					
Referrals to Treatment	4	3	0	0	7
Drug Test Ordered	967	1076	1054	0	3097
Drug Tests Conducted	1185	1294	973	0	3452
<b>Relapsed</b>					
Relapsed	5	4	7	0	16
<b>Major Violation Actions</b>					
Cease Practice/Suspension	8	7	8	0	23
Termination - PRP	3	2	0	0	5
Referral for Discipline	3	2	0	0	5
<b>Exit from PRP or Probation</b>					
Successful Completion	2	3	1	0	6
Termination - Probation	2	3	0	0	5
Voluntary Surrender	2	1	4	0	7
Surrender as a result of PTR	0	1	0	0	1
Public Risk	3	2	4	0	9
Non-compliance	19	11	1	0	31
Other	1	2	1	0	4
<b>Number of Patients Harmed</b>	0	0	0	0	0
<b>Drug of Choice at PRP Intake or Probation</b>					
<b>Pharmacists</b>	<b>July-Sep</b>	<b>Oct-Dec</b>	<b>Jan-Mar</b>	<b>Apr-Jun</b>	<b>Total 11/12</b>
Alcohol	9	3	4	0	16
Opiates	3	0	0	0	3
Hydrocodone	2	4	0	0	6
Oxycodone	0	1	0	0	1
Morphine	0	0	1	0	1
Benzodiazepines	0	1	0	0	1
Barbiturates	1	0	0	0	1

Marijuana	0	0	1	0	1
Heroin	0	0	0	0	0
Cocaine	1	0	0	0	1
Methamphetamine	0	0	1	0	1
Pharmaceutical Amphetamine	0	1	0	0	1
Phentermine	0	0	0	0	0
Methadone	0	0	1	0	1
Zolpidem Tartrate	0	0	1	0	1
Hydromorphone	0	1	0	0	1
Promethazine w/Codeine	0	1	0	0	1
<b>Intern Pharmacists</b>	<b>July-Sep</b>	<b>Oct-Dec</b>	<b>Jan-Mar</b>	<b>Apr-Jun</b>	<b>Total 11/12</b>
Alcohol	0	0	0	0	0
Opiates	0	0	0	0	0
Hydrocodone	0	0	1	0	1
Oxycodone	0	0	0	0	0
Benzodiazepines	0	0	0	0	0
Barbiturates	0	0	0	0	0
Marijuana	0	0	0	0	0
Heroin	0	0	0	0	0
Cocaine	0	0	0	0	0
Methamphetamine	0	0	0	0	0
Pharmaceutical Amphetamine	0	0	0	0	0
Phentermine	0	0	0	0	0
Methadone	0	0	0	0	0
Zolpidem Tartrate	0	0	1	0	1
Hydromorphone	0	1	0	0	1
Promethazine w/Codeine	0	1	0	0	1
<b>Pharmacy Technicians</b>	<b>July-Sep</b>	<b>Oct-Dec</b>	<b>Jan-Mar</b>	<b>Apr-Jun</b>	<b>Total 11/12</b>
Alcohol	3	2	5	0	10
Opiates	0	0	0	0	0
Hydrocodone	1	1	2	0	4
Oxycodone	0	0	1	0	1
Benzodiazepines	1	0	0	0	1
Barbiturates	0	0	0	0	0
Marijuana	3	0	1	0	4
Heroin	0	0	0	0	0
Cocaine	0	0	0	0	0
Methamphetamine	2	1	1	0	4
Pharmaceutical Amphetamine	0	0	0	0	0
Phentermine	1	0	0	0	1
Methadone	0	1	0	0	1
Zolpidem Tartrate	1	0	0	0	1
Hydromorphone	0	0	0	0	0
Promethazine w/Codeine	0	0	0	0	0
<b>Pharmacist Recovery Program</b>	<b>July-Sep</b>	<b>Oct-Dec</b>	<b>Jan-Mar</b>	<b>Apr-Jun</b>	<b>Total 11/12</b>
Participant Files Audited	0	6	0	0	6

# Drug Of Choice - Data entered from July 2011 to June 2012

- 1 Alcohol
- 2 Opiates
- 3 Hydrocodone
- 4 Oxycodone
- 5 Benzodiazepines
- 6 Barbiturates
- 7 Marijuana
- 8 Heroin
- 9 Cocaine
- 10 Methamphetamine
- 11 Pharmaceutical Amphetamine



# Attachment 3

# GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

## ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1	Achieve 100 percent closure on all cases within 6 months.						
Measure:	Percentage of cases closed.						
Tasks:	1. Complete all desk investigations within 90 days (for cases closed during quarter).						
		<u>N</u>	< 90 days	< 120 days	< 180 days	Longer	<u>Average Days</u>
	Qtr 1	383	135	51	91	106	164
			35%	13%	24%	28%	
	Qtr 2	379	172	30	58	119	135
			45%	8%	15%	32%	
	Qtr 3	536	170	89	120	157	162
			32%	17%	22%	29%	
	Qtr 4						
	2. Complete all field investigations within 120 days (for cases closed during quarter).						
		<u>N</u>	< 120 days	< 180 days	< 270 days	Longer	<u>Average Days</u>
	Qtr 1	275	123	50	37	65	187
			45%	18%	13%	24%	
	Qtr 2	220	111	34	34	41	159
			51%	15%	15%	19%	
	Qtr 3	325	144	56	54	71	184
			44%	17%	17%	22%	
	Qtr 4						
	Data is calculated from date received to the date the report was accepted by SI/Manager. Does not include split cases.						

3. Close (e.g., no violation, issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.

<b>Qtr 1</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed investigations, no additional action, license approvals	298	242	25	14	17
Closed 4301 letters, license denials, withdrawn by Board	138	112	12	6	8
Cite and/or fine letter of admonishment	138	62	22	12	42
Attorney General's Office	84	34	29	6	15
<b>Qtr 2</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed investigations, no additional action, license approvals	348	273	47	20	8
Closed 4301 letters, license denials, withdrawn by Board	123	81	34	5	3
Cite and/or fine letter of admonishment	89	35	29	8	17
Attorney General's Office	39	16	12	9	2
<b>Qtr 3</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed investigations, no additional action, license approvals	386	292	35	33	26
Closed 4301 letters, license denials, withdrawn by Board	173	124	21	17	11
Cite and/or fine letter of admonishment	261	146	43	42	30
Attorney General's Office	70	21	16	11	22
<b>Qtr 4</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed investigations, no additional action, license approvals					
Closed 4301 letters, license denials, withdrawn by Board					
Cite and/or fine letter of admonishment					
Attorney General's Office					

Data is calculated from date received to date closed or referred to the AG.  
 One case may have multiple respondents. The actual number of citations and letters of admonishment issued are shown on the next page.

Objective 1.2	Manage enforcement activities for achievement of performance expectations.						
Measure:	Percentage compliance with program requirements.						
Tasks:	<b>1. Administer the Pharmacists Recovery Program.</b>						
		Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program		
	Qtr 1	25	51	3	1		
	Qtr 2	26	55	2	1		
	Qtr 3	15	61	2	0		
	Qtr 4						
	<b>2. Administer the Probation Monitoring Program.</b>						
		Qtr 1	Qtr 2	Qtr 3	Qtr 4		
	Individuals	151	156	180			
	Sites	20	24	29			
	Tolled	28	27	28			
	Inspections Conducted	67	66	60			
Successfully Completed	4	4	2				
Petitions to Revoke Filed	3	2	0				
<b>3. Issue all citations and fines within 30 days.</b>							
	<u>N</u>	30 days	60 days	90 days	> 90 days	<u>Average Days</u>	
Qtr 1	241	141	90	9	1	31	
		59%	37%	4%	.4%		
Qtr 2	128	95	13	10	10	29	
		74%	10%	8%	8%		
Qtr 3	240	214	14	0	12	28	
		89%	6%	0%	5%		
Qtr 4							
<b>4. Issue letters of admonishment within 30 days.</b>							
	<u>N</u>	30 days	60 days	90 days	> 90 days	<u>Average Days</u>	
Qtr 1	15	10	5	0	0	25	
		67%	33%	0%	0%		
Qtr 2	15	12	1	2	0	24	
		80%	7%	13%	0%		
Qtr 3	42	39	1	0	2	27	
		93%	2%	0%	5%		
Qtr 4							
These data are actual number of citations and letters of admonishment (LOA) issued.							
One investigation may have multiple licensees that are issued a citation or LOA (split cases).							

**5. Obtain immediate public protection sanctions for egregious violations.**

	Interim Suspension Orders	Automatic Suspension Based on Conviction	Penal Code 23 Restriction
Qtr 1	2	0	0
Qtr 2	1	1	0
Qtr 3	0	5	0
Qtr 4			

**6. Submit petitions to revoke probation within 30 days once noncompliance with terms of probation is substantiated.**

	30 days	60 days	> 60 days	<u>N</u>
Qtr 1	0	0	0	0
Qtr 2	1	1	11	4
Qtr 3	1	0	0	1
Qtr 4				

Objective 1.3	Achieve 100 percent closure on all administrative cases within 1 year.																																																																							
Measure:	Percentage of administrative cases closed within 1 year.																																																																							
Tasks:	1. File pleadings within 90 days of referral.																																																																							
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Objective 1.4	Inspect 100 percent of all facilities once every 3 year inspection cycle ending 6/30/14.																																																							
Measure:	Percentage of licensed facilities inspected once every 3 year cycle.																																																							
Tasks:	<p data-bbox="370 220 1479 289">1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.</p> <table border="1" data-bbox="370 289 1479 506"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Aggregate Inspections This Cycle</th> <th>Percent Complete</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>449</td> <td>449</td> <td>5%</td> </tr> <tr> <td>Qtr 2</td> <td>572</td> <td>884</td> <td>9%</td> </tr> <tr> <td>Qtr 3</td> <td>332</td> <td>587</td> <td>6%</td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p data-bbox="370 548 1414 617">2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.</p> <table border="1" data-bbox="370 617 1166 833"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Number Inspected Late</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>81</td> <td>0</td> </tr> <tr> <td>Qtr 2</td> <td>85</td> <td>0</td> </tr> <tr> <td>Qtr 3</td> <td>49</td> <td>0</td> </tr> <tr> <td>332</td> <td></td> <td></td> </tr> </tbody> </table> <p data-bbox="370 875 1471 909">3. Initiate investigations based upon violations discovered during routine inspections.</p> <table border="1" data-bbox="370 909 1479 1125"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Number of Investigations Opened</th> <th>Percent Opened</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>530</td> <td>60</td> <td>11%</td> </tr> <tr> <td>Qtr 2</td> <td>572</td> <td>46</td> <td>8%</td> </tr> <tr> <td>Qtr 3</td> <td>332</td> <td>31</td> <td>9%</td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Number of Inspections	Aggregate Inspections This Cycle	Percent Complete	Qtr 1	449	449	5%	Qtr 2	572	884	9%	Qtr 3	332	587	6%	Qtr 4					Number of Inspections	Number Inspected Late	Qtr 1	81	0	Qtr 2	85	0	Qtr 3	49	0	332				Number of Inspections	Number of Investigations Opened	Percent Opened	Qtr 1	530	60	11%	Qtr 2	572	46	8%	Qtr 3	332	31	9%	Qtr 4			
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Objective 1.5	Initiate policy review of 25 emerging enforcement issues by June 30, 2011.
Measure:	The number of issues.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="370 218 1487 842"> <p><b>1. Monitor the implementation of e-pedigree on all prescription medications sold in California.</b></p> <p><i>Oct. 2009: Executive Officer provides information about California's e-pedigree requirements at a SecurePharma Conference of drug manufacturers and wholesalers in Philadelphia and at a SpecialtyPharma Conference (contract drug manufacturers) in Phoenix.</i></p> <p><i>Dec. 2009: Executive Officer provides information about California's e-pedigree requirements at the Health Care Distributors Association Trace and Track Conference in Washington D.C.</i></p> <p><i>March 2010: Executive Officer provides information about California's e-pedigree requirements via a Webinar hosted by IBS.</i></p> <p><i>April 2010: Board reviews Food and Drug Administration guidance on a unique serialized identifier released March 26.</i></p> <p><i>Oct. 2010: Executive Officer provides information about California's requirements to a GS1 training session in San Francisco.</i></p> <p><i>Feb. 2010: Executive Officer provides presentation on California's e-pedigree requirements at FDA workshop on developing a track and trace.</i></p> </li> <li data-bbox="370 848 1487 1062"> <p><b>2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products.</b></p> <p><i>Sep. 2006: Final phase-in of federal requirements takes effect on September 30. Board newsletter provides information for licensees.</i></p> <p><i>Oct. 2006: Board adds Consumer friendly materials regarding sales of these drugs to its website.</i></p> </li> <li data-bbox="370 1068 1487 1652"> <p><b>3. Monitor the efforts of the Drug Enforcement Administration and Department of Health and Human Services to implement e-prescribing for controlled substances.</b></p> <p><i>Nov. 2006: Board submits letter supporting change in Drug Enforcement Administration policy allowing prescribers to write multiple prescriptions for Schedule II drugs with "Do not fill before (date)" at one time, eliminating the need for patients to revisit prescribers merely to obtain prescriptions.</i></p> <p><i>Sep. 2008: Board submits comments on Drug Enforcement Administration proposed requirements for e-prescribing of controlled substances.</i></p> <p><i>Dec. 2009: Executive Officer meets with DEA officials in Washington D.C. to discuss interest in e-prescribing of controlled drugs.</i></p> <p><i>April 2010: Board reviews proposed Drug Enforcement Administration requirements for electronic prescribing of controlled substances.</i></p> <p><i>June 2010: Enforcement Committee received updates on DEA rule change.</i></p> <p><i>Jan. 2011: Board prepares guidance document for pharmacies and prescribers.</i></p> <p><i>May 2011: Medical Board reviews guidance document prepared to approve portion for prescribers.</i></p> </li> </ol>

4. **Evaluate establishment of an ethics course as an enforcement option.**
  - Oct. 2008:* Board holds regulation hearing on proposed requirements for the ethics class.
  - Jan. 2009:* Board adopts regulation.
  - Sept. 2009:* Regulation takes effect.
  - 3rd Qtr 09-10:* Board subcommittee of two board members begins work with staff on suggested specific components and topics for the program, in compliance with board regulations.
  - Oct. 2010:* First course provided.
  - March 2011:* Second provider begins offering course.
5. **Participate in emerging issues at the national level affecting the health of Californians regarding their prescription medicine.**
  - Dec. 2009:* Executive Officer provides presentation on California's e-pedigree requirements to three national association meetings.
  - 3rd Qtr 09-10:* Board initiates rulemaking on a regulation to establish requirements for patient-centered prescription container labels (see report on Legislation and Regulation Committee's Goals, Outcomes, Objectives and Measures).
  - March 2011:* Executive Officer participates in PEW Trust's public forum on what was learned about the 2008 heparin adulteration.
  - April 2011:* DEA and board cohost day-long conference for pharmacies of controlled substances. Due to interest and success, more conferences planned.
6. **Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing.**
  - Sep. 2007:* Provided comments on proposed statutory requirements.
  - Dec 2007:* Sought Department of Consumer Affairs' support for involvement in e-prescribing by the Administration.  
Provided comments on proposed e-prescribing initiatives.
  - Oct. 2008:* Executive Officer Herold joins a task force to achieve e-prescribing coordinated by the California HealthCare Foundation.
  - Nov. 2008:* Board hosts conference on e-prescribing as part of department's professionals  
Achieving Consumer Trust Summit. The Medical Board and Dental Board join us as sponsors.
  - Jan. 2009:* Executive Officer Herold works with California HealthCare Foundation and Medical Board to plan joint activities with licensees to facilitate e-prescribing.
  - March 2009:* Pharmacists and physicians in Visalia attend first of California HealthCare Foundation's public forums on e-prescribing.
  - April 2010:* Board reviews Drug Enforcement Agency proposed regulations on e-prescribing of controlled substance.
  - Nov. 2010:* Executive Officer provides presentations at annual California e-prescribing meeting.
  - Jan. 2011:* Board prepares guidance document for pharmacies on DEA's requirements.
  - May 2011:* Medical Board reviews same guidance document for prescribers.
7. **Implement in California the Center for Medicare and Medicaid Service requirements for security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.**
  - Oct. 2008:* Requirements for security forms in place..
  - 2nd Qtr 09/10:* Board executive staff and several board members attend California Healthcare Foundation's annual summit to implement e-prescribing.

**8. Liaison with other state and federal agencies to achieve consumer protection.**

**1st Qtr 07/08:** *Bimonthly meetings initiated with Department of Health Care Services audit staff to investigate pharmacies and pharmacists involved in MediCal fraud and drug diversion. Several joint investigations underway with state and federal agencies.*

**2nd Qtr 07/08:** *Bimonthly meeting with the Department of Health Care Services continue. Board inspectors attend 3-day-training with federal and state regulations on items involving fraud provided by the Office of Inspector General of the Department of Health and Human Services. Joint investigations with other state and federal agencies continue that involve the board's jurisdiction.*

**3rd Qtr 07/08:** *Bimonthly meetings with the Department of Health Care Services continue. Board works with the Drug Enforcement Administration on joint investigations and receives specialized training.*

**4th Qtr 07/08:** *Board staff meets with staff of the California Department of Public Health regarding joint inspections of licensed healthcare facilities in California to identify and remove recalled drugs.*

**3rd Qtr 08/09:** *Executive staff meet with Department of Health Care Services investigators on cases of mutual concern. Board investigators work with federal and state drug enforcement officers on search warrants and mutual investigations.*

**4th Qtr 08/09:** *Board staff meets with staff of the California Department of Public Health regarding joint inspections of licensed healthcare facilities in California to identify and remove recalled drugs. Executive staff meet with Department of Health Care Services investigators on cases of mutual concern. Board investigators work with federal and state drug enforcement officers on search warrants and mutual investigations. The federal Drug Enforcement Administration provides training to board staff on new requirements for online pharmacies selling controlled substances.*

**2nd Qtr 09/10:** *Executive staff meet with Department of Health Care Services staff on mutual investigations; DEA staff in Washington D.C. on enforcement issues involving controlled drugs; the U.S. Attorney General's office in Sacramento on two major enforcement matters; and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern.*

**3rd Qtr 09/10:** *Board supervising inspectors work with federal, state and local law enforcement agencies on emerging enforcement issues and investigations, and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern. Board staff redirected to complete HIPDB reporting.*

**4th Qtr 09/10:** *Board staff continue to report to HIPDB.*

**2nd Qtr 10/11:** *Board supervising inspectors work with federal, state and local law enforcement agencies on emerging enforcement issues and investigations, and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern.*

*3rd Qtr 10/11: Board supervising inspectors work with federal, state and local law enforcement agencies on emerging enforcement issues and investigations, and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern. Executive staff attend joint meeting with California District Attorneys Association.*

**9. Work with the California Integrated Waste Management Board to implement requirements for model programs to take back unwanted prescription medicine from the public.**

*March 2008: Second meeting with state agency stakeholders on developing components for model programs that conform with diverse state agency security and safety requirements.*

*June 2008: Supervising pharmacist inspector attended a two-day multi-disciplinary conference hosted by the Integrated Waste Management Board on drug take-back programs.*

*Aug. 2008: Executive Officer Herold speaks at conferences sponsored by the California Integrated Waste Management Board.*

*Oct. 2008: Enforcement Committee hears presentations on drug take-back programs, medical waste management processes and the take-back of sharps. Board to submit comments to California Integrated Waste Management Board on model programs for take-back programs.*

*Nov. 2008: Executive Officer provides written and verbal testimony at California Integrated Waste Management Board hearing on the model guidelines.*

*Dec. 2008: Executive Officer participates in public hearing at the California Integrated Waste Management Board on possible changes to the model guidelines adopted by the California Integrated Waste Management Board in November.*

*Feb. 2009: California Integrated Waste Management Board amends model guidelines to include provisions advanced by the board.*

*Jan. 2010: Board writes article on the guidelines for publication in the next issue of The Script.*

*Board executive staff attend meetings on "take back drugs" at a statewide conference of the California Integrated Waste Management Board. Executive Officer provides presentation on the CIWMB Model Guidelines at a meeting of 20 rural California counties.*

*March 2010: Board publishes the guidelines in The Script.*

*April 2010: Board inspector will collect information about take back programs in California pharmacies during inspections.*

*Aug. 2010: Executive Officer provides information regarding board policy on drug take back programs in pharmacies to CalRecycle and its draft report on model take back programs. Written comments are later provided on behalf of the board.*

*Jan. 2011: Board reviews final version of CalRecycle's report.*

*May 2011: Final report released.*

**10. Inspect California hospitals to ensure recalled heparin has been removed from patient care areas.**

**4th Qtr 07/08:** Board initiates inspections of 40 California hospitals looking for counterfeit heparin and unlicensed sales but discovers recalled heparin still in 40 percent of hospitals inspected. Board notifies the Food and Drug Administration and California Department of Public Health and initiates inspections of 533 hospitals during April-June.

Recalled heparin is found in 94 of these facilities. Data reported to board during June Board Meeting.

**1st Qtr 08/09:** *The Script* highlights problems found in heparin inspections. Citations and fines issued to facilities with recalled heparin. Work with hospitals begins to strengthen drug control within facilities.

**2nd Qtr 08/09:** Hospitals and Pharmacists-in-Charge fined where recalled heparin was discovered by the board.

**3rd Qtr 08/09:** First stakeholder meeting scheduled to discuss drug distribution within hospitals.

**March 2009:** First stakeholder meeting convened.

**June 2009:** Second stakeholder meeting convened. Development of model guidelines for recalls underway.

**Sep. 2009:** Stakeholder meeting convened.

Recall guidelines evaluated and additional comments solicited.

**Jan. 2010:** Board reviews final version of recommended steps for addressing recalls in hospitals.

**April 2010:** Manuscript of addressing recalls in hospitals completed, compiled into finished report and posted on Website.

Executive officer works with the Healthcare Distributors Management Association (representing drug wholesalers) to secure notices of recalls more timely to share with board subscriber list.

Appeals of citations and fines nearly complete.

**May 2010:** Outstanding enforcement/compliance completed.

**2011:** Board receives copies of drug recalls at the pharmacy level and releases them through the subscriber alert system.

**March 2011:** Board participates in international conference convened by the PEW Trust on the 2008 heparin contamination to identify ways to prevent a reoccurrence.

11. **Promulgate regulations required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for recovery programs administered by Department of Consumer Affairs health care boards.**  
*4th Qtr 08/09: Draft proposals for required components 1-6 developed.*  
*1st Qtr 09/10: Draft proposals for required components 7-13 developed.*  
*3rd Qtr 09/10: Board hears presentation on uniform standards. Staff/counsel identifies changes required to implement standards.*  
*1st/2nd Qtr 10/11: Proposed changes to Board Disciplinary Guidelines drafted. Staff continue working with DCA on standards.*  
*2nd Qtr 10/11: Board staff begin incorporating standards for Board consideration.*  
*3rd Qtr 10/11: Changes to standards are approved by Substance Abuse Coordination Committee.*  
*4th Qtr 10/11: Board updated on progress of language development and incorporated into disciplinary guidelines for Board consideration. Board staff initiate review of reporting requirements.*
12. **Develop and release Request for Proposal for vendor for Department of Consumer Affairs health care boards that operate license recovery programs.**  
*4th Qtr 08/09: Provisions for Request for Proposal developed: Request for Proposal released.*  
*2nd Qtr 09/10: Contract awarded.*
13. **Participate in Department of Consumer Affairs Consumer Protection Enforcement Initiative to strengthen board enforcement activities and reduce case investigation completion times for formal discipline.**  
*1st/2nd Qtr 09/10: Work with Department of Consumer Affairs on identification of Enforcement Best Practices. Board discusses SB 1441 components for Diversion Programs to strengthen consumer protection enforcement staff attend Enforcement Best Practices work group.*  
*3rd Qtr 09/10: Board senior staff and Board President meet with Department of Consumer Affairs to discuss enforcement program enhancements in SB 1111. Board staff begin submitting monthly reports detailing workload and improvement efforts to the department.*  
*4th Qtr 09/10: Board hears presentation on CPEI and current status of department and board efforts.*  
*1st/2nd Qtr 10/11: Board sponsors legislation to secure records more timely from licensees. Board conducts civil service exams for inspector and supervising inspector classifications. Hiring freeze prevents hiring of staff.*  
*2nd Qtr 10/11: Board submits freeze exemptions, all are denied.*  
*3rd Qtr 10/11: Governor Brown established a formal hiring freeze. New hiring freeze exemptions prepared for eight inspector positions.*  
*4th Qtr 10/11: Board staff secure an exemption to hire eight inspectors. Board staff secure a second exemption to hire three additional inspectors. Six new staff begin. Training is limited because of travel restrictions.*

14. **Initiate criminal conviction unit to review and investigate rap sheets received on licenses for arrests or convictions.**  
*1st Qtr 09/10: Unit created via budget change proposal, 6.5 staff hired, trained, initiate work.  
 There are 1,287 rapsheet investigations under review.*  
*2nd Qtr 09/10: There are 1,037 rapsheet investigations under review.*  
*3rd Qtr 09/10: There are 652 rapsheet investigations under review.*  
*4th Qtr 09/10: Post implementation review of Criminal Conviction Unit completed. Enforcement Committee advised of new unit outcomes.*
15. **Complete comprehensive review of investigative and enforcement internal processing to identify process improvements.**  
*1st Qtr 09/10: Board staff implemented on-line assignment of investigations.  
 Board staff implemented on-line review of draft pleadings.*  
*2nd Qtr 09/10: Board staff began drafting Default Decision and Orders.*  
*4th Qtr 09/10: Board staff began drafting Petition to Revoke Probation Pleadings.  
 Board staff implemented a pilot program to provide pre-populated investigation reports to the Compliance Team.*  
*3rd Qtr 10/11: Board staff review citation and fine program.*  
*4th Qtr 10/11: Board staff evaluates complaints closed without findings to ensure integrity of the process. Some deficiencies noted. Process improvements identified and staff educated.*
16. **Complete review of pharmacies dispensing prescriptions for Internet web site operators.**  
*2010: Updates on disciplinary actions provided at board meetings and in The Script.*
17. **Provide updates on the board's reporting to the Healthcare Integrity and Protections Data Bank (HIPDB).**  
*1st Qtr 10/11: 656 reports submitted (includes initial and revised submissions).*  
*2nd Qtr 10/11: 334 reports submitted (includes initial submissions).*  
*3rd Qtr 10/11: 432 reports submitted.*  
*4th Qtr 10/11: 96 reports submitted. Position vacant effective September 2011 due to employee retirement. Recruitment pending with Department of Consumer Affairs Human Resources.*  
*1st Qtr 11/12: 65 reports submitted.*  
*2nd Qtr 11/12: 22 reports submitted.*  
*3rd Qtr 11/12: 2 reports submitted.*