



**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 Report

**Randy Kajioka, PharmD, Chair, Professional Member**

**Greg Lippe, Public Member**

**Tappan Zee, Public Member**

**Neil Badlani, RPh, Professional Member**

### Report of the Meeting Held June 12, 2012.

- a. **FOR DISCUSSION AND POSSIBLE ACTION: Presentation and Discussion on the Use of the Pharmacist Assessment for Remediation Evaluation (PARE) in California as an Optional Enforcement Tool to Assess Pharmacist Practice Deficiencies**

#### ATTACHMENT 1

##### Background:

In years past, the National Association of Boards of Pharmacy had an examination that could be used to assess the knowledge and deficiencies in a pharmacist's education and training. This was an assessment that the board would periodically require in disciplinary matters where the skills of the pharmacist were in question. The NABP discontinued this examination several years ago.

In July 2011, representatives of the NABP attended the board meeting to discuss, among other items, a new pharmacist assessment process that could be used to assess a pharmacist's knowledge. This assessment was called the Pharmacist Assessment for Remediation Evaluation (PARE). At that time the PARE was undergoing pilot testing by NABP.

According to the NABP, the PARE is intended for use by boards of pharmacy in "instances when an objective measure is needed to assist in decisions regarding pharmacist practice deficiencies."

##### Committee Meeting Discussion:

According to the NABP, the PARE was developed to be used when an objective measure is needed to assist in decisions regarding pharmacist practice. The assessment is comprised of approximately 210 questions involving issues related to medication safety (50 percent), professional ethics (25 percent), and pharmacy practice (25 percent). It will take approximately 4.5 hours to complete and will cost \$250.

During this Meeting:

Carmen Catizone, executive director of the National Association of Boards of Pharmacy will present information on the PARE during the board meeting. Because question was raised during the committee meeting about if the exam has been psychometrically validated, the board may want to inquire about that topic specifically. **Attachment 1** contains information about the PARE.

Should the board determine it wishes to include completion of the PARE exam as an optional term and condition of probation. Should the board so choose, such a change could be integrated into the proposed changes to the board's Disciplinary Guidelines, which is being discussed under a separate agenda item during the board meeting. Provided below is language the board could incorporate into its guidelines:

Pharmacist Assessment for Remediation Evaluation (PARE)

Within the first year of probation, respondent shall complete the Pharmacist Assessment for Remediation Evaluation (PARE) examination provided by the National Association of Boards of Pharmacy (NABP). Respondent shall submit a record of completion to the board demonstrating he/she has completed this examination. Respondent shall bear all costs for the examination. Continuing education hours received for this examination shall not be used as part of the required continuing education hours for renewal purposes.

Failure to timely complete the PARE or submit documentation thereof shall be considered a violation of probation.

**Option A:** Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee.

**Option B:** (This term must be accompanied by the "Remedial Education" term. [Include/Modify Remedial Education Term to Conform].) Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee. Based on the results of the examination, the board shall determine which courses are appropriate for remedial education.

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

**b. FOR DISCUSSION: Counterfeit Avastin and Altuzan Identified in California Physician Offices**

**ATTACHMENT 2**

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. This wholesaler is not licensed to do wholesaling or pharmacy sales in California.

In April, the board learned that an additional 42 California physician offices had purchased unapproved foreign drugs from various unlicensed entities.

These cases remain under investigation by various entities, including the FDA.

**Attachment 2** contains some of the articles on this topic that were shared with Enforcement Committee.

More recently, counterfeit Adderal has been also discovered in the US, some of the origin has been from Internet sales initially, but there has been concerned expressed that the drug could find its way into the US supply chain.

The board released a subscriber alert in early April, reminding subscribers the dangers about unapproved drugs. In January, the board developed an earlier alert about buying drugs from unlicensed entities. Both of these alerts are provided below:

April 2012:

The U.S. Food and Drug Administration is alerting healthcare professionals that another cancer drug, originating from a foreign source and purchased by U.S. medical practices, has been determined to be counterfeit. Medical practices that purchase and administer illegal and unapproved foreign medications are putting patients at risk of exposure to drugs that may be fake, contaminated, improperly stored and transported, ineffective, and dangerous. Illegal drugs purchased from foreign sources may not be genuine or meet appropriate quality, safety, and efficacy standards, putting patients at risk and depriving them of proper treatment.

Patients receiving cancer drugs or other drugs not approved by the FDA for the U.S. market may not be receiving needed therapy. Patients are encouraged to discuss any concerns they may have about the source of their medications with their healthcare professional.

FDA lab tests have confirmed that a counterfeit version of Roche's Altuzan 400mg/16ml (bevacizumab), an injectable cancer medication, found in the U.S. contains no active ingredient. Even if the identified drugs were not counterfeit, Altuzan is not approved by FDA for use in the United States (it is an approved drug in Turkey). On February 14, FDA issued an alert about another cancer drug<sup>1</sup> in U.S. distribution that was purchased from a foreign source and found to be counterfeit.

Medical practices obtained the counterfeit Altuzan and other unapproved products through foreign sources, in particular from Richards Pharma, also known as Richards Services, Warwick Healthcare Solutions, or Ban Dune Marketing Inc (BDMI). Many, if not all, of the products sold and distributed through this distributor have not been approved by the FDA. The agency cannot

ensure that the manufacture and handling of these illegal products follows U.S. regulations, nor can FDA ensure that these drugs are safe and effective for their intended uses.

Any medical practice that has obtained unapproved products, in particular from Richards Pharma, Richards Services, Warwick Healthcare Solutions, or Ban Dune Marketing Inc (BDMI), should stop using them and contact the FDA. The products should be retained and securely stored until further notice by the FDA.

To view the entire FDA article go to: <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm298047.htm>

January 2012:

The California State Board of Pharmacy reminds pharmacies and pharmacists that when purchasing drugs from wholesalers that they must purchase prescription drugs only from wholesalers licensed by the Board. Even if a wholesaler is located out of state, the wholesaler must also be licensed with the California State Board of Pharmacy if it is shipping product or arranging/brokering sales into California.

During times of drug shortages, it may be tempting to turn to new sources to secure prescription drugs that are in short supply or are currently unavailable from your current wholesalers. However, unlicensed wholesalers – who have not taken the time to become licensed in California to operate legally – may also have taken business “shortcuts” elsewhere and may be selling drugs that are expired, adulterated, counterfeited, have been diverted, or are in other ways compromised, which could result in harm to patients.

To avoid problems with the safety and quality of prescription medications and comply with the law, use only Board-licensed wholesalers.

How can you tell if a business is licensed in California as a wholesaler? Go to [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) and click under verify a license.

To see a list of current drug shortages, please visit the FDA's webpage on Drug Shortages: <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm>

**c. FOR INFORMATION AND DISCUSSION: Dysfunction in California Supply of Prescription Medication Discovered During Board of Pharmacy Inspections**

During inspections of California pharmacies and wholesalers, the board’s inspectors are encountering numerous serious violations involving “redispensing” of previously dispensed medication.

During the Enforcement Committee meeting, a short presentation was provided on some of photos taken during these inspections.

d. **FOR INFORMATION: Board of Pharmacy Letters to Federal Representatives and Senators on Elements Needed in any Proposal for Federal Legislation**

**Attachment 3**

At the May board meeting, the board directed that a letter explaining California's e-pedigree requirements be sent to certain federal legislators who throughout May and June were deliberating on a possible federal system for drug chain security. This letter was sent in early May. A copy of the letter sent to Congress Member Waxman is provided in **Attachment 3**.

e. **FOR INFORMATION: Colloquy from Senators Enzi and Harkin in Support of Retaining Protections in California Law in Future Federal Requirements for Tracking Prescription Medications Through the Pharmaceutical Supply Chain**

**Attachment 4**

Senators Enzi and Harkin released a colloquy on May 22, 2012, supporting California's serialization requirements as elements in a federal supply chain system.

A copy of the colloquy is provided in **Attachment 4**.

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

1. Live Presentation to the Board by Robert Celeste, Director, Healthcare, GS1 US

Mr. Celeste will provide during the board meeting a presentation similar to the one he made during the Enforcement Committee meeting on the work of GS1 and supply chain companies to prepare for California's e-pedigree laws.

2. Presentations to the Board by Other Entities in Attendance at the Board Meeting

Various entities in the pharmaceutical supply chain or supporting the efforts to prepare entities for California's requirements may wish to address the board directly. This portion of the agenda is designed to permit such presentations or provide an opportunity for comment.

3. Summary of Other Presentations Made to the Enforcement Committee

Abbott Laboratories made a presentation on their efforts and challenges in preparing to comply with California's e-pedigree requirements. A summary of this presentation is provided in the minutes of the meeting.

**g. FOR DISCUSSION: Proposed Regulation Requirements Specifying a Unique Identification Number for Prescription Medication Pursuant to California’s E-Pedigree Requirements**

**Attachment 5**

At the May board meeting, the board directed the enforcement committee to reconsider the proposed parameters for a serialized numeric identifier that will be the tracking number for each prescription container, and aggregated groups of containers in cases.

The proposed regulation text mirrors a guideline developed by the FDA. **Attachment 5** contains the FDA’s “Guidance for Industry Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages.”

The committee reviewed slightly modified text developed by staff to reference the FDA’s Guideline.

**h. FOR ACTION: Initiate a Rulemaking to Adopt Proposed Section 1747 to Title 16, California Code of Regulations – Requirements Specifying a Unique Identification Number for Prescription Medication Pursuant to California’s E-Pedigree Requirements**

**Motion: Enforcement Committee: Initiate a Rulemaking to Adopt Section 1747 to Title 16 Code of Regulations as follows:**

**Title 16. Board of Pharmacy  
Proposed Language**

**Proposal to Add a New Article 5.5 and Article Title, and Add New Sections 1747 and 1747.1 and Section Titles to Article 5.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**Article 5.5. Pedigree Requirements.**

**1747. Unique Identification Number.**

For the purposes of Section 4034 of the Business and Professions Code, the "unique identification number" that is to be established and applied to the smallest package or immediate container by the manufacturer or repackager shall conform to requirements for Standardized Numerical Identifiers (SNIs) set forth in a March 2010 publication by the U.S. Food and Drug Administration (FDA) titled “Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages,” (FDA’S Guidance Document), hereby incorporated by reference. As stated therein, an SNI consists of a serialized National Drug Code (NDC) product identifier combined with a unique numeric or alphanumeric serial number of no more than twenty (20) digits or characters. For dangerous drugs for which no NDC product identifier is assigned or is in use, an equivalent serialized product identifier may be used in place of the NDC consistent with the FDA’s Guidance Document. This number shall be combined

with a unique numeric or alphanumeric serial number that is not more than 20 digits or characters in length to establish the unique identification number.

This regulation shall become operative on January 1, 2015.

**i. FOR DISCUSSION: Proposed Regulation Provisions for Non-pedigreed Dangerous Drugs Pursuant to Section 4163.2 of the California Business and Professions Code**

Also at the May board meeting, the board directed the enforcement committee to reconsider the proposed parameters for “grandfathering” non-serialized products so that they may remain in California commerce after the e-pedigree requirements take effect.

During the meeting, the committee reviewed a revised draft regulation for this purpose and recommended that the board take action to initiate a rulemaking to adopt this requirement.

**j. FOR ACTION: Initiate a Rulemaking to Adopt Proposed Section 1747.1 to Title 16, California Code of Regulations – Establishing “Grandfathering” Provisions for Prescription Drugs in California Commerce After Activation of E-Pedigree Requirements**

**Motion: Enforcement Committee: Initiate a Rulemaking to Adopt Section 1747.1 to Title 16 Code of Regulations as follows:**

**1747.1. Specification of Pedigreed Dangerous Drugs; Specification of Existing Stock**

(a)(1) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall submit to the board, by December 1, 2014, but no later than December 31, 2014, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

- (A) A list and quantity of dangerous drugs by name and product package (SKU) type representing at least fifty (50) percent of the manufacturer’s total that are ready for initial implementation of the serialized electronic pedigree requirements as of January 1, 2015;
- (B) A statement identifying which one of the following methods was used to measure the percentage of drugs ready to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;
- (C) A statement describing the calculation(s) used to arrive at the percentage figure of dangerous drugs ready for serialized pedigree requirements;
- (D) A list and quantity of dangerous drugs by name and product package (SKU) type that are in the remaining percentage not yet ready to be serialized or subject to pedigree requirements; and,

- (E) A statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.
- (2) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall also submit to the board, by December 1, 2015, but no later than December 31, 2015, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:
  - (A) A list and quantity of its remaining dangerous drugs by name and product package (SKU) type that are ready for implementation of serialized electronic pedigree requirements as of January 1, 2016;
  - (B) A statement identifying which one of the following methods was used to measure the final percentage of drugs to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;
  - (C) A statement describing the calculation(s) used to arrive at the final percentage figure; and,
  - (D) A statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.
- (3) Any failure to submit to the board a declaration compliant with subdivision (a)(1) by December 31, 2014, any failure to submit to the board a declaration compliant with subdivision (a)(2) by December 31, 2015, or any failure to re-submit either declaration to the board in fully compliant form within ten (10) days after notice of deficiency by the board, shall constitute a violation of the Pharmacy Law.
- (b) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any manufacturer, wholesaler or repackager seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the board, by no later than August 1, 2016, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, wholesaler or repackager, containing the following:
  - (1) A list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the manufacturer, wholesaler or repackager that were acquired prior to July 1, 2016;
  - (2) A statement that specifies the means and source of acquisition; and,
  - (3) A statement that specifies the anticipated means of any subsequent distribution or disposition.
- (c) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the board, by no later than August 1, 2017, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the pharmacy or pharmacy warehouse, containing the following:

- (1) A list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the pharmacy or pharmacy warehouse that were acquired prior to July 1, 2017;
- (2) A statement that specifies the means and source of acquisition; and,
- (3) A statement that specifies the anticipated means of any subsequent distribution or disposition.
- (d) The board or its designee shall have sole discretion to determine whether any of the declarations submitted pursuant to this Section are compliant, and to reject and require re-submission of any non-compliant declaration(s) until determined to be fully compliant.

**k. FOR DISCUSSION: Identification of Elements Warranting Inference as Provided by California Business and Professions Code Section 4163.3**

**Attachment 6**

The enforcement committee discussed the topic of inference. Inference would allow a read of a single serialized number on a case or pallet to link with every serialized package within the case or pallet, without having to separately read and confirm the presence of each individual container.

**Attachment 6** visually illustrates inference from a unit to a case to a pallet.

Inference is required because the numeric identifier that is likely to be affixed to a container will be a 2-D matrix code, which requires a line of sight scan. To access or append the pedigree, a “read” of the number will be needed.

Inference is referenced in Business and Professions Code section 4163.3:

- 4163.3.** (a) It is the intent of the Legislature that participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.
- (b) To meet this goal, and to facilitate efficiency and safety in the distribution chain, the board shall, by regulation, define the circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.
- (c) Manufacturers, wholesalers, and pharmacies opting to employ

the use of inference as authorized by the board to comply with the pedigree requirements shall document their processes and procedures in their standard operating procedures (SOPs) and shall make those SOPs available for board review.

- (d) SOPs regarding inference shall include a process for statistically sampling the accuracy of information sent with inbound product.
- (e) Liability associated with accuracy of product information and pedigree using inference shall be specified in the board's regulations.

The committee determined that industry input concerning inference and items (c) through (e) would be beneficial. A request to submit such data to the board will be released later this month.

**I. FOR INFORMATION: Minutes of the Meeting Held June 12, 2012**

**Attachment 7**

**Attachment 7** contains the minutes from the June 12, 2012, meeting.

**m. FOR INFORMATION: Board of Pharmacy's Letter to Federal Representatives and Senators on Proposed Amendments for Possible Inclusion in Pending 2012 Prescription Drug User Fee (Re-Authorization) Act**

**Attachment 8**

Immediately after the committee meeting in mid-June, the board was asked to provide comments on pending amendments to federal law that would have established supply chain requirements for prescription drugs. A copy of the board's comments is provided as **Attachment 8**.

The proposed amendments were not included in the pending 2012 Prescription Drug User Fee Act. There are still efforts underway to enact federal legislation in this area in 2012.

**n. FOR INFORMATION: Enforcement Statistics**

**Attachment 9**

**o. FOR INFORMATION: Fourth Quarterly Report on the Committee's Goals**

**Attachment 10**

# Attachment 1

## PARE Pilot Complete; Remediation Evaluation to Serve as Support Mechanism for the Boards of Pharmacy

With the Pharmacist Assessment for Remediation Evaluation<sup>SM</sup> (PARE<sup>SM</sup>) pilot now complete, this multidimensional assessment will soon be made available to all state boards of pharmacy. NABP developed PARE to serve as a contributory factor for the boards in instances when an objective measure is needed to assist in decisions regarding pharmacist practice deficiencies.

Created to empower the boards in cases of remediation or as part of their decision-making process, PARE provides a measure that can be considered when determining conditional pharmacist practice issues and can act as an aid in instances when a board is questioning a pharmacist's adherence to pharmacy practice standards. For example, boards may wish to use the assessment when considering cases such as reinstatement of a pharmacist's license after a brief departure from practice or other conditions related to disciplinary actions.

### The Pilot

The intent of the pilot was to obtain feedback regarding the PARE testing experience. During the pilot, PARE was administered to a representative sampling of boards of pharmacy. Each participating board was provided with a detailed

manual that included information on registering, administering, and proctoring the assessment, how the assessment is scored, and other general information. Boards were also provided with a sample handbook for examinees, which contained instructions for PARE registration, sample test questions, and a list of suggested study references.

Pilot participants were also asked to complete a brief survey in order to solicit feedback from stakeholders. These survey results were compiled and used to fine tune the administrative aspects of the assessment process.

### The Assessment

PARE will be available for a two-week testing window approximately four times per year. Since the assessment is an Internet-based test, scheduling during the two-week window is left to the discretion of each board of pharmacy; however, if the assessment is scheduled outside of NABP business hours (9 AM - 5 PM Central), the Association will not be able to guarantee that technical support will be available in the unlikely event of a technical issue.

The assessment consists of 210 test items representative of three distinct content domains, which were created by a group of subject matter

experts with input and approval from the NABP Executive Committee. The content domains include:

- Medication Safety and the Practice of Pharmacy (50%)
- Professional Ethics/ Pharmacist Judgment (25%)
- Clinical Pharmacy Practice (25%)

All test questions are stand-alone, four-option multiple choice items and each assessment will be delivered through a special lockdown Web browser that disables all nonessential functions on the examinee's computer for the duration of the assessment. Examinees will be allotted four and one-half hours to complete the assessment.

PARE outcomes will be reported on a number-correct scale. Both an overall composite score as well as individual content domain scores will be reported to the board and the examinee within

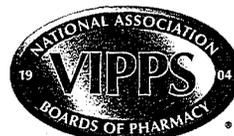
seven to 10 business days of the administration.

### Registering

Once a board has determined that an individual is required to take the PARE, the board will provide NABP with pertinent information on the individual through the NABP Clearinghouse. The board will then contact the individual to notify him or her to contact NABP to register. Upon contacting NABP, examinees will be asked to verify their personal information and submit payment for the assessment. Each PARE administration costs \$250. After registering, the examinee will contact the board to schedule an assessment date and NABP will work with the board to set up the logistics of the administration.

It is anticipated that PARE will be available to all boards of pharmacy by the end of second quarter 2012. Additional information regarding PARE will be forthcoming. ®

### Newly Accredited VIPPS Facility



The following Internet pharmacy was accredited through the NABP Verified Internet Pharmacy Practice Sites<sup>SM</sup> (VIPPS<sup>SM</sup>) program:

**Kmart Corporation**  
www.kmart.com

A full listing of the accredited VIPPS pharmacy sites representing more than 12,000 pharmacies is available on the NABP Web site at [www.nabp.net](http://www.nabp.net). ®



# Coming in June!

## Pharmacist Assessment for Remediation Evaluation<sup>SM</sup>

The PARE<sup>SM</sup> is a multidimensional assessment that the boards of pharmacy may use as an auxiliary tool when making decisions regarding pharmacist practice deficiencies that are due to noncompliance with pharmacy practice standards, laws, or regulations, and result in compromises to patient safety.

Created to support the boards, the PARE:

- Provides a measure that can be considered when determining conditional pharmacist practice issues.
- Acts as an aid in instances when a board is evaluating a pharmacist's adherence to pharmacy practice standards.
- Is useful when considering cases such as reinstatement of a pharmacist's license after a brief departure from practice.

### Exam Design

Examinees are given 4.5 hours to complete the 210-question, multiple choice assessment. The PARE has three content domains:

- **Medication Safety and the Practice of Pharmacy**  
(Area 1 – 50% of questions)
- **Professional Ethics/Pharmacist Judgment**  
(Area 2 – 25% of questions)
- **Clinical Pharmacy Practice**  
(Area 3 – 25% of questions)



### Flexible Administration

The PARE is a Web-based assessment that will be available during two-week periods at four different times throughout the year. During the testing periods, the board of pharmacy can administer and proctor the assessment at the time and place most convenient for them and the pharmacist. There are no tests to collect or score – *it is all done electronically.*

### Registration Process

Registering a pharmacist for the PARE is integrated with the submission of disciplinary actions. When submitting a disciplinary action to NABP through the online portal, select the PARE as a requirement of board action from the drop-down menu. After submission, the pharmacist contacts NABP to pay the assessment fees and then board staff may schedule the examination at their convenience.

Visit [www.nabp.net/programs](http://www.nabp.net/programs) today for more information!



National Association of Boards of Pharmacy  
1600 Feehanville Drive, Mount Prospect, IL 60056  
(P) 847/391-4406 • (F) 847/391-4502 • [www.nabp.net](http://www.nabp.net)

# **PARE<sup>SM</sup>**

## **Pharmacist Assessment for Remediation Evaluation**

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### **Board of Pharmacy Administration Manual**



National Association of Boards of Pharmacy®  
1600 Feehanville Drive  
Mount Prospect, IL 60056

# **PARE**

## **Board of Pharmacy Administration Manual**

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## *Assessment Day Schedule*

- ✓ Proctor ensures that they are in possession of the exam link and unique test code at least one hour prior to the scheduled start time of the Pharmacist Assessment for Remediation Evaluation<sup>SM</sup> (PARE<sup>SM</sup>).
- ✓ Examinee reports for the assessment, is checked-in, and is seated.
- ✓ All personal items are properly stored away from the examinee.
- ✓ Instructions are read to the examinee.
- ✓ Scratch paper and pencils are distributed to the examinee.
- ✓ Test code is given to examinee. The assessment begins.
- ✓ When examinee has finished, or the end of the assessment arrives, scratch paper and pencils are collected and examinee is dismissed. A test session report is completed.
- ✓ Scratch paper is destroyed.
- ✓ Test Session Report is mailed or faxed to the PARE contact person at NABP. Any/all irregularities must be noted on the Test Session Report. If no irregularities occurred during the test session, the form may be faxed or an e-mail sent indicating that there were no unusual issues with the test session.

## *Contact Information*

Prior to the day of the assessment, if you have any questions regarding the assessment downloads, administration, report forms, or exam security, please e-mail, call, or fax:

Maria Boyle  
Competency Assessment Senior Manager  
E-mail: [mboyle@nabp.net](mailto:mboyle@nabp.net)  
Office Telephone: 847/391-4426

Or

Crystal Kaya  
Competency Assessment Statistical Analyst  
E-mail: [ckaya@nabp.net](mailto:ckaya@nabp.net)  
Office Telephone: 847/391-4557

National Association of Boards of Pharmacy  
1600 Feehanville Drive  
Mount Prospect, IL 60056  
Customer Service: 847/391-4406 (Monday-Friday, 9 AM to 5 PM CST)  
Fax: 847/375-1129

## *PARE Overview*

The purpose of the PARE is to provide a multi-dimensional assessment that the boards of pharmacy may use as an auxiliary tool when making decisions regarding pharmacist practice deficiencies that are due to noncompliance with pharmacy practice standards, laws or regulations, and result in compromises to patient safety.

### **Exam Design**

The PARE is a Web-based examination administered on a computer. It contains 210 four-option, multiple-choice questions. Examinees are given a maximum of 4.5 hours to read pre-exam information and to take the assessment. The PARE is comprised of three content domains: Medication Safety and the Practice of Pharmacy (Area 1), Professional Ethics/Pharmacist Judgment (Area 2), and Clinical Pharmacy Practice (Area 3). A list of competency statements per content domain is located in Appendix 1. The assessment content is distributed so that approximately 50% of questions come from Area 1, 25% from Area 2, and 25% from Area 3.

### **Scoring**

To pass the PARE an overall score of 80 as well as a minimum score of 75 in each of the three content areas must be achieved. Scores are calculated as proportion correct and are reported to examinees as Pass/Fail. In the case of a Fail, the score report will include the overall score and the performance in each of the three content areas. NABP will make available the area scores in the case of a PASS at the request of the board of pharmacy.

Within one week of testing, scores will be reported to the examinees and their respective boards. Scores will be conveyed to the boards via posting on a protected FTP site. Login and password information will be provided to each board as needed. Examinees will receive their score from NABP via e-mail.

NABP recommends that outcomes of the PARE be interpreted within context of each examinee's situation and used in conjunction with other information in support of board action.

## *Administrative Details*

### **How to Register an Individual for the PARE**

Boards of pharmacy may register pharmacists to take the PARE through the NABP Clearinghouse for Individuals tab in the Board Portal. When entering disciplinary information for an individual there will be a drop-down menu where boards can indicate whether or not the PARE is required. By selecting the Yes option for the PARE the board is indicating that the individual is required to take the assessment and is now eligible to register. If the board determines at a later time that the PARE must be taken, the individual's disciplinary record may be edited to select the PARE as long as the record is still active.

In addition, NABP will need to know if the pharmacist will be using a personal computer or if the board will supply one so that information on the WebLock can be provided to the individual if necessary. After you have registered an individual to take the PARE through the Clearinghouse, NABP will e-mail you with a request for this information. Once this information has been received the individual will be able to contact NABP to complete registration for the PARE.

To register to take the PARE, examinees will contact NABP Customer Service, who will verify that the individual's information matches what the board provided. The board of pharmacy should direct the pharmacist to contact the NABP Customer Service Department **after** NABP has been provided with the registrant's information. (Examinees may contact Customer Service by calling 847/391-4406 from 9 AM to 5 PM Central time Monday through Friday.)

When registering for the PARE, examinees will need to provide the following information so that it can be verified against what the board supplied through the Clearinghouse record:

1. Examinee's name
2. Examinee's address
3. Phone number
4. Date of birth
5. Social Security number
6. E-mail address
7. Corresponding board of pharmacy

Upon registration, NABP will provide the registrant with a link to the *PARE Examinee Handbook*, which contains details about the processes and procedures on the test day as well as other important information. A link to the WebLock software and instructions for download will also be provided if the individual is using his or her own computer for the assessment. The board will be alerted that the individual has completed the registration process when they receive the test code for the individual. More information on the test code can be found in the General Instructions section of this manual.

### **Exam Cost**

Each administration of the PARE costs \$250 and is payable to NABP. MasterCard, Visa, and American Express are accepted means of payment. Payment confirmation will be e-mailed by NABP.

## Scheduling

Because the PARE is a Web-based examination, scheduling will be at the discretion of the board of pharmacy. If the PARE is scheduled outside of NABP's normal business hours (9 AM to 5 PM Central), NABP cannot guarantee that technical support will be available in the unlikely event of a technical issue.

## Repeater Policy

If an examinee's score falls below the passing threshold, retaking the PARE is at the discretion of the board of pharmacy.

## Testing Windows

The PARE will be available for a two-week testing window approximately four times per calendar year. Dates for the testing windows can be accessed on at [www.nabp.net](http://www.nabp.net) (URL TBD).

## Technical Preparations for the PARE

The PARE is administered via computer. It is up to each board of pharmacy to decide if examinees will supply their own laptop for testing or if a board-issued laptop/desk-top computer will be provided. Prior to exam day, NABP will e-mail a link to the exam to the designated board of pharmacy's contact person. This link will be used by the examinee on the day of the assessment.

Technical requirements for the PARE include:

<b>Requirement</b>	<b>Supported</b>
Web Browser	Microsoft Internet Explorer Version 8.0+ With compatibility view disabled
	Mozilla Firefox Version 1.9+
	Google Chrome WebKit Version 531+
	Apple Safari WebKit Version 531+
Adobe Flash Plug-in	Version 9.0.115+
Java Script	1.5+ Must be enabled; automatically included with supported browsers
Cookies	Must be enabled; supported in the above browsers
Screen Resolution	1024 x 768+

During the test session, there must be a continuous power source for the laptop/desk-top and Internet connectivity available (DSL or better).

For security purposes, NABP requires the use of a special WebLock browser. This application locks the computer and prevents the examinee from accessing applications outside of the examination. To ensure seamless delivery of the PARE on assessment day, this browser must be downloaded and installed prior to administration of the exam. Approximately two weeks prior to each scheduled exam, NABP will provide either your office or the examinee with a link to the lockdown browser depending on the computer

that will be used. Instructions for installation and contact information in case of technical issues will be provided along with the link. Installation should take one to two minutes. It is strongly recommended that the WebLock browser be installed at least one day prior to the assessment day to avoid any issues on the day of the PARE. Downloading the browser ahead of time will not impair the functionality of the computer or any of its applications. On the day of administration, the proctor should ensure the WebLock program has been downloaded on the computer designated for the exam and that all programs on the computer have been closed. Furthermore, the WebLock software can be uninstalled after the examination by going through the computer's Add/Remove Programs feature.

Each examinee will be assigned a test code that is unique to them. See the General Instructions section for more information on how this code is used.

## FastTEST WebLock Installation and Launch Instructions

### *Step 1: Install WebLock*

8. Before you start, ensure that:
  - a. You have Admin rights for the computer that will be used
  - b. The computer is connected to the Internet
  - c. All other programs running on the computer are closed
  - d. For installing on a Mac, the latest version of Java must be installed on the computer
2. Go to <http://WebLock.fasttestweb.com>



**FastTEST Web**  
Innovative solutions for online testing

**Secure Testing with FastTEST WebLock**

Follow the steps below to set up the FastTEST WebLock secure browser. If the browser has already been installed on this computer, proceed to Step 2.

Step 1: Install WebLock	Step 2: Launch WebLock
Note: You must have administrator privileges to install FastTEST WebLock.	Note: You must close all other programs before launching FastTEST WebLock
<a href="#">Click here to install the FastTEST WebLock secure browser*</a>	<a href="#">Click here to launch FastTEST WebLock and continue to the testing system*</a>
* Click Run, Install, Next, or Allow when prompted	* Click Run or Allow when prompted

If there is any problem installing FastTEST WebLock, please contact [support@fasttestweb.com](mailto:support@fasttestweb.com).

FastTEST Web v2 5.0  
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3. Click on the installation link listed under Step 1: “Click here to install the FastTEST WebLock secure browser” (box on left side of screen).
4. For Windows, clicking this link will download an installer. Run the program and click “Yes” or “Continue” for all prompts. For Mac, you will be directed to a download page that contains instructions for installation. The Mac download requires the use of Java. Users will download an installer

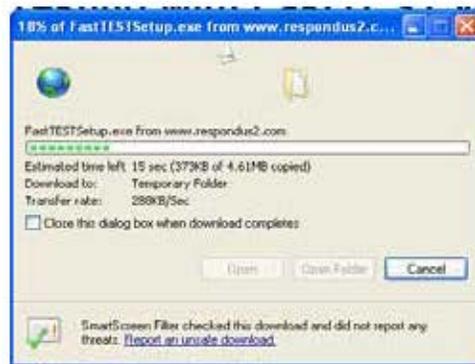
through a Java applet and then run the installer. If the Java applet fails to load, try running in a different browser such as Mozilla Firefox.

Note that Step 1 does not need to be done the moment before the examinee begins taking the test. However, it should be done ahead of time to ensure that the examinee can begin immediately at the scheduled test time.

The following images show the screens from #4 above in a Windows environment. Click “Run” in the first screen.



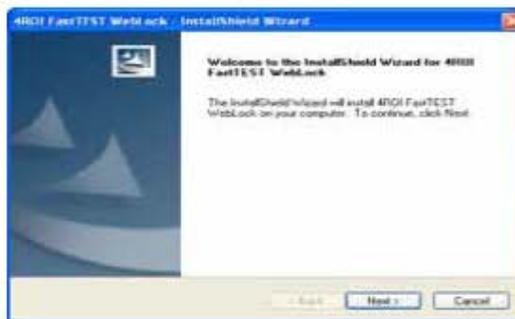
The setup installer will then download....



Click “Run” on the next screen.



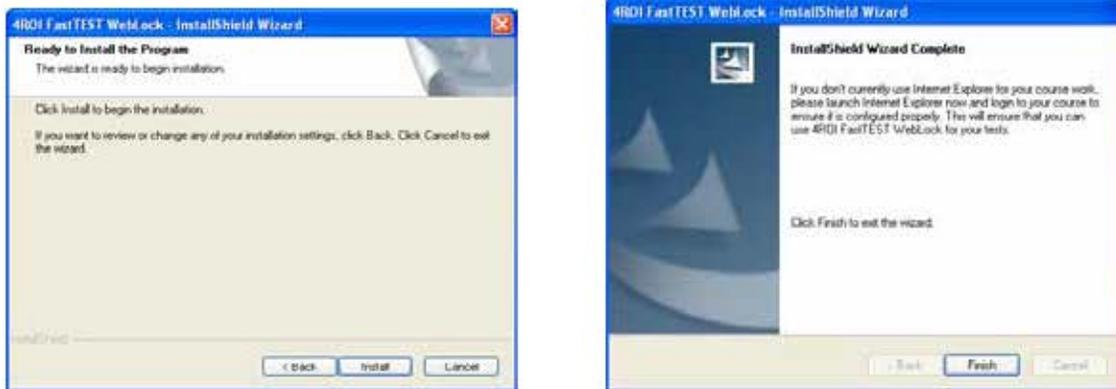
The installer will then open. Click “Next.”



Click “Next” to install to the default folder.



Click “Install” to run the installer. Click “Finish” to close the installer and return the browser.



### Step 2: Launch WebLock

1. Before you start, ensure that:
  - b. The computer is connected to the Internet
  - c. All other programs running on the computer are closed
2. Go to: <http://WebLock.fasttestweb.com>
3. Click “Click here to launch FastTEST WebLock and continue to the testing system.” If the screen shown below is displayed, click “Allow.” Prior to launching the exam, you should have closed all other programs, such as Google Desktop and any other auto-start program. If this step was not taken, right click the icon on the toolbar. If WebLock fails to launch after 10-15 seconds, try a different browser such as Mozilla Firefox.



4. The WebLock browser will then open to the examinee login screen as seen on the next page. You can be certain the WebLock browser is running if most of the buttons seen in the computer’s tool tray are gone.
5. In the box labeled “Test Code,” have the examinee enter his or her test code, and then click on “Login.” This procedure will allow the examinee to take the test in a secure setting where he or she is not allowed to run any other programs, visit other Web sites, or access information on the computer.



### To Turn Off WebLock

1. Click "Submit Exam" to finish the test.
2. Click "Return to the examinee login page." You can then leave the testing system by clicking "Exit."
3. If the specific computer is only being used for one test and no other test will be given via WebLock, you can uninstall the lockdown browser program. In Windows XP, uninstall via Start -> Control Panel -> Add or Remove Programs. In Windows Vista and Windows 7, it is located at Start -> Control Panel -> Programs and Features.

If the computer loses Internet connection or power during the exam, the exam session can be restarted by launching WebLock again and reentering the test code. No test data will be lost and the exam will restart at the point where connectivity/power was lost.

## *General Instructions*

### **General Duties of the Proctor**

The test proctor's primary responsibilities are to keep the examination code secure, to conduct the assessment according to the instructions put forth in this manual, to guard against cheating or any form of testing irregularity, and to protect the integrity of the test session.

If any special problems or questions arise **prior** to the examination date, please contact the NABP representative listed in the "Contact Information" section on page 5 of this manual.

The proctors should familiarize themselves with:

1. Check-in and admission procedures
2. Distribution, collection, and security of any examination materials, including scratch paper
3. Downloading the required test browser and launch of the exam
4. Continued surveillance of the examination area
5. Completion of the test session and the assessment time reports
6. Contact information for NABP

A proctor should be present in the area at all times during the exam and refrain from conversation or activities that might disturb or distract the examinees. Only examinees and an authorized proctor should be present during the examination.

### **Receiving Examination Materials**

The WebLock program, test code(s) for logging in, and test access information will be e-mailed to the individual designated by the board to receive this information.

Within five business days of each scheduled exam, the board's designated proctor will receive an e-mail from NABP containing test codes for the examinees. Each examinee will be assigned a test code that is unique to them. **It is essential that the test code(s) be kept secure.** On the day of the exam, specific instructions will be read to the examinee by the proctor. At this time, the proctor will provide each examinee with the respective test codes; examinees will use the provided code to log in to the test session.

### **Materials for the Examination Administration**

The following materials are provided by NABP:

1. Administration Manual
2. Test Session Report (TSR) – see Appendix 2

### **Materials/Items Provided by the Board**

1. Designated area in which to take the exam
2. Scratch paper
3. Pencil/pen

## *Examination Preparation*

### **Examination Proctor Preparation**

Prior to admitting and seating the examinee, the proctor should designate a secure place inside or outside the examination room for the storage of all personal belongings such as cell phones, backpacks, purses, briefcases, books, and study notes. **Examinees are not allowed access to personal property during the examination.**

### **Check-In**

The proctor must be in a position to check and recheck the examinees as they enter and leave the room.

**Examinees must check-out with the proctor before leaving the testing room.**

## *Admitting and Seating Examinee for the Assessment*

The board will notify the examinee of how early he or she may arrive prior to the start time for the PARE.

### **Admission of Examinee**

Upon arrival at the test session, the examinee must provide a valid government-issued photo ID. Acceptable forms of identification include the following non-expired documents:

- ✓ Driver's license
- ✓ Passport
- ✓ State-issued identification card that contains a current photo ID

The proctor will:

1. Verify that the name on the ID matches the name of the examinee scheduled to test.
2. Visually check the picture on the ID against the face of the examinee presenting the identification card. If the person's identity is in question, it is at the proctor's discretion whether or not to admit the examinee.

Once an examinee has been admitted to the test area, he or she may not leave the room unless authorized by a proctor.

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## *Conducting and Supervising the Assessment*

### **WebLock Program Activation Check**

Prior to launching the exam, the proctor must ensure that the WebLock browser has been installed and is activated. All programs on the computer must be closed prior to launching the WebLock browser. If programs such as Google Desktop are left running, the WebLock browser will not be properly activated.

Any problems regarding WebLock should be noted in the Test Session Report.

### **How to Access the PARE**

Accessing the PARE is a two-step process: locking down the computer is Step 1; activating the examination is Step 2. Prior to exam day, NABP will e-mail a link to the exam to the designated board of pharmacy's contact person. On the day of the exam, the examinee will open the link in the presence of a proctor. If the WebLock browser has already been installed (highly recommended), then the examinee will be instructed to skip Step 1 and go directly to Step 2. If the WebLock browser was **not** installed prior to the test session, then it will need to be done at the beginning of the test session by clicking on Step 1. Once the initial instructions have been read by the proctor to the examinee, the proctor will direct the examinee to enter the test code and select "Login." The exam will begin immediately.

In order to take the exam, each examinee must agree electronically to the Authorization/Release and Confidentiality Agreement. This Agreement will be available in the *Examinee Handbook* for examinees to review prior to the day of the exam. A copy of the Agreement can be found in Appendix 3 of this manual.

### **Distributing Materials**

At the scheduled examination time, the initial instructions should be read to the examinee and the scratch paper, pencils, and test code distributed. Each examinee will have a unique test code.

**Only the examinee may enter the test code to access the exam.**

### **Supervising the Assessment**

Detailed instructions to be read to the examinee before and during the assessment are provided on pages 20-22 of this manual.

Examinees may not use resources during the assessment or take written notes (scratch paper) out of the exam session. An on-screen calculator will be available throughout the exam. Use of personal, hand-held calculators is prohibited. There should be nothing on the examinee's desk or workspace other than board-provided scratch paper and pencils. Because no credit will be given for any answers written on the scratch paper, the proctor should emphasize that all answers must be recorded electronically. Upon completion of the test session, all scratch paper must be collected by the test proctor. Examinees may **not** remove scratch paper from the test session.

During the examination, the proctor should be present in the room at all times to guard against possible misconduct.

## Cheating or Other Misconduct

Be firm and professional in approaching an examinee that appears to be cheating or trying to cheat. Let the examinee know that you have been watching him or her. Do **not** accuse the examinee of cheating. Suggest that the examinee correct his or her misleading behavior. Make a detailed note of the incident on the TSR and allow the examinee to continue with the examination.

It is extremely important that you write a complete explanation of the incident on the TSR. Provide detail about what you saw, what you did about it, what you said, and what the examinee replied. A copy of this documentation should be retained by the board and a copy sent to NABP.

Suspected misconduct is a delicate issue and must be handled with diplomacy and very close observation. You should document your observations and sign and date the TSR. **Following procedures correctly and documenting exactly what took place makes invalidation of an examinee's examination score more defensible.**

All irregularities should be noted on the TSR and a copy retained for the board's records. The original TSR should be scanned and e-mailed or faxed to NABP attention Maria Boyle or Crystal Kaya. Contact information is located on page 5.

## Restroom Visits

The exam cannot be paused for restroom breaks. The exam time continues to run when an examinee is excused to use the restroom. Time lost for restroom breaks cannot be made up at the end of the exam.

**If an examinee is excused to go to the restroom during the examination session, the following protocol should be followed:**

1. Proctor collects scratch paper prior to the examinee being excused.
2. Proctor ensures the security of the computer while examinee is out of the room.
3. If a laptop is used and if more than one examinee is present at the exam session, the computer screen should be tilted down so that test questions cannot be viewed. If a desktop computer is used, turn the monitor off or tape a piece of paper over the screen.
4. Upon the examinee's return from the restroom, the proctor should return scratch paper to the examinee.

## Withdrawing During the Examination

If an examinee needs to withdraw from the examination for any reason, including illness, collect his or her examination materials and apply the following instructions:

1. Ask the examinee if he or she wants the assessment scored.
2. Note on the TSR that the examinee did not complete the exam. Indicate the time, date, reason for the withdrawal, and whether or not the exam is to be scored. The board should retain a copy of this documentation for its records and send a copy to NABP.

Note that it is the board's decision whether or not to allow an examinee to retest.

## Examinee Questions

Proctors may not answer any questions regarding individual examination questions.

## Collecting Assessment Materials

**Before** the examinee is dismissed at the close of the examination session, the proctor must make a complete count of the scratch paper provided. The proctor must account for all assessment materials, used and unused. **Under no circumstances is the examinee permitted to keep the scratch paper or to copy any questions from the exam.**

The assessment materials must be guarded so that the examinee does not have access to them as he or she leaves the room. No one may examine the scratch paper after it has been turned in to the proctor.

Since the proctor is solely responsible for the security of the assessment materials, he or she should see that the materials are carefully stored in a secure location under lock and key at the close of each examination session. Examination materials must **never** be left unattended. All scratch paper must be destroyed at the end of the exam.

## *Detailed Instructions for the Assessment*

**Good morning/afternoon/evening.**

**We are about to begin the exam. It is important that you follow along as I read the directions to you. Do not skip ahead as it may impact your exam time.**

**Please open an Internet browser and go to *WebLock.FastTestWeb.com*. You should see a Web page with the words FastTEST Web at the top. Before we move on, are you able to view this page? At this time, make sure that your computer is plugged in to a continuous power source.**

(If the board has already installed the WebLock skip to the next paragraph. If the examinee is using his or her own computer and was supposed to install the WebLock prior to coming to the assessment say:)

**On the FastTEST Web page, there are two boxes, labeled Step 1 and Step 2. Have you completed Step 1 to install the WebLock browser? If not, then click the hyperlink under Step 1 and follow the on-screen instructions.**

**Now click on the link under Step 2, titled “Click here to Launch FastTEST WebLock and continue to the testing system” and follow the on-screen prompts. If you receive an error message, click YES as many times as necessary to resolve the problem.**

**You should now see a page that says “FastTEST Web Examinee Login” and an empty box titled “Test Code.” I will distribute your individual test code shortly**

**During the course of the exam, the only items allowed at your seat are your computer, the provided scratch paper, and a writing instrument. You are required to remove all other items and place them with your personal belongings.**

**There is no scheduled restroom break. If you must leave for the restroom, raise your hand and wait for my instructions. Before leaving your seat, partially lower the top cover of your laptop or turn off your monitor and proceed to the restroom.**

**You will have 4 and a half hours or 270 minutes to complete the exam. A clock will be located in the upper right corner of your screen to display the time remaining for the exam.**

**To select an answer, left-click either the bubble or the text that corresponds to the chosen answer. Clicking the item letter alone will not select**

**the answer.** There will be 210 numbered boxes at the top of your screen. Boxes align with the items on the exam. If a question has been answered, the corresponding box will show a slash through it. The item you are currently working on will be shaded in blue, and any unanswered items will be white. Questions may be designated for review by clicking the “review” button, located at the bottom of your screen. This will highlight the item box yellow. You may go back at any time during the exam to review or change your answers.

At the top of your screen is a “Calculator” button. Clicking this button on any screen will make the calculator available to you. Note that to enter a number less than 1, you must first enter a leading zero (Example 0.5). Click the “X” in the right corner of the calculator to close it.

If you finish in less than the allotted time and wish to leave, you may do so. If you want to leave early, please raise your hand so that I can make sure that you have correctly submitted your exam.

Your score on this exam will be result from the questions you answer correctly. There is no penalty for guessing, so it is to your advantage to answer every question.

I will now provide you with your test code. This code enables you to begin the test. You will need to enter your test code into the Test Code box and press the Login button.

(Give the unique test code to the examinee. If there are multiple examinees please approach each one individually.)

**After you press the Login button you should see a screen that has 210 item boxes on it. Do you see that screen?**

We are now ready to move to the next screen. Please click on the button marked **NEXT**. This will take you to Question Number 1, which is the first of your three demographic questions. We will walk through questions 1 through 4 together. **Do NOT proceed to question Number 5 until you are told to do so.**

The first screen contains the Authorization/Release and Confidentiality Agreement. Please read through this carefully. By clicking the bubble you electronically agree to the terms stated in the agreement. If you do not agree to these terms you may not take the exam. When done, click NEXT.

**In question Number 2, type your last name.**

**In question Number 3, type your first name and for question Number 4, your middle initial if you have one. After completing question Number 4 please stop.**

**Are there any questions?**

(Answer any questions.)

**You may now proceed to question Number 5. Your 4 and a half hours begin now.**

### **TESTING**

At the conclusion of the exam, say:

**Your time is up. Please remember that you must leave all scratch paper at your test station.**

**Thank you for participating in the PARE. You are dismissed.**

Any issues/irregularities that arise before, during, or after the exam should be noted in the TSR, which can be found in Appendix 2 of this manual. In the event that there is an issue, this report should be faxed or mailed to NABP. If no issues arise, the proctor should mail or fax the report, or send an e-mail indicating that no irregularities took place.

## *FastTEST Troubleshooting*

### **Preliminary Troubleshooting**

- ✓ Shutting down all other programs before entering WebLock is preferred.
- ✓ Cookies must be enabled.
- ✓ If an error message appears stating *“You must close the following program before starting the browser: (program name here) Do you want 4ROU FastTEST WebLock to attempt to close this program for you?”* click “Yes” as many times as necessary. If problem persists, try using a different Web browser.
- ✓ If an error message appears stating *“4ROI FastTEST WebLock was unexpectedly launched without a custom URL to process. The application will now exit,”* you must launch WebLock through a Web browser with the indicated link, not by directly clicking on the installed program’s icon.

### **For Mac computers:**

- ✓ Firefox is the preferred browser. WebLock is not compatible with Safari.
- ✓ If WebLock browser does not install or launch properly, ensure that the latest version of Java is installed.

### **Exam Troubleshooting**

Force computer to shut down, restart, and log in again using the same log in key if:

- ✓ Pictures do not show up on exam questions
- ✓ Blue slashes do not appear in the boxes at the top of the screen for questions already answered
- ✓ Computer freezes
- ✓ “Submit exam” button does not appear
- ✓ If the refresh button is pushed and blue slashes get cleared out from the already answered questions
- ✓ Any other unique problems occur during the exam

## *Appendix 1: Content Areas*

### **Area 1 Medication Safety and the Practice of Pharmacy 50% (105 items)**

#### 1A Safe and Effective Preparation and Dispensing of Medications

1A1- Extemporaneous Compounding/Parenteral/Enteral including Calculations, Sterile Admixture Techniques, USP <797>, Stability and Sterility Testing and Dating, Clean Room Requirements, Infusion Devices and Catheters

1A2- Preparation, Dispensing, Distribution, and Disposal of Medications and Devices including Appropriate Labeling, Storage, Packaging, and Handling

1A3- Distribution Systems Associated with All Types of Practice Settings

1A4- Role of Automation and Technology in Workload Efficiency and Patient Safety

#### 1B Prevention of Medication Errors

1B1- Practice Management Tools Needed to Assess and Address Change, Improve Quality, and Optimize Patient Services

1B2 - Identification and Prevention of Medication Errors Within the Dispensing and Distribution System

1B3- Medication Error Reduction Programs

1B4- Medication Safety: Causes of Errors, Strategies for Reducing Errors

#### 1C Continuous Quality Improvement

### **Area 2 Professional Ethics/Pharmacist Judgment 25% (52-53 items)**

#### 2A Professional Ethics

2A1- Ethical Principles

#### 2B Decisions/Actions Affecting Patient Care

2B1- Ethical Issues in Delivery of Patient-Centered Care/Clinical Research

#### 2C Code of Ethics, Professional Behavior

2C1- Dealing with Ethical Dilemmas

2C2- Conflicts of Interest

2C3- Ethical Issues in Teamwork

### **Area 3 Clinical Pharmacy Practice 25% (52-53 items)**

#### 3A Patient Assessment, Clinical Pharmacology, Therapeutics

3A1-Pharmacotherapy: Selection of Drug Products, Dosing, Routes of Administration, Disease State Management

3A2- Patient Assessment Triage and Referral Skills: Identify and Assess the Patient's Current Health Status, Health Problems, Need for Treatment and/or Referral, and Desired Therapeutic Outcomes

3A3- Diagnostic Tests in the Diagnosis of Various Disease States, Knowledge of the Basis for Common Clinical Laboratory Values and Diagnostic Tests and the Influences of Common Disease States

3A4- Patient Monitoring: Drug Monitoring for Positive and Negative Outcomes, Methods of Outcome Monitoring and Assessment Techniques, Drug Monitoring for Positive/Negative Outcomes in Special-Population Patients, Pharmaceutical Care Plans

3A5- Problem Identification and Resolution (eg, Dosage, Frequency, Dosage Form, Interactions, Adverse Drug Reactions, Indication, Contraindication, Safety, Efficacy, Non-compliance, Abuse)

3B Promotion of Wellness and Public Health

3B1- Disease Prevention and Monitoring

3B2- Infection Control (Pharmacist Intervention, Recommendations)

3B3- Promotion of Wellness (Nutrition, Non-pharmacologic Therapies, Lifestyle)

3C Drug Information

3C1-Fundamentals and Application of Drug Information Skills for the Delivery of Care (Identifying and Using Resources, Accessing References etc)



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### *Appendix 3: Authorization/Release and Confidentiality Agreement*

1. I agree to sit for the Pharmacist Assessment for Remediation Evaluation<sup>SM</sup> (PARE<sup>SM</sup>) and agree to provide to the National Association of Boards of Pharmacy<sup>®</sup> (NABP<sup>®</sup>) my full name, date of birth, and my Social Security number as set forth in the registration process. I authorize NABP to use such information for purposes of confirming my identity, calculating and evaluating my PARE score, and PARE program-related activities including, but not limited to, validity of the PARE and quality assurance. I further authorize NABP to release such identifying information and my PARE score to my Board of pharmacy. NABP will not use such identifying information or my PARE score for commercial or solicitation purposes.
2. Except as permitted herein or in the event that NABP is legally required to disclose the information that I authorize, NABP will keep confidential and will not disclose any of the information that I release and authorize for use pursuant to this authorization and release form (hereinafter "Form"). This paragraph will survive expiration or revocation of this Agreement.
3. I understand and agree that I am expressly prohibited, at all times, from disclosing, reproducing, transmitting, receiving or utilizing without authorization, or making available the PARE including, but not limited to, examination question format, questions, profiles, answers, and scenarios, in whole or in part, in any form and by any means, whether verbal, written, electronic, or mechanical, for any purpose.
4. I understand and agree that if NABP obtains information that I, at any time, disclosed, reproduced, transmitted, received or utilized without authorization, or made available any portion of the PARE in any form to or from individuals, organizations, study groups, or the like, that I forfeit the right to have my examination scored, that NABP has the right to invalidate my examination score, and I understand that NABP may initiate civil, criminal, and/or administrative proceedings against me that may result in civil penalties, criminal punishments, and/or disciplinary action.
5. NABP disclaims all liability and responsibility arising from this Agreement except to the extent that NABP breaches its responsibilities or is negligent in performing under this Agreement and only to the extent that the liability or responsibility is caused by such breach or negligent performance. Further, NABP disclaims all liability and responsibility for all individuals' or entities' use, maintenance, or disclosure of the information described herein after NABP's release of such information in accordance with this Agreement.
6. I understand that I may revoke this Agreement at any time if I sign and send a letter, via certified, registered, or overnight mail with return receipt requested, to the executive director/secretary, National Association of Boards of Pharmacy, 1600 Feehanville Drive, Mount Prospect, IL 60056, or such other address where NABP may be located at the time of sending such letter. Unless I revoke this Agreement as described herein, the Agreement is valid upon the date of my signature and for a period of seven years after the PARE program, and any of its successor programs, cease to exist.



The National Association of Boards of Pharmacy®  
1600 Feehanville Drive  
Mount Prospect, IL 60056

# Attachment 2

# FiercePharma Manufacturing

Published on FiercePharma Manufacturing (<http://www.fiercepharmamanufacturing.com>)

## FDA commish suggests putting more bite in laws for counterfeiting

June 7, 2012 | By Eric Palmer

FDA Commissioner Margaret Hamburg called on drugmakers to be "accountable for the integrity of their supply chains" to help fight counterfeit drugs, a reference to the need for a track and trace system in the U.S. She also called for stronger penalties for traffickers.

In an interview with *The Financial Times*, Hamburg said, "We need to really strengthen the integrity of the supply chain to really be able to assure safe passage of products through the complex network of packagers and distributors and redistributors and importers."

Her remarks came as the House and Senate will reconcile their separate versions of the bill reauthorizing the FDA to collect user fees to help fund nearly half its 5-year budget. The FDA wants the final law to have a track and trace system with unique identifiers on each drug container and requirements that they be scanned along their distribution route. The industry has agreed to the unifiers but wants only lot scanning.

It also comes after two recent high-profile cases of counterfeits being found in the U.S. Just last week, the FDA sent out an alert that fakes of Teva Pharmaceutical Industries' (STEVA) attention-deficit drug Adderall, were being sold over the Internet. In February, the agency discovered counterfeits of Roche's (SRHHBY) cancer drug Avastin had been sold directly to physician clinics.

Hamburg also called for harsher penalties for those trafficking in fakes, saying that criminals are now viewing drug counterfeiting as a lucrative enterprise with no more threat of jail time than selling fake purses. The FDA reauthorization bill would give drug counterfeiting penalties more punch.

"We need legal authorities to give teeth to our actions," Hamburg said. "We are increasingly concerned that this is becoming an attractive area for bad guys, including organized crime."

*The International Journal of Clinical Practice* warns that increasing numbers of fakes are getting into legitimate supply chains, and global sales of fake meds doubled from 2005 to 2010, to \$75 billion.

- read the *Financial Times* [interview](#) (reg. req.)

### Related Articles:

[Fake Adderall surfaces as Congress turns attention to track and trace](#)

[Fake Avastin case highlights need for supply-chain controls](#)

# FiercePharma

Published on FiercePharma (<http://www.fiercepharma.com>)

## Fake Avastin case highlights need for supply-chain controls

March 12, 2012 | By Tracy Staton

Global pharma police have few weapons against fly-by-night drug distributors that deal in counterfeits. This is no secret to drugmakers; Pfizer ([\\$PFE](#)), for instance, has a vast security force focused on cracking down on fake versions of its meds, including--perhaps especially--that little blue pill, Viagra. And before phony [Avastin](#) surfaced in the U.S., Roche ([\\$RHHBY](#)) teams tracked fake versions of the company's drugs in the Middle East.

Now, that phony Avastin has cast a spotlight on the pharma supply chain. The fake cancer drug--which contained none of the real thing's active ingredient--had passed through several countries and half a dozen companies before the FDA warned U.S. doctors about it. "The business about counterfeit Avastin really demonstrates how easy it is to be fooled," Sandra Kweder, deputy director of FDA's Office of New Drugs, said, as quoted by *Reuters*.

Complicating matters is distributors and customers themselves ignore red flags--such as markedly discounted prices, as in Avastin's case--which only feeds the counterfeit trade. In other cases, import/export rules prohibit middlemen from opening boxes to inspect their cargo; Switzerland's Hadicon, for instance, blamed such rules for its unwitting participation in the Avastin fraud. Plus, experts say, many counterfeiters are simply good at faking it.

"The perpetrators certainly acted in a highly professional manner and knew that drugs would not be allowed to be opened once smuggled into the delivery chain," Hadicon CEO Klaus-Rainer Toedter told *Reuters*. And one anonymous buyer said the U.S. Avastin distributor was "a good con man" with documentation and licenses that appeared authentic.

What's to be done? Drug-tracking systems have been proposed, and Europe starts requiring unique identifiers on all drug packages beginning in 2016. But even RFID tags can be circumvented, especially if customers are willing to look the other way, *Reuters'* sources said. And drug shortages have healthcare providers casting about for new suppliers, which could aid counterfeiters. Some U.S. lawmakers have proposed harsher penalties for counterfeiters and increased tracking along the supply chain.

- read the *Reuters* [analysis](#)

### Related Articles:

[Fake Avastin adds urgency to foreign-drug importation probe](#)

[Phony Avastin vials contained chemicals, but no drugs](#)

[Fake Avastin's path shows tangled global supply chain](#)

# FiercePharma Manufacturing

Published on FiercePharma Manufacturing (<http://www.fiercepharmamanufacturing.com>)

## Fake Adderall surfaces as Congress turns attention to track and trace

May 31, 2012 | By Eric Palmer

Another counterfeit drug, this time the ADHD drug Adderall, has surfaced in the U.S. even as details of how the FDA and the industry should track drugs to protect against fakes is about to be hashed out by Congress.

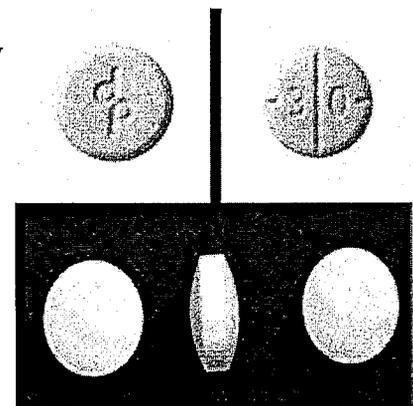
The FDA this week warned that fake versions of the drug have shown up on Internet sites as shortages have made it difficult to get. Made by Teva Pharmaceutical Industries ([\\$TEVA](#)) and other generics companies, the short-acting form of Adderall has been in short supply since last year because of "active pharmaceutical ingredient supply issues," *The Wall Street Journal* reports.

There are concerns about counterfeits sold over the Internet making their way into the legitimate supply chain, and the industry and the FDA are looking at ways to better police the problem. The urgency was raised earlier this year when counterfeit versions of Roche's ([\\$RHHBY](#)) cancer drug [Avastin](#) were sold to more than four dozen physician practices throughout the U.S.

The House and Senate versions of the FDA reauthorization bill include language that would set up more stringent tracking of drugs to help prevent counterfeiting, but the details have yet to be set, *Reuters* reports. The FDA wants a nationwide program that includes and tracks identifiers on individual containers. The plan put up by an industry coalition would put unique serial numbers on individual drug packages but require scanning drugs only in "lots" when they get to distributors. They have argued that to expect individual tracking from truck to warehouse to distributor to pharmacies is unworkable, at least for now.

FDA Commissioner [Margaret Hamburg](#) has made her case to consumers on the FDA blog, writing, "To learn that the cancer drug you were taking to save or prolong your life might be nothing but a counterfeit is unthinkable. We ... need authority to require a robust system to track and trace all drugs throughout the supply chain."

The U.S. is not the only country thinking this way. Europe starts requiring unique identifiers on all drug packages beginning in 2016. The Senate and House reconciliation process will sort out whether the FDA or the industry has the most clout on this issue, but the appearance of more fakes as the



*Teva's Adderall (top) can be distinguished from counterfeits (bottom) by its color and insignia--courtesy of the FDA*



U.S. Food & Drug Administration



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### Another counterfeit cancer medicine found in U.S. - Illegal practice puts patients at risk

Statement Update Issued: April 25, 2012

FDA has issued letters to medical practices in the United States that purchased unapproved cancer medications from Quality Specialty Products (QSP) (also known as Montana Health Care Solutions), and distributed through Volunteer Distribution of Gainesboro, Tennessee that may include counterfeit versions of Altuzan.

Letters to Doctors about Risks of Purchasing Medications from Foreign or Unlicensed Suppliers<sup>1</sup>

Statement Update Issued: April 17, 2012

In a related action, FDA has issued letters to medical practices in the United States that purchased unapproved cancer medications that may include counterfeit versions of Altuzan.

Statement Issued: April 3, 2012

The U.S. Food and Drug Administration is alerting healthcare professionals that another cancer drug, originating from a foreign source and purchased by U.S. medical practices, has been determined to be counterfeit. Medical practices that purchase and administer illegal and unapproved foreign medications are putting patients at risk of exposure to drugs that may be fake, contaminated, improperly stored and transported, ineffective, and dangerous. Illegal drugs purchased from foreign sources may not be genuine or meet appropriate quality, safety, and efficacy standards, putting patients at risk and depriving them of proper treatment.



Patients receiving cancer drugs or other drugs not approved by the FDA for the U.S. market may not be receiving needed therapy. Patients are encouraged to discuss any concerns they may have about the source of their medications with their healthcare professional.



FDA lab tests have confirmed that a counterfeit version of Roche's Altuzan 400mg/16ml (bevacizumab), an injectable cancer medication, found in the U.S. contains no active ingredient. Even if the identified drugs were not counterfeit, Altuzan is not approved by FDA for use in the United States (it is an approved drug in Turkey). On February 14, FDA issued an alert about another cancer drug<sup>2</sup> in U.S. distribution that was purchased from a foreign source and found to be counterfeit.



Medical practices obtained the counterfeit Altuzan and other unapproved products through foreign sources, in particular from Richards Pharma, also known as Richards Services, Warwick Healthcare Solutions, or Ban Dune Marketing Inc (BDMI). Many, if not all, of the products sold and distributed through this distributor have not been approved by the FDA. The agency cannot ensure that the manufacture and handling of these illegal products follows U.S. regulations, nor can FDA ensure that these drugs are safe and effective for their intended uses.

Any medical practice that has obtained unapproved products, in particular from Richards Pharma, Richards Services, Warwick Healthcare Solutions, or Ban Dune Marketing Inc (BDMI), should stop using them and contact the FDA. The products should be retained and securely stored until further notice by the FDA.

Healthcare professionals and patients should report adverse events related to the use of suspect injectable cancer medicines to the FDA's MedWatch Safety Information and Adverse Event Reporting Program either online, by regular mail, by fax, or by phone. Health care professionals and consumers can either:

- Complete and submit the report online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)<sup>3</sup>, or
- Download form<sup>4</sup> or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

FDA is asking the public to report suspect counterfeit products and other suspect products obtained from Richards Pharma, Richards Services, Warwick Healthcare Solutions, Ban Dune Marketing Inc (BDMI), or other sources:

- Call FDA's Office of Criminal Investigations (OCI) at 800-551-3989, or
- Visit OCI's Web site ([www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm](http://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm))<sup>5</sup>, or
- Email - [DrugSupplyChainIntegrity@fda.hhs.gov](mailto:DrugSupplyChainIntegrity@fda.hhs.gov)

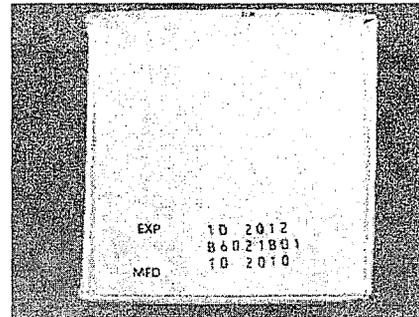
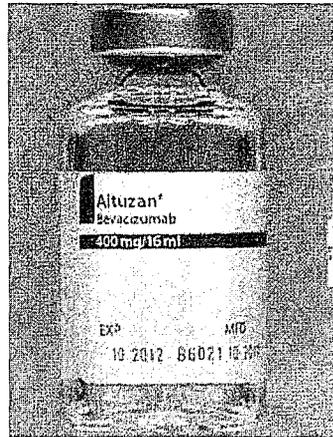
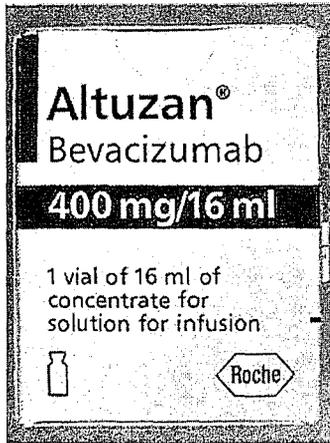


For more information about counterfeit medicine:

<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/default.htm><sup>6</sup>.

Pictures of the counterfeit version of Altuzan are shown below:

Packaging or vials found in the U.S. that claim to be Roche's Altuzan with lot number B6021 should be considered counterfeit.



**Links on this page:**

1. [/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm)
2. <http://www.fda.gov/Drugs/DrugSafety/ucm291960.htm>
3. <http://www.fda.gov/MedWatch/report.htm>
4. <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>
5. <http://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm>
6. <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/default.htm>

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Silver Spring, MD 20993  
Ph. 1-888-INFO-FDA (1-888-463-6332)  
Email FDA

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## FDA Tracks Fake Avastin to Foreign Supply Distributed in U.S.

By: KERRI WACHTER, Oncology Report Digital Network

02/21/12

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The Food and Drug Administration has tracked counterfeit bevacizumab, the cancer drug marketed as Avastin, to at least one foreign supplier and identified 19 medical practices in the United States that purchased unapproved cancer medicines, possibly including counterfeit bevacizumab.

The FDA said the practices obtained the fake Avastin from Quality Specialty Products (QSP), a foreign supplier also known as Montana Health Care Solutions. QSP products are also distributed by Volunteer Distribution in Gainesboro, Tenn., the agency said.



Courtesy of Genentech

**This package of counterfeit Avastin has the letter B in the lot number and a date of manufacture -- neither of which appears on packages of Avastin approved for use in the United States. Also, Genentech is not identified on the label, and the expiry date is written entirely in numerals.**

The FDA has requested that medical practices stop using any remaining products purchased from these suppliers "or any other unapproved foreign source," because the agency cannot ensure the safety or efficacy of any of these unapproved products.

"The Agency is very concerned that these products may cause harm to patients because they are unsafe or ineffective. ... These products may be from unknown sources; have unknown ingredients; and may not have been manufactured, transported or stored under proper conditions required by U.S. law, regulations, and standards," the agency said.

Avastin's manufacturers announced Feb. 14 that they learned of the distribution of the counterfeit in the United States. "The counterfeit product is not safe or effective and should not be used. Chemical analyses of the counterfeit vials tested to date have confirmed the product does not contain the active ingredients for Avastin," warned F. Hoffmann-La Roche and Genentech.

Avastin, an injectable medicine used to treat many cancers, is administered to patients in clinics, hospitals, and doctors' offices. The counterfeit version does not contain the monoclonal antibody bevacizumab.

The FDA similarly warned health care professionals and patients about a counterfeit version of Avastin 400mg/16mL, which may have been purchased and used by some medical practices in the United States.

The FDA has since issued letters to 19 U.S. medical practices that purchased unapproved cancer medicines that may include the counterfeit Avastin. It is believed that some product in the United States labeled as Avastin 400 mg/16 mL with the following lot numbers on either the vials or packaging may be counterfeit: B86017, B6011, and B6010.

Importantly, the counterfeit product does not look like authentic Avastin. Authentic Avastin's cartons and vials (approved for use in the United States) have "Genentech" or "Genentech, a member of the Roche Group" printed on the labels. The counterfeit version is labeled as

Avastin, manufactured by Roche, which manufactures Avastin for marketing outside of the United States.

In addition, the lot number on the carton and vial should be six digits with no letters; the expiry date is formatted as a three-letter month and four-digit year (such as, JUL 2014); the date of manufacture is not printed on the carton or vial; and all the text on the vial labels, cartons, and package inserts is in English on products approved for sale in the United States.

The fake Avastin scandal comes at a time when many injectable cancer drugs are in short supply – a situation that "may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply," the FDA warned on Jan. 13.



Courtesy of Genentech

**These authentic Avastin packages are in English and carry the Genentech name.**

At that time, it advised health care providers about the risks of purchasing unapproved injectable cancer medications that are not in short supply from unlicensed sources. The agency named Faslodex (fulvestrant), Neupogen (filgrastim), Rituxan (rituximab) and Herceptin (trastuzumab) – but not Avastin – in [the January warning](#).

"In certain circumstances, the FDA may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the U.S. through a controlled network, and would not be sold in direct-to-clinic solicitations," the agency advised.

"If the FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available on the FDA drug shortages website, often in the form of a 'Dear Healthcare Professional' letter."

Based on information to date, the FDA has determined that none of the unapproved cancer medicines that medical practices are known to have received from Volunteer Distribution are in short supply in the United States. FDA-approved versions of these medicines are available in adequate supply to meet current demand.

Medical practices that have obtained unapproved products from foreign sources, in particular from Volunteer Distribution and/or QSP, should stop using them and contact the FDA. These products should be retained and securely stored.

To report suspect counterfeit products and other suspect unapproved products obtained from Volunteer Distribution or QSP/Montana Health Care Solutions or other sources: Call FDA's [Office of Criminal Investigations](#) (OCI) at 800-551-3989, or visit OCI's website.

For information about this counterfeit medicine, see Roche's [statement](#).

Click [here](#) for more information about counterfeit medicines found in the United States.

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## Cancer Patients Fume Over Counterfeit Avastin

By KATIE MOISSE

Feb. 15, 2012—

abcnews.go.com

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### Fake Version Missing Cancer-Fighting Ingredient, FDA Warns

Cancer patients are furious that a counterfeit version of the drug Avastin has landed in U.S. clinics.

Avastin, which is made by the California-based company Genentech, is used in combination with chemotherapy to treat cancers of the colon, brain, kidneys and lungs. But the counterfeit lacks the tumor-starving ingredient some patients need to survive.

"It's an outrage," said Diane Barraza, 48, who takes Avastin for stage IV colon cancer. "For a company to sell this drug, put it in our blood, it's an outrage."

The U.S. Food and Drug Administration announced Tuesday that 19 clinics in California, Texas and Illinois may have purchased the phony Avastin from Quality Specialty Products, an "unapproved" foreign supplier also known as Montana Health Care Solutions. The counterfeit vials are labeled "Avastin" but indicate "Roche" as the manufacturer. Roche is the parent company of Genentech.

"The counterfeit contains no Avastin, no generic Avastin, no active ingredient whatsoever," Genentech spokesman Ed Lang told ABC News. Lang said the contents of the vials are still under investigation.

For patients like Barraza, a fake cancer drug would be the cruelest con.

"To sit in the chemo chair and watch that stuff drop into my veins," said an emotional Barraza, who lives in Fullerton, Calif., with her 6-year-old daughter. "It's all I've got. And it might just be water?"

Avastin is expensive, costing upwards of \$650 for a small vial. But Montana Health Care Solutions sold the counterfeit vial for \$480, according to one of the clinics -- a cost savings of 25 percent.

"Obviously it makes good business sense to try to get the drug at a reduced cost," said Dr. Jack Jacoub, a medical oncologist at Orange Coast Memorial Medical Center in Fountain Valley, Calif. "But when you start to get drug pricing that's markedly different from that of the standard distributor, it should raise a red flag."

Only four U.S. distributors are authorized to sell Avastin to doctor's offices; another four can sell the drug wholesale to hospitals. Montana Health Care Solutions is not an authorized Avastin distributor. Jacoub, who treats Barraza, said his clinic buys Avastin in bulk from an approved distributor for \$593.20.

Montana Health Care Solutions claimed to be based in Belgrade, Mont. But the company's

recently disconnected phone number has a New Brunswick, Canada, area code. It's unknown whether Montana Health Care Solutions knew the Avastin was counterfeit. They also sold other cancer drugs, including Neulasta and Faslodex, at a significantly discounted price.

The FDA was alerted to the possible counterfeit in December 2011 by the Medicines and Healthcare Products Regulatory Agency in the U.K., according to Genentech's Lang. In a Feb. 10 letter, the agency urged the 19 clinics known to have purchased through unapproved distributors to "retain and secure" any unused drugs. The counterfeit Avastin vials have the lot numbers B86017, B6011, B6010, and the labels are slightly different.

Counterfeit or illegally imported drugs are rare in the U.S. but not unheard of. In 2008, heparin (a blood thinner) imported from China killed 81 Americans.

"Counterfeit drug makers have reached a level of sophistication where the real and fake products look almost identical," said Peter Pitts, president of the Center for Medicine in the Public Interest and former associate commissioner for the FDA. Pitts estimated that counterfeit drugs generated \$75 billion in 2010, a figure expected to grow by 20 percent annually. "It's a low risk, high reward proposition. It's almost a perfect crime -- people aren't getting the drugs they need and they end up dying."

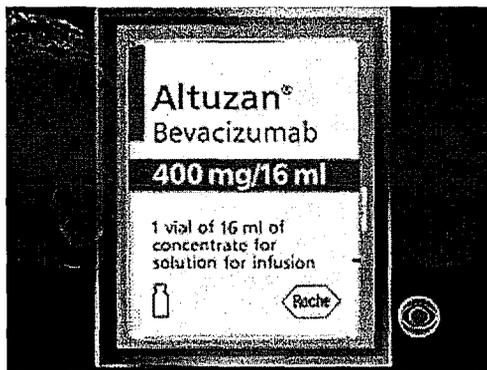
For Barraza, who will have four more Avastin treatments over the next two months, the thought of criminals profiting from her disease is sickening.

"I wish they could understand what it feels like to be a cancer patient, to take a drug and to suffer," she said. "I'd do anything to stay alive, but I need the right medication."

April 4, 2012 7:02 PM

# Fake cancer drug surfaces again from overseas

By Armen Keteyian



(CBS News) It is just about the worst kind of fraud you can imagine -- fake cancer drugs, not much more than a vial of water with a drug label on it. CBS News previously reported on this, but it's happened again: A number of clinics received counterfeit vials of cancer drugs. CBS News chief investigative correspondent Armen Keteyian has traced the source overseas.

This week, the Food and Drug Administration alerted healthcare professionals that 120 vials of fake Altuzan -- which contained no active ingredient -- had entered the U.S. from distributors in the U.K. after being purchased from wholesalers in Turkey.

CBS News' Armen Keteyian looks into the distribution of counterfeit Altuzan from U.K. distributors to the U.S.

Connie Jung is with the FDA's Office of Drug Security, Integrity and Recalls. "What we're seeing is a pattern of this risky practice of purchasing unapproved drugs from foreign suppliers," she said.

(Credit: CBS News)

Altuzan has the same active ingredient as the cancer-fighting Avastin, but is sold only in Turkey and not approved for use in the United States.

According to British authorities, 82 of the counterfeit vials were shipped to the U.S. by River East Supplies, located in the U.K. and owned by Canadian businessman Tom Haughton. Haughton is currently under federal investigation for shipping counterfeit Avastin into the U.S., offering Avastin for about \$2,000 a vial -- some \$400 less than the manufacturer's price.

We tracked Haughton down last month in Barbados. He denied any wrongdoing and took a strong stance against counterfeits.

Fake Avastin importer claims he broke no laws  
Following the trail of fake Avastin  
How fake Avastin from overseas ends up in U.S.

"We're depending on the governments and regulators to make sure these supply chains are indeed safe. I will do everything within my power to ensure this never happens ever again."

The FDA said one distributor of the worthless Altuzan was California-based Ban Dune Marketing. In February, its owner pleaded guilty to distributing "adulterated prescription drugs" used for cancer treatment and not approved by the FDA.

According to the government, it offered big discounts on cancer treatment drugs -- "14 to 60 percent" -- requesting doctors keep its price list confidential.

When contacted by CBS News Wednesday, Tom Haughton had no comment. The FDA, meanwhile, would not tell us how many doctors may have received the fake Altuzan, but said these counterfeit products are potentially dangerous to patients who are relying on these medicines to get better.

# Attachment 3



**California State Board of Pharmacy**  
1625 N. Market Blvd., Suite N219, Sacramento, CA 95834  
Phone (916) 574-7900  
Fax (916) 574-8618  
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
EDMUND G. BROWN, JR., GOVERNOR

May 9, 2012

Representative Henry Waxman  
2204 Rayburn House Office Building  
Washington, DC 20515

RE: SECURING PHARMACEUTICAL DISTRIBUTION INTEGRITY  
Comments of the California State Board of Pharmacy  
*H.R. 3026 – Safeguarding America’s Pharmaceuticals Act of 2011*  
*Securing Pharmaceutical Distribution Integrity Act of 2012 (Senate)*

Dear Representative Waxman:

I write on behalf of the California State Board of Pharmacy (Board). We are pleased to have this opportunity to share with you our comments and concerns regarding the development of federal legislation addressing the security of the pharmaceutical distribution supply chain, a topic of considerable interest to this Board. We understand that this legislation is or may soon be included in bills relating to the Prescription Drug User Fee Act (PDUFA) reauthorization that are in motion in the Senate and/or the House of Representatives. We hope that you will consider our comments as you are asked to review, sponsor, or vote on legislation that addresses this topic.

We would first like to thank you for your historical and continued leadership on the topic of pharmaceutical supply chain security, and for your ongoing effort to solicit Board input on the path forward. We appreciate the regular contacts your staff have made with Board staff, and are pleased to have a partner at the federal level who is so supportive of California’s pedigree law(s).

We support the idea of a federal approach. It would be best for supply chain security to be addressed at the federal level by a bill approximating the principles of the California law(s), given the scope of the regulated market. California stepped into this area of regulation out of a perceived need, in the absence of federal standard(s) and in response to acts of counterfeiting and other threats to security that led to the formation of the U.S. FDA Counterfeit Drug Task Force in 2003. But we acknowledge that a federal standard and enforcement would be advantageous. However, we also share your view, expressed during a May 1, 2008 hearing on H.R. 5839, that “federal legislation that seeks to nullify California’s law must provide the same or greater degree of protection, or else preserve California’s ability to proceed with its legislation.”

We believe that H.R. 3026, the “Safeguarding America’s Pharmaceuticals Act of 2011,” as introduced on September 22, 2011, has the potential to establish this kind of robust federal standard. However, we do not believe the same can be said of another proposal under review, known variously as the “Pharmaceutical Traceability Enhancement Code (RxTEC) Act” or the “Securing Pharmaceutical Distribution Integrity Act of 2012.” We are writing to express our concerns about this legislation, that would preempt California’s law and replace it with what we believe is a less robust, and less secure, supply chain infrastructure.

## History and Structure of California's Pedigree Law(s)

As you know, California and this Board have taken a leading role in setting standards for securing the prescription drug supply through deployment of our pedigree law(s). Inspired in part by a vision of a universal electronic pedigree/track-and-trace infrastructure laid out in FDA Counterfeit Drug Task Force reports in 2003, 2004, 2005, and 2006, between 2003 and 2008 the Board worked with the California Legislature to enact and amend California law(s) requiring adoption of such an infrastructure. The most recent amendments to the law(s), in 2008, were the outcome of careful and protracted legislative negotiations involving many stakeholders. Our legislative record includes statements of support from many of the most important players in all segments of the industry, reflecting a rough consensus that the California approach is the best way forward. As you are aware, the basic elements of the California approach call for staggered implementation between 2015 and 2017 of a pedigree/track-and-trace infrastructure including:

- An electronic pedigree record showing each change in ownership, from original manufacturer (and/or subsequent repackager), through all drug distributor(s), to final dispenser/furnisher/administerer(s) of the dangerous drug;
- Data that is exchanged in an interoperable electronic system incorporating track and trace infrastructure, based on a unique identifier established at point of manufacture;
- Tracking at the smallest package or immediate container (saleable unit); and
- Data that is passed, certified, and authenticated by all supply chain participants.

In our view, deployment of such an infrastructure promises significant benefits. It was originally designed to prevent or diminish introduction of counterfeit, misbranded, or adulterated drugs into the secure supply chain. It clearly serves this purpose, while also providing tools for investigation and enforcement of any such intrusions, promoting accountability. As has recently been shown by the Avastin example,<sup>1</sup> pharmaceutical counterfeiting remains a real and perhaps growing threat to the security of our drug supply.<sup>2</sup> As does drug diversion and black market sale of pharmaceuticals, as illustrated by the indictment recently announced by New York Attorney General Schneiderman of a ring distributing black market/diverted HIV medications.<sup>3</sup>

A universal electronic pedigree/track-and-trace infrastructure also has great potential to address other significant threats to our drug supply. For instance, our experience in California with the Heparin recall(s) in 2008,<sup>4</sup> and with more recent drug and device recalls, has convinced us there are gaps and deficiencies in our nation's current recall practices. Problems include the sheer number of recalls initiated each year, resulting confusion over whether any recall notice that is received is new or duplicate information, and confusion and debate over the "voluntary" nature of most recalls. As the Heparin example demonstrated, it is unlikely that most recalls result in the desired effect of removing all doses of a drug from the market. Universal electronic pedigree/track-and-trace infrastructure could vastly improve the operation, specificity, reliability and accountability of recall processes. Recalls could be targeted, and their accuracy tracked.

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<sup>1</sup> See "Counterfeit Version of Avastin in U.S. Distribution," Statement by the FDA, February 14, 2012, available at <http://www.fda.gov/Drugs/DrugSafety/ucm291960.htm>.

<sup>2</sup> See also, e.g., Dr. Sanjay Gupta's report on counterfeit prescription drugs for "60 Minutes," aired March 13, 2011.

<sup>3</sup> See Press Release, April 4, 2012, available at <http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrests-274-million-black-market-prescription-drug-operation>.

<sup>4</sup> See, e.g., "Information on Heparin" in Postmarket Drug Safety Information for Patients and Providers, available at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM112597>.

Likewise, the historical problem of “shrinkage” and loss of inventory control via theft and/or diversion seems to be growing dramatically in scale, as more and more drugs disappear on a daily basis for resale and/or are taken in large cargo thefts or warehouse burglaries.<sup>5</sup> There is very likely growing involvement by organized crime in theft and resale of pharmaceuticals. The obvious motivators include lesser exposure to criminal penalties and a ready market for resale of those drugs into the supply chain. A universal electronic pedigree/track-and-trace infrastructure could significantly diminish if not eliminate the market for stolen and diverted products, since a stolen or diverted drug would not have the requisite electronic documentation for such resale.

The Board and its staff have several years’ experience developing and then implementing pedigree laws. Further, since 2005 the Board and its staff have engaged in extensive outreach to all segments of the drug supply chain on the California pedigree law, including hosting regular public meetings and workgroups, conducting private meetings with members of all segments of the industry, attending industry conferences, publishing Question and Answer documents on the law and its implementation, and other similar efforts. We have been repeatedly assured through that process that the California pedigree approach to drug security is the “gold standard” among the various approaches outlined to date, either at the federal level or by the various states.

That “gold standard” consists of several basic elements and requirements that make the California drug pedigree law a uniquely comprehensive approach to prescription drug security. The elements of the law that we consider crucial to its purpose include the following:

- The requirement of a “pedigree” record for every prescription drug, initiated by every manufacturer and transmitted and appended through the supply chain, with required data regarding each transaction resulting in a change of ownership of every drug – to be fully effective, we believe the pedigree requirement must be universally applied;
- The record must be created, transferred/received, and maintained, in an electronic form, using secure electronic transactions to enhance the security of the data – in our experience, paper pedigrees are more easily counterfeited and duplicated;
- The pedigree tracks each drug down to its smallest saleable unit, e.g., each bottle in a case of 48 bottles – the only way to effectively track and prevent counterfeits or drug adulteration is by a system that requires individual-unit mass serialization;
- The pedigree uses and is based on a unique identification number affixed to smallest unit packages by the manufacturer, and is created/maintained within an interoperable electronic system using a standardized nonproprietary data format and architecture – reliance on standards and nonproprietary formats discourages data segmentation;
- One pedigree record tracks all changes of ownership of a given prescription drug in a supply chain, including lateral transfers (e.g., wholesaler to wholesaler), downstream transfers (e.g., manufacturer to wholesaler), and upstream transfers (e.g., pharmacy to wholesaler, including returns and recalls) – without one universal record as to all such transactions, there is no reliable audit trail to source counterfeits or adulterations; and
- The pedigree must contain certifications of delivery and receipt, and a certification of the authenticity of the pedigree data from each source/owner of the drug – this assists with traceability, auditability, and accountability of the pedigree record.

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<sup>5</sup> See, e.g., Katherine Eban, “Drug Theft Goes Big,” *Fortune*, March 31, 2011.

In large part, these basic elements arise from and are consistent with the recommendations of the FDA Counterfeit Drug Task Force, first convened by then-FDA Commissioner Mark McClellan in July 2003. In its 2004 Report, the Task Force recommended industry adoption of RFID as the standard track and trace technology, to be used for mass serialization/unique identification (at the unit level) of all drugs in or by 2007, and further recommended industry implementation of a full electronic track and trace/pedigree system by the same date. (2004 Report, pp. 9-15.) In its most recent (2006) Report, the Task Force again noted the desirability and feasibility of a universal e-pedigree system based on package-level RFID serialization, and expressed disappointment that it would not be achieved by 2007. (2006 Report, pp. 7-17). The 2006 Report reinforced the utility of package-level identifiers and tracking (pp. 12-14), and of a universal and uniform requirement that all participants in the distribution chain be required to send or receive pedigrees (pp. 14-16). That Report specifically singled out California as having advanced the pedigree cause (p. 9).

This mention of California in the 2006 Report mirrors a level of support that California has received from the FDA for its law since its enactment, particularly over the last several years, wherein the FDA has repeatedly testified at Board hearings in support of the California law. The Board of Pharmacy has been grateful for this support, and remains very engaged with the FDA.

Because of California's size and share of the market for prescription drugs, the California model for a universal electronic pedigree/track-and-trace infrastructure has been driving industry action for the last several years. All segments of the supply chain appear to be actively preparing for the negotiated 2015-2017 deadlines in California law. We believe in that model, and will be ready to enforce its provisions should it become necessary to do so. We are excited about what it will mean for the supply chain to have full compliance with the infrastructure requirements. We fully expect a more dynamic, secure, and accountable supply chain to be the result.

#### Pending Federal Legislation

We also know, however, that to be most effective the universal electronic pedigree/track-and-trace infrastructure ought to be deployed and enforced at the federal level.<sup>6</sup> We are therefore pleased to see that the FDA is making real strides toward this goal. The Final Guidance issued in March 2010 defining the Standardized Numerical Identifier (SNI) that the FDA recommends for serializing drug products in a pedigree/track-and-trace infrastructure is an excellent document, by all reports the result of an industry consensus on this standard.<sup>7</sup> And it is clear that the FDA has made substantial progress toward defining its preferred "System Attributes" for track-and-trace infrastructure requirements since convening a public workshop on this subject in February 2011.<sup>8</sup>

We are especially pleased to see so many commonalities between the California law and the "System Attributes" distributed by the FDA for discussion at the public workshop, and made public in various fora (including Board meetings) since. We hope that the FDA, and legislation that may result at the federal level in consultation with the Board and the FDA, will continue to look to California for an effective model, one for which the industry is now actively preparing.

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<sup>6</sup> The 2008 amendment(s) to the California pedigree law(s) also contemplated federal action in this arena, providing that any enactment of federal statutes or regulations addressing pedigree or serialization of drugs would render the California law(s) inoperative, and that any provision inconsistent with subsequent FDA rulemaking is likewise void. In other words, California law contains "self-preemption" provisions, even if any eventual federal law does not.

<sup>7</sup> The Board has taken initial steps to make clear that the SNI should be used for serialization under California's law.

<sup>8</sup> The Board, through its Executive Officer, was a primary participant in the public workshop in February 2011.

Unfortunately, we feel that the legislative proposal now circulating at the federal level, known variously as the “Pharmaceutical Traceability Enhancement Code (RxTEC) Act” or the “Securing Pharmaceutical Distribution Integrity Act of 2012” (and perhaps also by other names), is not an effective equivalent to the California pedigree law(s). Rather, by its own terms as well as by the operation of the “self-preemption” language in the California law, this proposal would preempt the California pedigree requirements, and replace them with a less robust and ultimately less purposeful federal infrastructure. Therefore, while we are excited to see some action on this subject at the federal level, and while we recognize that in some small ways this proposal makes improvements in existing federal law,<sup>9</sup> we are writing to convey our concern that this legislation, if enacted as proposed, would provide less immediate supply chain security than California law.

As we understand the various versions of that proposal,<sup>10</sup> our primary concerns relate to the following features of the “RxTEC System” that it envisions creating:<sup>11</sup>

- **Timing:** The proposal calls for various implementation dates triggered by issuance of final regulations by the Secretary. Even assuming those regulations are issued by the 18-month deadline set forth in the proposal, the “RxTEC System” would not be fully rolled out (i.e., require participation by dispensers) until 6 years after that date. So the earliest date for full implementation would be sometime in 2020, a full three years after the final implementation date of the California law. And given the failure to fully promulgate or implement regulations required under the Prescription Drug Marketing Act (PDMA) in the nearly 25 years since its enactment, it is not difficult to imagine that federal implementation of this law would likewise be further delayed.
- **Non-Utilization of Serialized Numeric Identifiers:** Although the proposal calls for manufacturers (and repackagers) to apply “RxTEC” data carriers that include the SNI to individual saleable units and homogeneous cases, it frankly does not require much to be done with those data carriers or the associated data. For one thing, the proposal requires that tracking routinely take place only at the lot level (a lot could include up to hundreds of thousands of individual units). It is not clear what purpose is served by using an RxTEC data carrier to track at the lot level, since this would be entirely duplicative of the (human-readable) lot numbers that are already printed on individual units. The proposal envisions a significant investment to affix serialized identifiers to individual units and cases without any clear purpose for doing so. And even within this apparent requirement to affix numeric identifiers, there is significant ambiguity, since the proposal also seems to provide numerous exemptions to this requirement in the “Limitations” subdivision that would appear to be transaction-specific (e.g., sales in an emergency), but which arguably provide a broad exemption to all requirements.

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<sup>9</sup> For instance, we acknowledge that this would be the first federal requirement to serialize drug products at the unit level, though as our subsequent comments make clear too little is being done by supply chain participants with those serial numbers to ensure supply chain security. Similarly, we recognize that the proposal(s) aim to tighten up/ make more uniform 3PL, wholesaler, and manufacturer licensing requirements (by states), but again, because California is already a leader in these requirements, in some ways these provisions would actually relax California standards. We do welcome the proposal’s efforts to rein in online pharmacies, and to increase the penalties for drug counterfeiting.

<sup>10</sup> Because several drafts of the proposal have circulated, and additional changes may have been made since the latest copy was shared with us, we will not attempt to tie our comments to particular sections or provisions of the proposal but will instead offer general comments on provisions that appear to be in common among the various drafts or that seem to have been retained in the latest versions of the proposal that were shared with Board staff.

<sup>11</sup> We have not attempted to be comprehensive in our comments, and are limiting ourselves to our primary concerns.

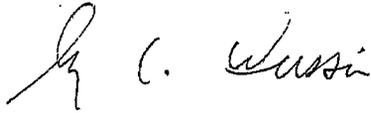
- Specification of 2D Barcode Technology:** The RxTEC proposal also specifies the use of 2D data matrix barcodes as standard data carriers. California has assiduously avoided specification of carrier technology, although at the time its law was originally enacted the author of the bill assumed, as did the FDA, that this data would be coded and read using RFID tags. California has preferred to let the market dictate the means of data transmission, and has sought to avoid interfering with technology innovations that may be developed to respond to the outcomes dictated by California law. While it is true that to this point 2D data matrix barcodes appear (based primarily on cost) to be the preferred carrier being employed by the industry participants who are readying for California compliance, there is still the chance that a further drop in price of RFID technology, or development of some other technology, will result in adoption of some other form of data carrier in addition to or as an alternative to 2D barcodes. There are some obvious disadvantages to 2D barcodes, including most notably that 2D barcodes require line-of-sight scanning (which RFID tags do not). We are hesitant to “freeze” innovation by specifying 2D data matrix barcodes as the default data carriers, even if the Secretary is given latitude to allow other data carrier technologies as supplements. It is difficult to imagine supply chain participants, where the default under the law is a 2D data matrix barcode, ever investing in any other data carrier technologies.
- Lack of Verification/Validation of Product and Data:** As the FDA has repeatedly expressed, the best way to interdict and prevent counterfeits and other sub-standard drugs from reaching patients is to create a “closed system” within which every drug product is tied to a data infrastructure (by its SNI), and is scanned at each point in the distribution chain so that if a product *does not have* a valid SNI, it can be immediately quarantined and its origins investigated. The RxTEC proposal does not envision this kind of universal verification/validation of drug products to the data that is required under California law to accompany physical transfer of the drugs. In fact, the RxTEC proposal does not appear to require that the SNI data carriers will *ever* be scanned by wholesalers, pharmacies, or other downstream participants in the supply chain, and certainly does not envision that any supply chain participants will ever validate the drug product that is received. Again, under these circumstances it is not clear what purpose would be served by affixing an RxTEC data carrier, where the data carrier will never be read. As a practical matter, the RxTEC proposal does not enhance the ability of supply chain participants to *automatically detect and intercept* counterfeits or other suspect products; they will not scan that product and detect anything about its SNI or other identifiers that is suspicious. Under California law, a counterfeiter will have to steal or fabricate enough SNIs to be able to label counterfeit product, but then that product should be intercepted almost immediately, because the illegitimate SNIs would be read by the first buyer and compared to SNIs authorized by the legitimate manufacturer. By contrast, under the RxTEC proposal, there is no opportunity to intercept illegitimate SNIs (assuming the counterfeiter even bothered to apply SNIs).
- Practical Inability to Investigate/Trace “Suspect Product”:** Along the same lines, although the RxTEC proposal says that the Secretary or a state could require one-up, one-down investigation of “suspect product,” without an infrastructure within which a product is being scanned and tracked at each level of distribution, this is not possible to do at the unit level. All investigations and recalls will remain at the lot level.

- Broad Exemptions from Participation:** As mentioned above, even the reach of the “RxTEC System” requirements is called into significant question by the inclusion of a laundry list of exemptions in the “Limitations” section of the proposal. Particularly curious about many of these exemptions is that while they appear to describe specific *types* of transactions (e.g., intracompany sales, group purchasing transfers, charitable sales, emergency sales, transfers pursuant to mergers, etc.), the exemptions granted to these transactions relate to the entire chapter, and are not transaction-specific. So for a given transaction (e.g., an intracompany sale), it is not clear at what point in time an exemption would be applied. Would any drug product that is ever transferred within a company or a purchasing group be forever exempted from the requirements of this chapter? This is how this list of exemptions appears to read. If so, these exemptions are so broad as to render the legislation’s requirements effectively meaningless.
- Prohibition on Aggregation:** We also believe that an infrastructure that intends to track drug products at the unit level within an industry that distributes these units in a non-regular aggregate format (e.g., homogeneous and non-homogeneous totes, cases, pallets, etc.), especially one that depends on a non-line-of-sight technology such as a 2D data matrix barcode, must rely on aggregation of product and product data into a hierarchical data structure. For instance, the only way to track individual units within an aggregation (such as a case or pallet), without having to open every case or pallet and individually scan its contents, is to have the individual SNIs for those drug units associated with another data point (e.g., a case or pallet SNI). There are legitimate questions to be explored about whether it is appropriate to *infer* from a “good read” on a case or pallet identifier that the expected contents of that aggregate container are contained within, but it is difficult to imagine a serious data sharing infrastructure for tracking and tracing drug products that does not make at least some use of aggregate structures and data identifiers. Yet the RxTEC proposal not only does not require or encourage aggregation, it specifically prohibits the regulations from doing so. This seems to signal that there is no intention to ever track products at the unit level.
- Restrictions on State Enforcement:** And finally, we are concerned that if our own law(s) are preempted by the RxTEC proposal, California’s enforcement capacities as to investigations of counterfeits or other suspect products will likely be significantly curtailed. First, the proposal contemplates that even the FDA will only be authorized to “request” RxTEC data from supply chain participants in the event of a recall or as necessary to investigate “suspect product.” But this allowance for investigation of a “suspect product” appears to be circular, since it is not clear how “suspect product” is ever likely to be identified in the absence of FDA (or state) inspection of same, where the supply chain is not routinely validating that product. Also, as mentioned above, it is not clear what data could possibly be transmitted by the supply chain in aid to any such investigation. Second, even this limited authority given to the FDA is available to the states only upon specific delegation from the Secretary. So whereas the Board is now authorized under California law to inspect California wholesalers/pharmacies, and could review maintenance of pedigree data, implementation of the pedigree law, and receipt of serialized, pedigreed drug products as part of its routine inspections, it would not appear to have that same ability if this proposal becomes federal law.

For all of these reasons, we are concerned about the impacts that the RxTEC proposal is likely to have on the security of the supply chain in California, and by extension in the rest of the country, by replacing California's pedigree law with a less robust infrastructure. While we agree in principle that a uniform national standard would be ideal, we would like to see that standard a much closer approximation of the California model than is reflected in the RxTEC proposal. We would encourage something closer to the Bilbray-Matheson model of H.R. 3026. We once again commend you for your leadership on these vital issues of national drug security.

Thank you for your attention to these matters, and for your willingness to hear our input. We look forward to continuing to work together to secure the nation's drug supply. Please feel free to contact the Board at any time if we can be of assistance. The best ways to reach me are on my cell phone, (909) 633-2574, or by email to [stanweisser@aol.com](mailto:stanweisser@aol.com).

Sincerely,

A handwritten signature in cursive script that reads "Stanley C. Weisser".

STANLEY C. WEISSER, R.Ph.  
President, California State Board of Pharmacy

# Attachment 4

**Michael B. Enzi**

**Colloquy with Sen. Harkin on Downstream Distribution  
Security**

**Food and Drug Administration Safety and Innovation Act of  
2012**

**May 22, 2012**

Mr. President, I have been working very hard with Senator Harkin on the underlying bill to reauthorize the Food and Drug Administration user fee program. We have been working together across the aisle for many months and our Committee recently approved this bill by voice vote.

As part of that process, Sen. Harkin and I gave our commitment to Senators Burr and Bennet to work with them on the supply chain amendment they filed to the bill in Committee.

We have been working very hard to reach an agreement on this issue – and we have come a long way. Stakeholders including industry, consumer groups, and the FDA, have been sitting around a table to find a consensus solution. We've made good progress, but we still have work to do.

The language in the Manager's Amendment is a placeholder to show our intent to continue working on this critical, but complex, policy. Currently, the stakeholders do not agree on a policy solution, but feel we could get a solution with continued work.

Further, we do not want this language to preempt state laws that address this policy.

The provision focuses on the "downstream" supply chain, or from the finished product to the pharmacy. Currently, there is no common system for drug manufacturers to serialize their products. Further, different states have different requirements for

wholesalers and other supply chain participants. Stakeholders have been working to solve this problem for over a decade.

California, specifically, has been a leader in enacting regulations on the distribution of drugs. It is important that my colleagues from California are comfortable with the consensus solution that results of this hard work; we do not want to preempt their regulations without their support.

It would be a landmark accomplishment to find a consensus policy to ensure the safety of drug distribution systems in this country, without adding unnecessary burden and costs to rural pharmacists. I intend to continue to work with Senators Bennet and Burr on their proposal, and the language here will allow us to do so as this bill goes to conference.

Chairman Harkin is here to discuss what this language represents, and his views of a path forward with this important policy.

**###**

**SENATOR HARKIN:**

Mr. President, for well over a year I have been working with Senator Enzi to craft the FDA Safety and Innovation Act. As part of that effort we have worked closely with Senators Bennet, Burr, Grassley, and Whitehouse to examine and modernize the integrity of our supply chain, to help ensure that drugs and drug ingredients coming into the U.S. are safe for American patients.

The logical next step in this policy is to work to improve the safety of the drug distribution system that gets drugs from manufacturers to the pharmacists and other providers who dispense them to patients. The FDA currently lacks the authority to establish a uniform, comprehensive national system to secure the pharmaceutical distribution supply chain. There is no common system for drug manufacturers to serialize their products, and different states have different requirements for wholesalers and

other supply chain participants. Stakeholders have been working to solve this problem for over a decade.

I applaud the special interest Senators Bennet and Burr have taken in drug distribution security, and appreciate the work they have done to propose policy ideas in this area. Since they filed their drug distribution security amendment with the HELP committee we have been working very hard to reach an agreement on this issue. Manufacturers, distributors, pharmacists, consumer advocates and the FDA have all devoted significant time and effort to helping us find a solution to this policy problem. We have been working cooperatively and in good faith, and have gained a better understanding of the perspective of each of the stakeholders involved. We have come a long way, and are moving closer to consensus. But this is very complicated policy, with a lot of competing priorities and interests, and we still have work to do.

Senator Enzi and I have made a commitment to Senators Bennet and Burr to continue working on this policy. The language in the Manager's Amendment is a placeholder to show our commitment to continuing to work on this critical policy. I firmly believe that we need a uniform, comprehensive approach to ensuring drug distribution security. A patchwork of differing state systems is not only inefficient for supply chain participants, but makes it impossible to develop a comprehensive system to protect patient safety nationwide. I am personally committed to getting this done.

Currently, the stakeholders do not agree on what any drug distribution security system should look like, but are working together cooperatively. With additional time, I think we can find a policy solution that – like the other aspects of the underlying bill – will be bipartisan, consensus policy. The placeholder language included in the manager's package does not represent an

agreement on how drug distribution should work, but it does represent a strong commitment to finding agreement in this area.

Notably, the placeholder language does not pre-empt state law in this area. California has been a particular leader in enacting regulations on the distribution of drugs. While we hope and expect that we will find a consensus policy that my colleagues from California are comfortable with, and that we can make that policy the uniform national standard, we simply are not there yet.

I am proud of the work that we've done to secure the route drug ingredients travel on their way into the United States, and think that securing the drug distribution chain is a critical next step to ensuring patient safety. I agree with Senator Enzi that finding a consensus policy in this area would be a landmark accomplishment, and I am looking forward to continued work to get that done.

# Attachment 5

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

*FINAL GUIDANCE*

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

# Guidance for Industry

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

*Additional copies are available from:  
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druginfo@fda.hhs.gov*

*<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>  
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Food and Drug Administration  
Office of the Commissioner (OC)  
Center for Drug Evaluation and Research  
Center for Biologics Evaluation and Research  
Office of Regulatory Affairs**

**March 2010**

*Contains Nonbinding Recommendations*

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# **Guidance for Industry<sup>1</sup>**

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

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

### **I. INTRODUCTION**

This guidance is intended to address provisions set forth in Section 505D of the Federal Food, Drug, and Cosmetic Act (the Act) regarding development of standardized numerical identifiers (SNIs) for prescription drug packages. In this guidance, FDA is identifying package-level SNIs, as an initial step in FDA's development and implementation of additional measures to secure the drug supply chain.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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<sup>1</sup> This guidance has been prepared by the Office of the Commissioner (OC), the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

## *Contains Nonbinding Recommendations*

### **II. BACKGROUND**

#### **A. Food and Drug Administration Amendments Act of 2007**

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85) was signed into law. Section 913 of this legislation created section 505D of the Federal Food, Drug, and Cosmetic Act, which requires the Secretary of Health and Human Services (the Secretary) to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs. Section 505D directs the Secretary to consult with specific entities to prioritize and develop standards for identification, validation, authentication, and tracking and tracing of prescription drugs. The statute also directs that, no later than 30 months after the date of enactment of FDAAA, the Secretary shall develop an SNI to be applied to a prescription drug at the point of manufacturing and repackaging at the package- or pallet-level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug. An SNI applied at the point of repackaging is to be linked to the SNI applied at the point of manufacturing and, to the extent practicable, the SNI should be harmonized with international consensus standards for such an identifier. (See Section 505D(b)(2)). The provisions in section 505D(b) of the act complement and build upon FDA's longstanding efforts to further secure the U.S. drug supply. This guidance finalizes the draft guidance of the same title dated January 16, 2009 (74 FR 3054).

#### **B. Scope of this Guidance**

This guidance is intended to be the first of several guidances and regulations that FDA may issue to implement section 505D of the Act, and its issuance is intended to assist with the development of standards and systems for identification, validation, authentication, and tracking and tracing of

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prescription drugs.<sup>2</sup> This guidance defines SNI for package-level identification only. For the purpose of this guidance, FDA considers the prescription drug package to be the smallest unit placed into interstate commerce by the manufacturer or the repackager that is intended by that manufacturer or repackager, as applicable, for individual sale to the pharmacy or other dispenser of the drug product. Evidence that a unit is intended for individual sale, and thus constitutes a separate “package” for purposes of this guidance, would include the package being accompanied by labeling intended to be sufficient to permit its individual distribution. For example, if a manufacturer’s smallest unit of sale package is a container holding six drug-filled syringes, a single SNI would be the package-level identifier for the container holding the six drug-filled syringes; there would be no SNIs for the individual syringes, not intended by the manufacturer for individual sale. If a repackager then breaks that container down and repackages each syringe for individual sale, then the repackager must ensure that appropriate labeling accompanies each individual syringe<sup>3</sup> and a new and unique SNI would be the package-level identifier for each new package (e.g., each individual drug-filled syringe). SNIs applied to each new package by the repackager are to be linked back to the manufacturer’s SNI for the container of six drug-filled syringes (505D(b)(2)).

This guidance does not address how to link a repackager SNI to a manufacturer SNI, nor does it address standards for prescription drug SNI at levels other than the package-level including, for example, the case- and pallet-levels. Standards for track and trace, authentication, and validation are also not addressed in this guidance because this guidance only addresses the standardized numerical identifier itself and not implementation or application issues.

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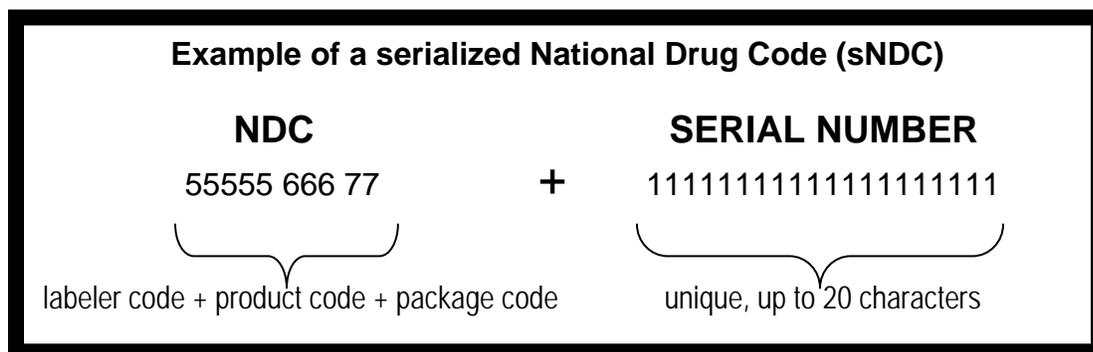
<sup>2</sup> Prescription drugs as defined in section 503(b)(1) of the act.

<sup>3</sup> See, e.g., Sections 502 (b) and (f).

### **III. STANDARDIZED NUMERICAL IDENTIFIERS**

#### **A. What should be a package-level SNI for most prescription drugs?**

The SNI for most prescription drug packages should be a serialized National Drug Code (sNDC). The sNDC is composed of the National Drug Code (NDC) (as set forth in 21 CFR Part 207) that corresponds to the specific drug product (including the particular package configuration)<sup>4</sup> combined with a unique serial number, generated by the manufacturer or repackager for each individual package. Serial numbers should be numeric (numbers) or alphanumeric (include letters and/or numbers) and should have no more than 20 characters (letters and/or numbers). An example is shown below with a 10-character NDC.



#### **B. What should be the package-level SNI for certain biological products that do not use NDC numbers?**

Some prescription drugs approved under Section 351 of the Public Health Service Act, such as blood and blood components and certain minimally manipulated human cells, tissues, and cellular and tissue-based products (HCT/Ps), do not currently use NDC numbers. Examples of HCT/Ps that do not use NDC numbers include allogeneic placental/umbilical cord blood, peripheral blood progenitor cells, and donor lymphocytes for infusion. Instead, such products

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<sup>4</sup>In the case of repackaged drugs, each package type should have an NDC that corresponds to the repacker or private label distributor for whom the drug is repacked and to the new package configuration.

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currently use other recognized standards for identification and labeling, such as ISBT 128, which creates a unique identification number for each product package. See

[http://iccbbba.org/about\\_gettoknowisbt128.html](http://iccbbba.org/about_gettoknowisbt128.html), “Guidance for Industry: Recognition and Use of a Standard for Uniform Blood and Blood Component Container Labels,”

(<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm073362.htm>.) The SNI for these products should be the unique identification number created for each package under these other recognized standards, such as ISBT 128.<sup>5</sup>

#### **C. Does the SNI include expiration date and/or lot or batch number?**

Expiration date and/or lot or batch numbers are not part of the recommended SNI. Expiration date and/or lot or batch numbers are already accessible because FDA regulations require the inclusion of this information on the label of each drug product. (See 21 CFR §§ 201.17, 201.18, 211.130, 211.137, 610.60, and 610.61.) In addition, the SNI can be linked to databases containing this and other information. Addition of this information within the SNI will unnecessarily increase the length of, and introduce complexity into, the SNI. However, if a manufacturer or repackager chooses to include expiration date and/or lot or batch number with the SNI, it should ensure that the resulting number still permits users to distinguish and make use of the SNI. For example, expiration date and lot or batch number may be incorporated in accordance with the GS1 standards for use of Global Trade Item Numbers (GTIN)<sup>6</sup> (discussed below in Section F).

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<sup>5</sup> FDA currently also recognizes Codabar as a standard for blood and blood component container labels. We note that ISBT 128 is becoming the more widely-used industry standard.

<sup>6</sup> See [www.gs1.org](http://www.gs1.org) -- Healthcare GTIN Allocation Rules ([http://www.gs1.org/docs/gsmpr/healthcare/GS1\\_Healthcare\\_GTIN\\_Allocation\\_Rules.pdf](http://www.gs1.org/docs/gsmpr/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf)).

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### **D. Why did FDA select the serialized NDC for package-level SNI for most prescription drugs?**

FDA chose the sNDC as the package-level SNI for most prescription drugs because we believe that it serves the needs of the drug supply chain as a means of identifying individual prescription drug packages,<sup>7</sup> which in turn should facilitate authentication and tracking and tracing of those drugs. Most prescription drug product packages already have an NDC on them. By combining a serial number of up to 20 characters with the NDC, the sNDC should be sufficiently robust to support billions of units of marketed products without duplication of an SNI. This approach will allow manufacturers and repackagers to assign serial numbers to combine with the NDC for unique identification of individual product packages. The SNI can also be linked to databases containing such product attributes as lot or batch number, expiration date, distribution/transaction history information, and other identifiers related to a product. As already noted, defining the SNI is expected to be a first step to facilitate the development of other standards and systems for securing the drug supply chain. Many aspects of the implementation of package-level identification will take shape in the future, as the standards that make use of SNI are developed.

### **E. Should the SNI be in human- and machine-readable forms?**

FDA believes that an SNI generally should be applied to each package in both human-readable and machine-readable forms. However, at this time, FDA is not specifying the means of incorporating the SNI onto the package. The SNIs described in this guidance are compatible with, and flexible for, encoding into a variety of machine-readable forms of data carriers, such as

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<sup>7</sup> As described above, ISBT-128 and Codabar serve the same function for certain biologics that lack NDCs.

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2-dimensional bar codes and radio-frequency identification (RFID),<sup>8</sup> leaving options open as technologies for securing the supply chain continue to be identified, and standards making use of SNI are developed. A redundant human-readable SNI on the package would provide the ability to identify the package when electronic means are unavailable (e.g., in the event of hardware/software failure). Due to the wide-variety of packaging required to accommodate different products and product integrity needs, FDA also is not specifying a location on the package where an SNI should be placed. If the NDC is already printed on the package in human-readable form, then the serial number could be printed in human-readable form in a non-contiguous manner elsewhere on the product package. Any SNI placed on the package must not obstruct FDA-required labeling information<sup>9</sup> and should be placed in a manner that allows it to be readily scanned/viewed without damaging the integrity of the packaging or product..

#### **F. Is the SNI that FDA is recommending compatible with international standards?**

In addition to facilitating other actions to secure the drug supply chain, adoption of the sNDC as the SNI for most prescription drugs, and of other recognized standards, such as ISBT 128, for certain biological products, satisfies the requirement in 505D(b)(2) that the SNI developed by FDA be harmonized, to the extent practicable, with internationally recognized standards for such an identifier. Specifically, use of an sNDC is compatible with, and may be presented within, a GTIN, which can be serialized using an Application Identifier (AI) (21) to create a serialized GTIN (sGTIN) for use with RFID or for certain barcodes.<sup>10</sup> GTIN is a global standard for item and object identification, established by GS1, a consensus-based, not-for-profit, international

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<sup>8</sup> FDA's enforcement policy with respect to the application of current good manufacturing practices to RFID technology is provided in Compliance Policy Guide (CPG) Section 400.210. See <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074357.htm>. This CPG would apply if an SNI were embedded into an RFID tag.

<sup>9</sup> See section 502(c) of the Act.

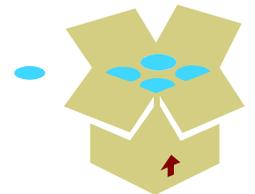
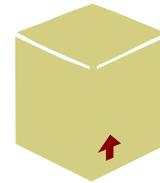
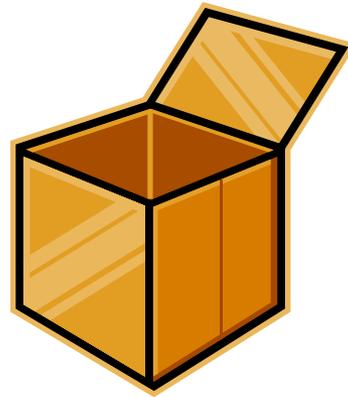
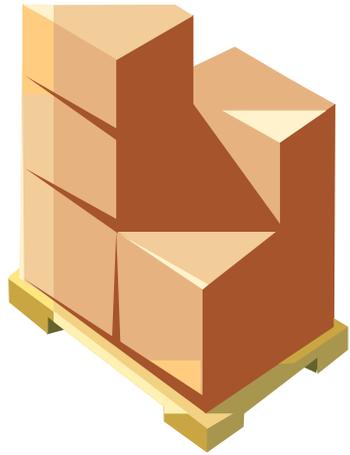
<sup>10</sup> See [www.GS1.org](http://www.gs1.org) -- Healthcare GTIN Allocation Rules ([http://www.gs1.org/docs/gsmf/healthcare/GS1\\_Healthcare\\_GTIN\\_Allocation\\_Rules.pdf](http://www.gs1.org/docs/gsmf/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf)).

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standards organization that works with manufacturers, distributors, retailers, and others in the drug supply chain. A GTIN may be used to uniquely identify items at the package level throughout the supply chain. FDA has been an active observer and participant in GS1 standards development related to healthcare and drug products. According to documentation from GS1, the GTIN is used worldwide by twenty-three industry sectors, including healthcare, and has been adopted by sixty-five countries to uniquely identify pharmaceutical products.

# Attachment 6

# Serialization



# Attachment 7



## MINUTES

### Enforcement Committee and E-Pedigree Public Meeting

June 12, 2012

**COMMITTEE MEMEBERS PRESENT:**

Randy Kajioka, RPh, Chair

Neil Badlani, RPh

Gregory Lippe, Public Member

**LOCATION:**

The Westgate Hotel

1055 Second Avenue

San Diego, CA 92101

**COMMITTEE MEMBERS ABSENT:**

Tappan Zee, Public Member

**STAFF MEMBERS PRESENT:**

Virginia Herold, Executive Officer

Carolyn Klein, Manager

Kristy Shellans, DCA Senior Counsel

Joshua Room, Deputy Attorney General

The meeting was Webcast at [http://www.pharmacy.ca.gov/meetings/current\\_webcasts.shtml](http://www.pharmacy.ca.gov/meetings/current_webcasts.shtml)

The meeting was called to order at 9:35 a.m. Chairman Kajioka recognized Board President Stan Weisser who was present in the audience.

**I. Presentation and Discussion on the Use of the Pharmacist Assessment for Remediation Evaluation (PARE) in California as an Optional Enforcement Tool to Assess Pharmacist Practice Deficiencies.**

Mr. Kajioka noted that representatives from the National Association of Boards of Pharmacy were unable to attend the Committee Meeting; however, their attendance is expected at the Board Meeting scheduled for July 17, 2012. Mr. Kajioka summarized the Pharmacist Assessment for Remediation Evaluation (PARE), developed by the NABP for use when an objective measure is needed to assist decisions regarding pharmacist practice. The PARE is comprised of approximately 210 questions comprised of issues related to medication safety (50 percent), professional ethics (25 percent), and pharmacy practice (25 percent) and it is estimated that it will take approximately 4.5 hours to complete and will cost \$250 to take. Ms. Herold said that the PARE was brought to the Enforcement Committee as a first step in getting to the board; she referenced the documents provided in the committee materials, and noted that the board may wish ask the NAPB more about the PARE when representatives attend the Board Meeting in July. Supervising Deputy Attorney General Room suggested the committee may wish to verify whether or not the PARE has been

psychometrically validated when NABP attends the Board Meeting in July. Mr. Kajioka made a specific request that NABP representatives attend the July Board Meeting.

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

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

Mr. Kajioka referenced articles provided in Attachment 2a regarding counterfeit drugs, such as Avastin and Altuzan. Executive Officer Herold noted that at the present time there are seven different drugs where patient complaints have been received because the drugs aren't working (one being Adderal). The committee discussed that with e-Pedigree, the source of the drug would be known. Executive Officer Herold presented information regarding the drug supply chain and answered questions by the committee members. (See PowerPoint slides appended to these minutes.)

Ms. Herold said that recent reports about counterfeit Adderal started out from purchases via the Internet. She said that during her 20+ years of employment at the board, rarely did the board do drug assays of pills that are part of an investigation. Even more rare were complaints received alleging that drugs received were not efficacious. She added that right now, there are seven drugs where patients have complained that the drugs are no longer working. One of the complaints is about Adderal, and the complaint surfaced prior to the time the article had come out. For that complaint, she does not know if the Adderal noted in the complaint was an Internet prescription. Consumers are complaining about the quality of their medication.

Board Member Greg Lippe asked if the board knew of these counterfeits were coming from out of the U.S. Ms. Herold indicated that is one reason we are moving forward with e-Pedigree – so that we know the origin of the drug. Even if a prescription is picked up at a legitimate pharmacy, sometimes even the pharmacy does not know the origin of where the drug came from.

Mr. Lippe asked about the physician offices that purchased counterfeit Avastin and Altuzan. Ms. Herold indicated that for the cases referenced, the FDA has invoices, and the physicians purchased the drugs from wholesalers (none of which were licensed in California). In California, a wholesaler must be licensed by the Board to be able to ship drugs into California.

Reports in the media indicate that the drugs were found to have come from outside of the U.S. and were likely attractive to the physician because they could be acquired at significant savings compared with drugs purchased from US sources.

### **b. Dysfunction in California's Supply of Prescription Medication Discovered During Board of Pharmacy Investigations**

There was discussion of findings of inspections of California pharmacies and wholesalers, and the serious violations involving the "redispensing" of previously dispensed medications. Ms. Herold shared photos from board inspections showing egregious violations of redispensing prescription drugs that had previously been dispensed to patients, yet were acquired by the pharmacy(s) and being redispensed. Ms. Herold reviewed a complex chart of drug movement by persons and entities of both legitimate and counterfeit drugs, demonstrating a serious

compromise of the legitimate drug supply and other slides showing findings of drug investigations.

**c. Board of Pharmacy’s Letters to Federal Representatives and Senators on Elements Needed in any Proposal for Federal Legislation**

Mr. Room indicated that the board’s letters to Member of Congress Waxman was one of several letters sent to three members of Congress and five senators.

Mr. Room said that on the Senate side, the Senate passed placeholder language – specifically NOT to preempt California’s law.

A Conference Committee will work to resolve language between the House and Senate versions of the bill in the next couple of weeks.

Mr. Room added that the letter was written at the board’s request, noting that the RxTEC proposal insufficiently mirrored California’s e-pedigree language. Mr. Room noted that as is shown in the Colloquy (see next agenda item), the senators are taking great care to consider California’s position.

**d. Colloquy from Senators Enzi and Harkin in Support of Retaining Protections in California Law in Future Federal Requirements for Tracking Prescription Medications Through Pharmaceutical Supply Chain**

In mid-May, Senators Enzi and Harkin provided a colloquy in support of retaining protections in California Law in future federal requirements for tracking prescription medications through the pharmaceutical supply chain.

The committee reviewed the colloquy.

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

Mr. Robert Celeste, Director, Healthcare, GS1 US presented. He offered information from a standards perspective and also from an implementation perspective within the US and also share some information on what is happening globally on serialization and track and trace.

GS1 looks at Pedigree as a document which shows the tracing of an object or medication to the point of origin. The term “Track and Trace” is used by the FDA; the GS1 standards body chose to use the term “traceability.” Traceability shows where the drug came from, and – looking forward – where it is now. Who is using the standards for track and trace? They would also capture visibility data – which is built on the same standards of track and trace, or pedigree.

In the area of visibility, it shows how industries like to use the data for other purposes. He provided an example of an infusion pump in a hospital. He noted that the nurse may not care to know where the pump has been in the supply chain – only but that it works correctly now.

Who is using the standards? Food service, pharmaceuticals, aero space, consumer goods, providers, etc. It is used in many different levels. Some are interested in large lot numbers or shipments, but at the end, the receiver is interested in item serialization for payment purposes. In food service, it also helps those who are interested in how products are represented.

Mr. Celeste said the challenge for tracking serialization through the supply chain is the cases – the things in which items are put in for shipping. Regulations do not require that pallets, cases, totes, etc., be traced – but these must be traced to track the items within them. He spoke to the practice of inference and how the term is used today. He said GS1 has developed a tool with Stanford on how inference might be applied. GS1 uses 14-16 standards on how to track something through the supply chain, and he summarized GS1’s continued efforts to address scenarios, issues, challenges, and implementation of pedigree. Such as: how do we detect counterfeits, and how do you trace it back? From a business perspective, what do you do with the information?

Mr. Room referenced GS1’s 2010 inference document. Mr. Celeste said that is a document used as a tool for discussion among stakeholders. Mr. Badlani asked about how data may be shared and maintained. Mr. Celeste noted the FDA’s 2011 workshop where architecture was discussed. There, the industry discussed the centralization or de-centralization of the data – and that discussion continues.

The next presentation was provided by Mr. Lloyd Mager from Abbott Laboratories, a large drug and healthcare company. He noted that the business is in the process of splitting but they are very focused and committed to meeting the objectives of e-pedigree.

Mr. Mager noted that Abbott has been working on pilot programs to serialize products, purchasing hardware and software, working through technology, dealing with aggregation, and working through problems. He discussed various pilots that Abbott has performed, and the successes and challenges associated with those. He said they still have a lot of work to do to be ready by 2015. He reviewed slides demonstrating technology on a packaging line – serializing units, putting those in cases and on pallets. In 2009, they started working on a third pilot to serialize Humira.

Mr. Mager spoke about lessons learned during their pilots. Between 2010 and 2012, they have had a pilot with Cardinal Health where Humira pens would be serialized and returned. One difficulty they experienced was when third-party packagers packaged for them. From the perspective of product packaging levels, he talked about the data that would be coded and maintained using GS1 standards. They continue to look at RFID, and challenges related to certifying what goes out of the distribution centers.

Mr. Mager spoke to the pedigree data and how that is communicated between the trade partners. He said they need to figure out their tools and trade models, adding there is not a line industry interpretation of an accepted trade model. He noted errors that occurred with the process (not the technology). He spoke to the tools of communication, data collection, serialization, lessons learned during trading product and data, and certification of product at the item and case levels. Mr. Mager said that they have shared their pilot experiences with GS1.

Mr. Mager spoke to “inference” and distribution models and model comparisons. He spoke to central or semi-central data, versus inference that ways within an organization. Inference is upon receipt. He spoke to DPMS language and how the California language (where the inference stays within the four walls). The DPMS model is dependent upon the certification of items. He said he felt that the California language is aligned with the DPMS model back at the time the language was drafted. He said that language has a lot of flexibility. He spoke of being in control of a process – and how the FDA wants you to be in control of an accountable for your

process. He stressed the importance of controlling your process – citing an example, if there is a problem with the certification of Case A – then what happened with Cases B and C?

Mr. Mager cited the board’s letter to Congressman Waxman, and the term ‘gold standard.’ He noted there is a short amount of time left before e-pedigree must be in place, and that there is not a universally accepted trade model in place yet. He stated that Abbott’s implementation approach is that they want the information and the data to be meaningful; noting that technology will play an important role in the process. They want to make sure that they can serialize every item, box, case, pallet in a manner that they can serialize and certify every item.

In closing, Mr. Mager said Abbott wishes to work with industry to accurately aggregate data and to verify product and achieve pedigree. They want to be accurate, and have reliable processes. Work with industry to improve T&T and visibility (supply chain integrity). Abbott supports business rules for the decommissioning of serialized numbers. He said they are putting serial numbers on products, tracking them through the supply chain, and the need to close the serial at the end of the road through methods that still need to be discussed. Abbott also desires definition and acceptance of an industry designed trade model. At this time, the law is not prescriptive enough to define the trade model, so this is an area that is challenging.

Mr. Room spoke to inference models and asked if in the future he could provide information on standard operating procedures that are supportive of an inference model.

### **General Discussion**

Mr. Steve Lewis provided public comment on the challenges related to certification of case contents without “inference” requirements being specified by the board. Mr. Lewis commented their pilots with trade partners and the flow of process, the flow of data, and of decommissioning a pedigree. Executive Officer Herold commented on the importance of decommissioning a pedigree and stressed the necessity of certifying the decommissioning of the pedigree.

Mr. Lewis said that at this time, inference is the biggest challenge. He said that as a provider, he wants– upon receipt of a product – be able to see the data related to the case. He added that for an accepted trade model, there is need to define not just product, but also the associated data; how the data is handled, etc. He also noted that decommission of a serial needs to be further addressed. He said their biggest challenge at this time is inference.

Mr. Room commented about distributed data models, and Mr. Lewis said those vary among trade partners. Mr. Lewis said that when the board begins to make rules on inference, it will be important to understand the various distributed data models.

Ms. Herold thanked the participants for sharing experiences, challenges and information with the board. She said that the board will look for outcomes, and that industry needs to determine how best to meet the outcome(s).

The committee broke for lunch at 11:45 a.m. and reconvened at 1:00 p.m.

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

The committee discussed a proposal to establish parameters for an electronic standardized numerical identifier (SNI) that would be the tracking number for each prescription container. The committee considered draft regulation text which mirrored language developed by the U.S. Food and Drug Administration (FDA) as a <sup>1</sup>guideline (FDA guidance document). Mr. Kajioka noted that the board’s proposed text explicitly incorporates by reference the FDA guidance document, noting the same parameters for California. Supervising Deputy Attorney General Joshua Room noted a small correction to the proposed text for 16 CCR § 1747 – on the ninth line, after the word “SNI” instead of saying “requires” the language would say “consists of.” Mr. Room explained the necessity of “grandfathering” drugs in the supply chain, and noted that the SNI is the data itself – not the data carrier.

*M/S (Lippe/Badlani) – Motion to recommend to the Board to initiate a rulemaking to add Article 5.5 to Division 17 of Title 16 of the California Code, and to Add Section 1747 as proposed with the correction noted by counsel.*

*Vote: 3-0-0*

**Article 5.5. Pedigree Requirements.**

**1747. Unique Identification Number.**

For the purposes of Section 4034 of the Business and Professions Code, the "unique identification number" that is to be established and applied to the smallest package or immediate container by the manufacturer or repackager shall conform to requirements for Standardized Numerical Identifiers (SNIs) set forth in a March 2010 publication by the U.S. Food and Drug Administration (FDA) titled “Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages, (FDA’S Guidance Document),” hereby incorporated by reference. As stated therein, an SNI consists of a serialized National Drug Code (NDC) product identifier combined with a unique numeric or alphanumeric serial number of no more than twenty (20) digits or characters. For dangerous drugs for which no NDC product identifier is assigned or is in use, an equivalent serialized product identifier may be used in place of the NDC consistent with the FDA’s Guidance Document. This number shall be combined with a unique numeric or alphanumeric serial number that is not more than 20 digits or characters in length to establish the unique identification number.

This regulation shall become operative on January 1, 2015.

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<sup>1</sup> See “Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages, Final Guidance” issued by the U.S. Department of Health and Human Services, Food and Drug Administration, March 2010.

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

The committee discussed the proposed text, noting changes in format and counsel suggested the correction of dates in (a)(2) and (a)(3) to more clearly specify the dates in which declarations shall be submitted.

*M/S (Lippe/Badlani) – Motion to recommend to the Board to initiate a rulemaking to add Article 5.5 to Division 17 of Title 16 of the California Code, and to Add Section 1747.1 as proposed with the correction noted by counsel.*

*Vote: 3-0-0*

**1747.1. Specification of Pedigreed Dangerous Drugs; Specification of Existing Stock**

(a)(1) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall submit to the board, by December 1, 2014, but no later than December 31, 2014, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

- (i) a list and quantity of dangerous drugs by name and product package (SKU) type representing at least fifty (50) percent of the manufacturer’s total that are ready for initial implementation of the serialized electronic pedigree requirements as of January 1, 2015;
- (ii) a statement identifying which one of the following methods was used to measure the percentage of drugs ready to be serialized: (A) unit volume, (B) product package (SKU) type, or, (C) drug product family;
- (iii) a statement describing the calculation(s) used to arrive at the percentage figure of dangerous drugs ready for serialized pedigree requirements;
- (iv) a list and quantity of dangerous drugs by name and product package (SKU) type that are in the remaining percentage (up to fifty (50) percent) not yet ready to be serialized or subject to pedigree requirements; and,
- (v) a statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(a)(2) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall also submit to the board, by December 1, 2015 but no later than December 31, 2015, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

- (i) a list and quantity of its remaining dangerous drugs by name and product package (SKU) type that are ready for implementation of serialized electronic pedigree requirements as of January 1, 2016.
- (ii) a statement identifying which one of the following methods was used to measure the final percentage of drugs to be serialized : (A) unit volume, (B) product package (SKU) type, or, (C) drug product family;
- (iii) a statement describing the calculation(s) used to arrive at the final percentage figure; and,

(iv) a statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(a)(3) Any failure to submit to the board a declaration compliant with subdivision (a)(1) by December 31, 2014 but any failure to submit to the board a declaration compliant with subdivision (a)(2) by December 31, 2015, or any failure to re-submit either declaration to the board in fully compliant form within ten (10) days after notice of deficiency by the board, shall constitute a violation of the Pharmacy Law.

(b) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any manufacturer, wholesaler or repackager seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than August 1, 2016, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, wholesaler or repackager, containing the following:

(i) a list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the manufacturer, wholesaler or repackager that were acquired prior to July 1, 2016;

(ii) a statement that specifies the means and source of acquisition; and,

(iii) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(c) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than August 1, 2017, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the pharmacy or pharmacy warehouse, containing the following:

(i) a list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the pharmacy or pharmacy warehouse that were acquired prior to July 1, 2017;

(ii) a statement that specifies the means and source of acquisition; and,

(iii) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(d) The Board or its designee shall have sole discretion to determine whether any of the declarations submitted pursuant to this Section are compliant, and to reject and require re-submission of any non-compliant declaration(s) until determined to be fully compliant.

#### **h. Discussion Concerning Elements for Inference as Provided by California Business and Professions Code Section 4163.3**

Supervising Deputy Attorney General Room lead a discussion and spoke to 'within an entity' inference versus that which is outside of an entity.

Under 4163 the board is charged with promulgating a rule on inference, as appropriate, noting the board is to determine when inference shall be used. To that end the committee requested

that industry provide the board with information on industry's use of inference, and where that would be beneficial to secure the supply chain.

**Public Comment:**

A representative from a manufacturer, Bio Marin indicated that they are a small manufacturer who uses contractors (via technical agreements/contracts) that uses Bio Marin's quality procedures to seal cases. She spoke to the challenges of having a contracted partner seal and certify product, noting that Bio Marin owns and controls the product but the contracted partner is packaging.

Mr. Room stated that only a change of ownership must be recorded in a pedigree. He spoke of the separate issue of certifying the contents, reflecting on Mr. Mager's conversation about who and when the contents are certified. This could be an area where inference is also used within an entity for its own products.

Steve Tadovich, representing McKesson said it has been McKesson's position all along that inference made when products are received, and that they certify the contents when a case is broken and that when the pieces are shipped out.

Mr. Room asked if McKesson could provide data on cases that the board could use so that they could start to understand how the products are moving through. He asked partners to share with the board their thinking of business models and how to justify inference, as well as who would bear the risk of discovering errors after the fact, speaking to the validation of unit and case identifiers. He said it would be helpful for the board to have this type of information.

Mr. Kajioka said that a standard operating procedure should address how to deal with exceptions and errors. Mr. Tadovich spoke to the need to specify what time frame will be utilized when dealing with exceptions and errors that are discovered.

Supervising Inspector Judi Nurse asked Mr. Tadovich if once a case is opened to either stock a shelf or distribute, are the contents verified when the case is opened, or when the product is being shipped out. Mr. Tadovich indicated at this time the verification is done when the product is shipped out.

Mr. Steve Lewis with the Department of Veterans Affairs addressed the committee sharing his perspective that as soon as the case is broken, he thinks the contents should be verified to ensure the integrity of the contents. He noted that for the DVA's pilot, they are certifying when the case is broken before contents are shipped out.

She asked what steps a manufacturer could take to ensure products are sealed/tamper resistant and how tampering is discovered. One participant said a visual inspection is done, or if there is any reason to believe there has been tampering, the box/case is looked at more closely to determine if there has been a breach of product integrity.

Additional public comment spoke to the need to determine where the liability may lie when product is accepted based on inference.

The committee discussed the possibility of counsel coming up with some type of "request for comments" by which the committee could request information from industry. A representative from Teva asked if industry partners would be receiving feedback from the board on any standard operating procedures that are provided to the board; Ms. Herold indicated no feedback would likely be provided.

Mr. Kajioka adjourned the meeting at 2:16 p.m.

# Dysfunction in California's Prescription Medication Supply

June 12, 2012

Enforcement Committee

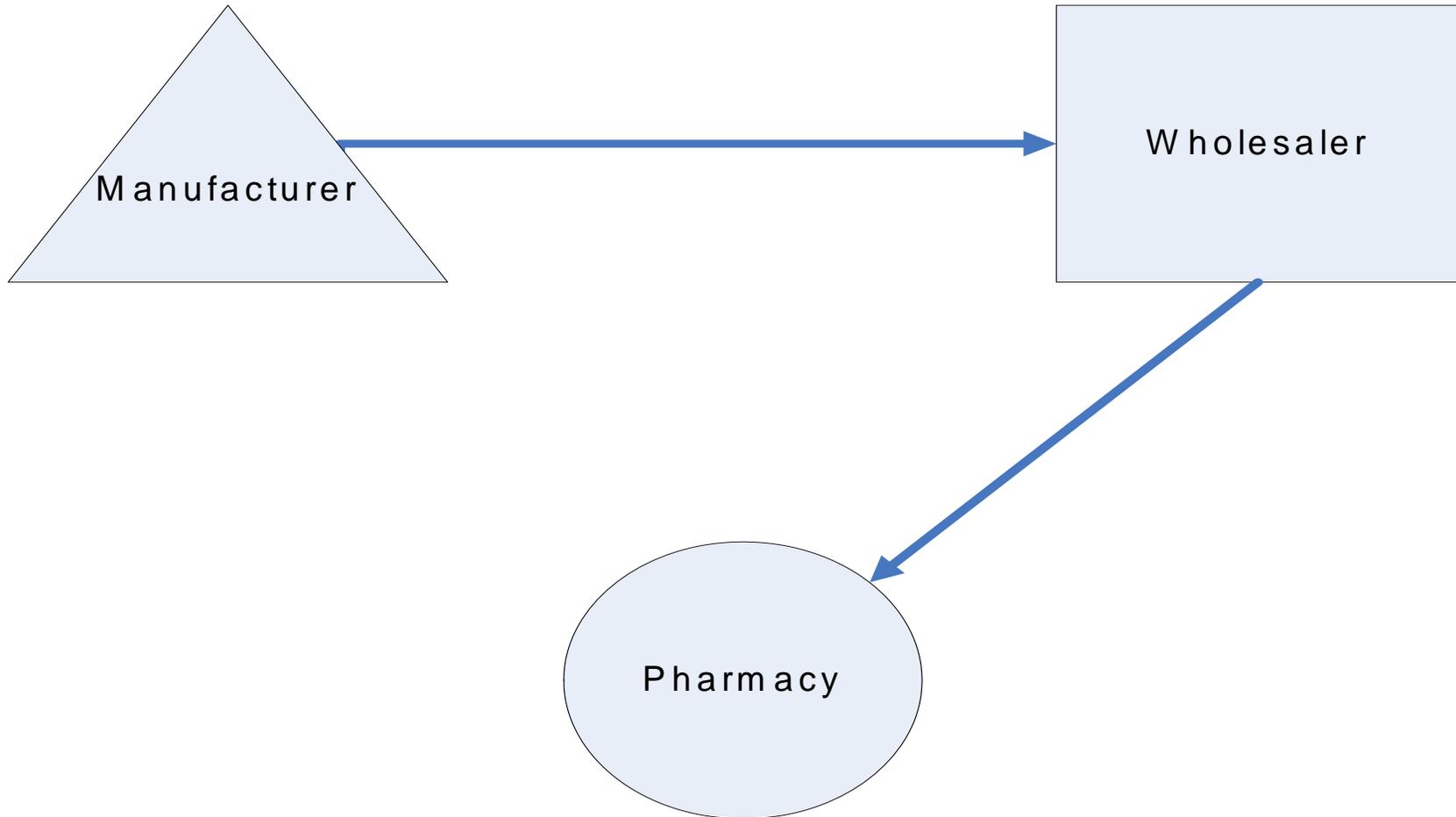
CA State Board of Pharmacy

# 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*

# Supply Chain is Not Really a Chain but a Network



**Wholesale Broker Z: Unlicensed California Wholesaler  
Arranges Sales & Purchases Through the Following**

WHOLESALER Nevada CA Licensee	WHOLESALER Puerto Rico Not CA licensee	WHOLESALER New York Not CA licensee	WHOLESALER Ohio CA Licensee	WHOLESALER Kentucky CA Licensee	WHOLESALER Mexico Not CA licensee	WHOLESALER New Jersey Not CA licensee	WHOLESALER Louisiana Not CA licensee	WHOLESALER Ohio Not CA licensee	WHOLESALER Texas Not CA licensee	WHOLESALER 2 Individuals Location unknown Employer unknown
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WHOLESALER  
New York  
Not CA licensee

WHOLESALER  
Oregon  
Not CA licensee

WHOLESALER  
Oregon  
Not CA licensee

WHOLESALER  
Minnesota  
Not CA licensee

PHARMACY  
California  
CA Licensee

Pedigree is created by **Pharmacy** Located in California  
Same address as another **Pharmacy**  
Address on ALL pedigrees show purchase by **Pharmacy**  
located in California – licensed as a pharmacy, not as a wholesaler.

WHOLESALER  
California  
CA Licensee

WHOLESALER  
California  
CA Licensee

WHOLESALER  
California  
CA Licensee

Brokers sales to  
pharmacies.

PHARMACY  
California  
CA Licensee

PHARMACY  
Hawaii  
CA Licensee

PHARMACY  
California  
CA Licensee

Pharmacy  
California  
CA Licensee

Wholesaler  
Puerto Rico  
Not CA licensee

PHARMACY  
California  
CA Licensee

Wholesaler  
New Jersey  
Not CA licensee

PHARMACY  
California  
CA Licensee

Wholesaler  
Connecticut  
Not CA licensee

Wholesaler  
Arizona  
CA Licensee

Wholesaler  
California  
Not CA licensee

Wholesaler  
California  
Not CA licensee

Wholesaler  
California  
Not CA licensee

Wholesaler  
Georgia  
Not CA licensee

Pharmacy  
New Jersey  
Not CA licensee

Pharmacy  
California  
CA Licensee

Pharmacy  
California  
CA Licensee

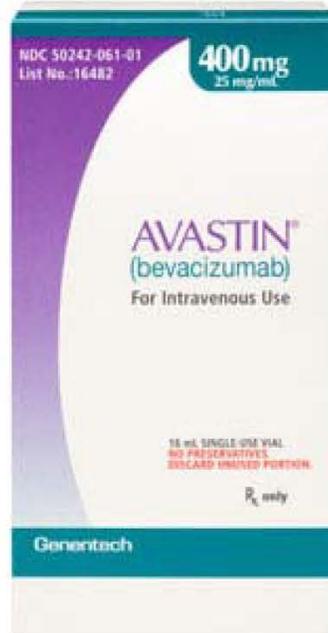
WHOLESALER  
Puerto Rico  
Not CA licensee

Puerto Rico  
Not CA licensee

# Who's in the Chart?

- 28 wholesalers, 21 non-licensed in CA; 17 pharmacies; one wholesale broker overseeing all
- Overly complex drug distribution makes investigation involving diversion and counterfeiting difficult

# What Is Unusual Here?



# Which One Is the Counterfeit?



# Which is the counterfeit?





- Counterfeit Adderall on the bottom, the real drug on the top; purchased from Internet May 2012

# How did each get to pharmacy?



# Problems with Supply “Network”

## April 2012

- NY pharmacy purchased \$274 million worth of black market HIV medications from a web of shell companies
  - Drugs obtained from numerous sources
  - Rebottled with fake labels and serial numbers, broken seals, outdated, or contain different medications than what is indicated on the labels.
- Result: patients exposed to potential adverse drug interactions, overdoses, or a decline in their condition by not getting the treatment prescribed

# Empty Containers in Pharmacy



# Drugs Sorted to Fill Empty Containers





# Rapid Introduction of Counterfeits into US Commerce

- Within 4 months of bringing new product onto market, counterfeit versions indentified.

# It can never happen here

- Never event identified
  - Chain store pharmacy
  - Invoices only from one of Big 3 Wholesalers for the counterfeited drug product
  - Maintenance medication, not drug of abuse
  - Low cost

# Market Manipulations Exacerbating Drug Shortages

- In CA, pharmacies can only resell medication to the wholesaler they bought it from
- More than 50 pharmacies worked with one wholesaler to purchase their full allotment of short-supply drugs for profit, then wholesaler greatly increased price.
- Other non-licensed wholesalers purchased product from these pharmacies.

# More Problems

- Recalls are now frequent and supply chain not able to remove all product recalled
- Drugs from US suppliers are “too expensive” for pharmacies and some wholesalers so they purchase made from outside US illegally.

# Meetings:

- Calendar for Remainder of 2012  
Established  
(All “Enforcement Committee Meetings”)  
Sept. 11  
Dec. 4
- Join our subscriber alert by going to  
[www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)



# 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.

# VISIBILITY, TRACEABILITY, TRACK AND TRACE

## WHO ARE USING GS1 STANDARDS FOR TRACK & TRACE?

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**Apparel**

**Sea Food**

**Fresh Foods**

**Food Service**

**Consumer Goods**

**Aerospace**

**Pharmaceuticals**

**Healthcare Providers**

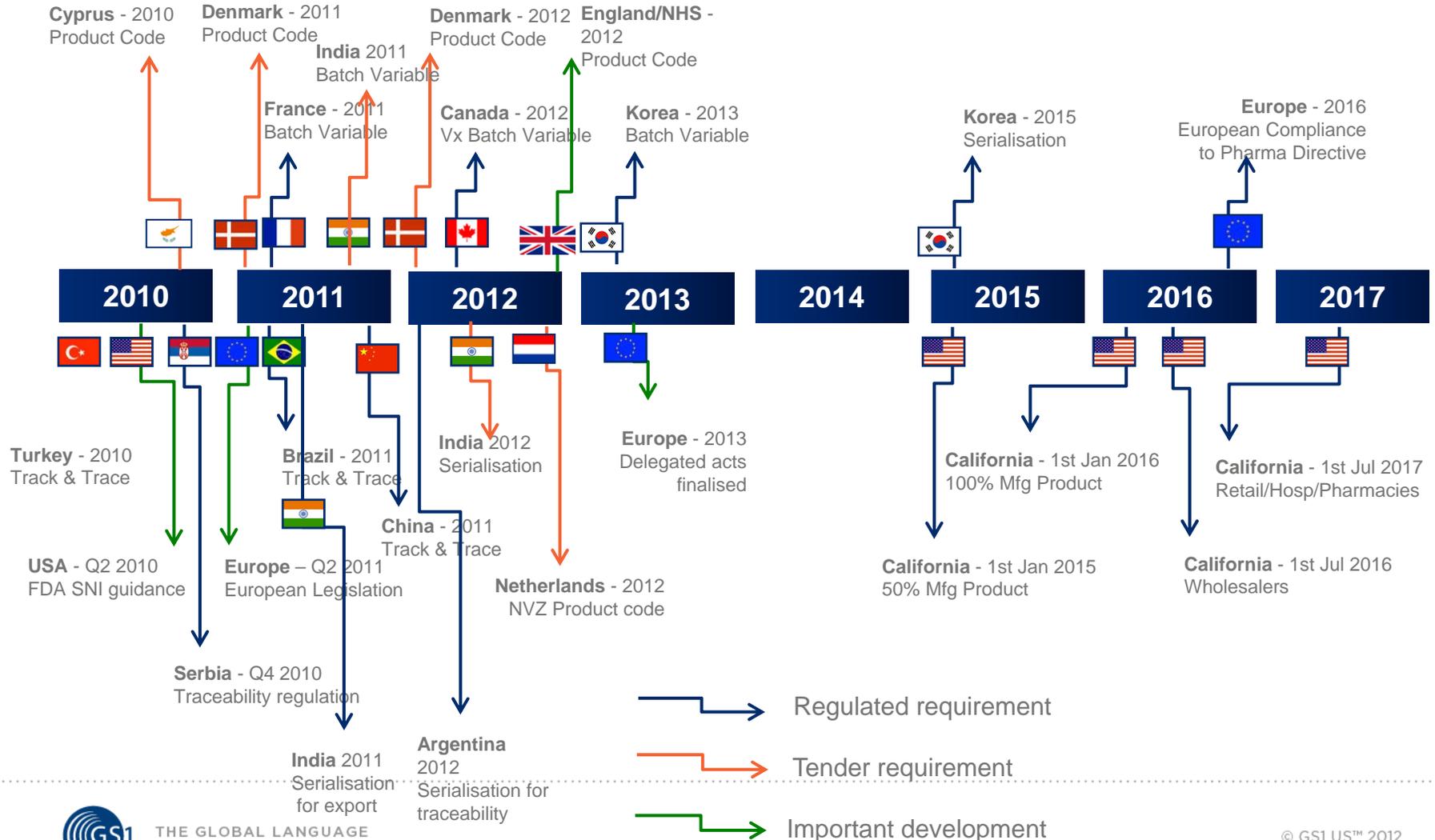
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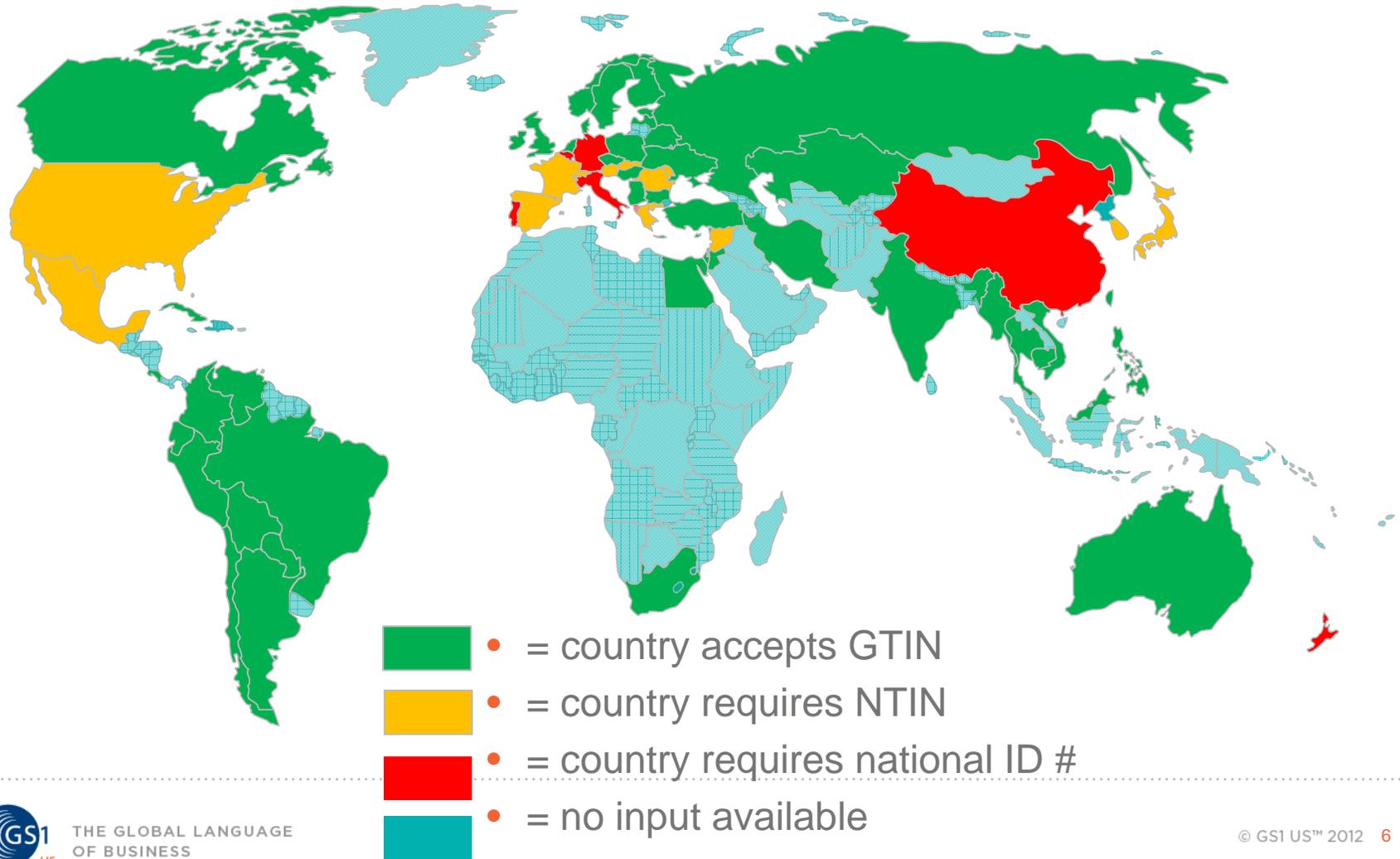
# SERIALIZATION AROUND THE WORLD

# PHARMACEUTICALS

## NEW CODING & SERIALISATION REQUIREMENTS

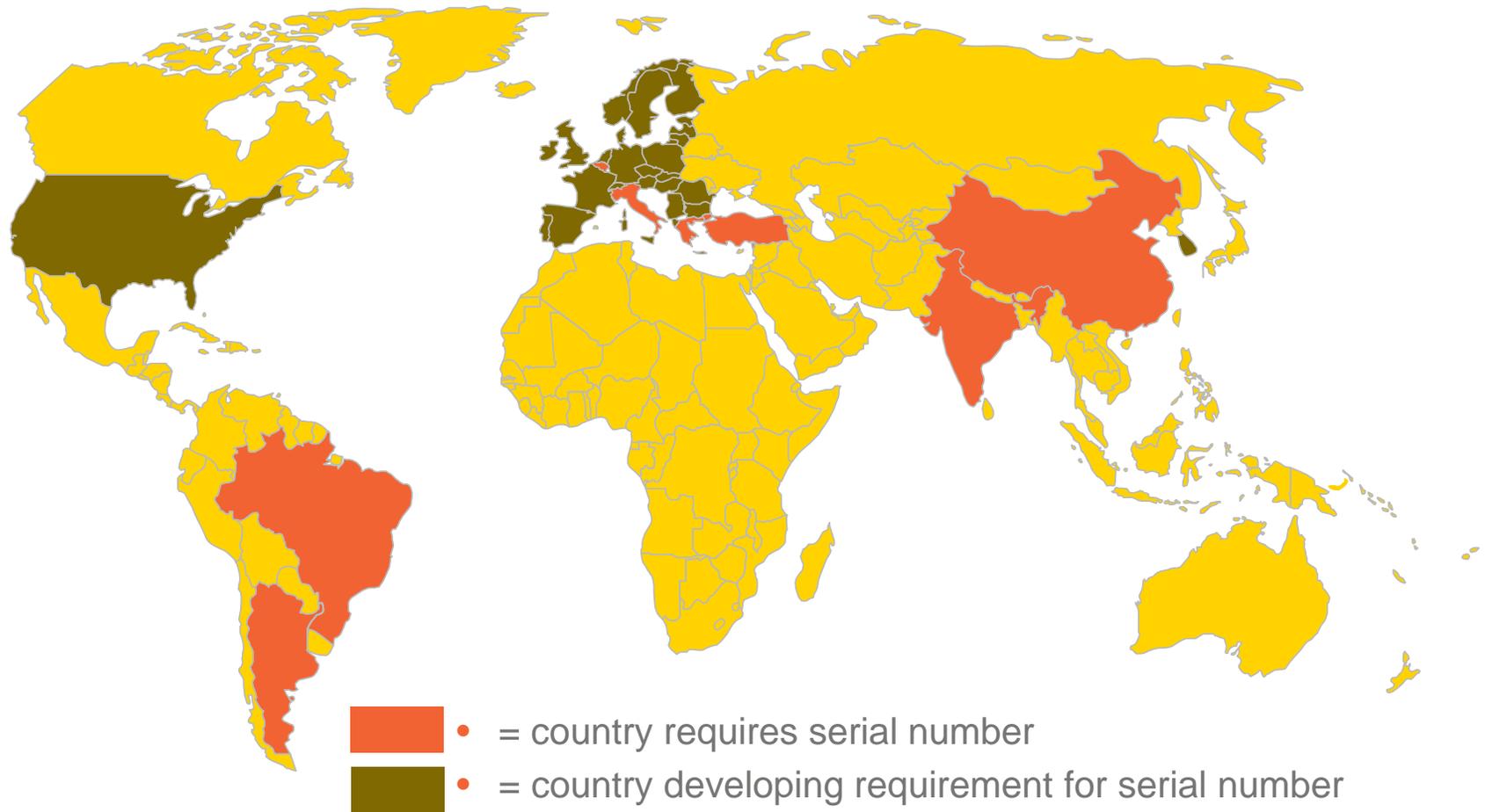


# IDENTIFICATION OF PHARMACEUTICALS

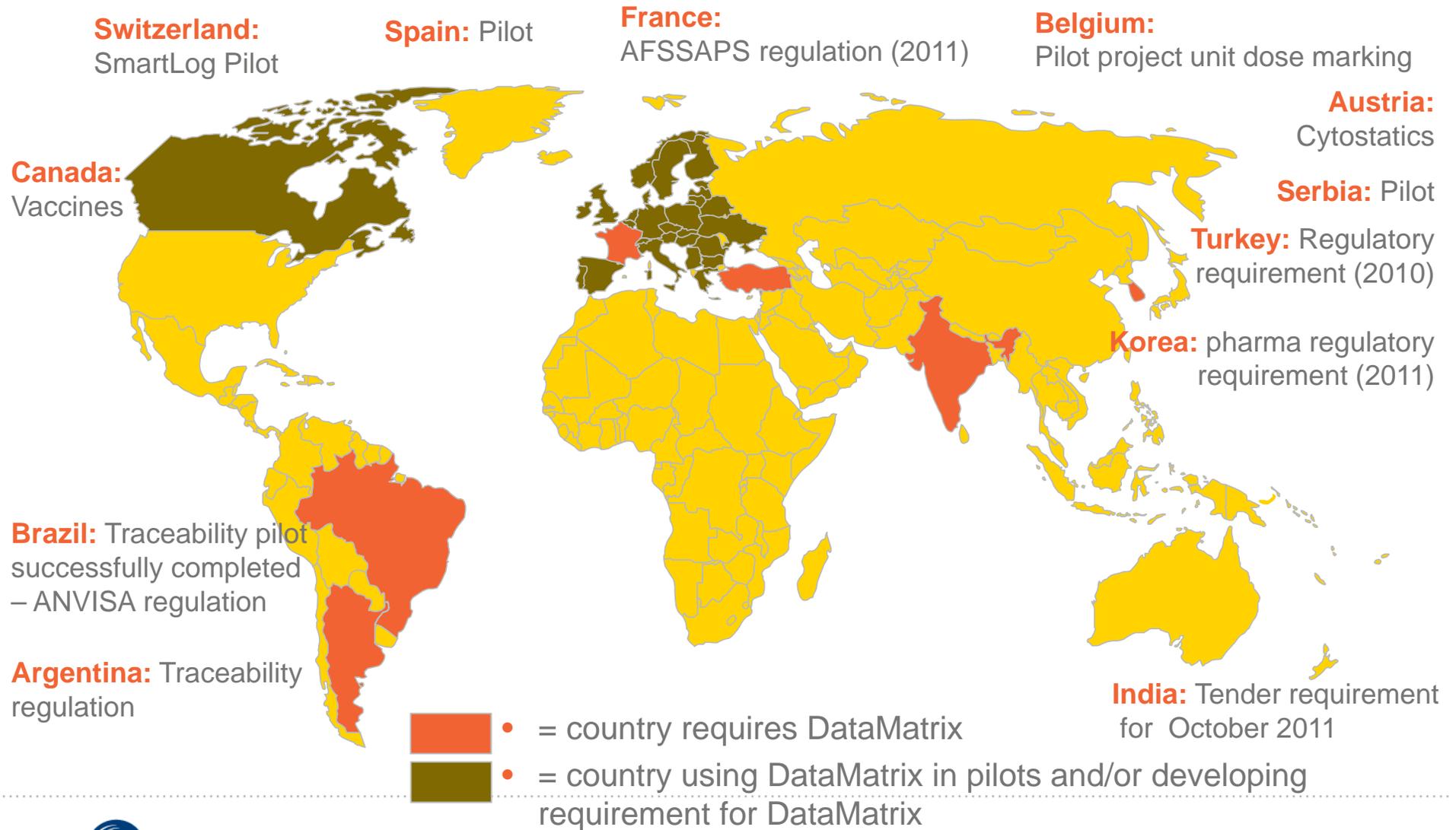


# SERIALIZATION OF PHARMACEUTICALS

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# DATAMATRIX ON PHARMACEUTICALS





# WHY SERIALIZATION / TRACK & TRACE?

# WHY SERIALIZATION / TRACK & TRACE?

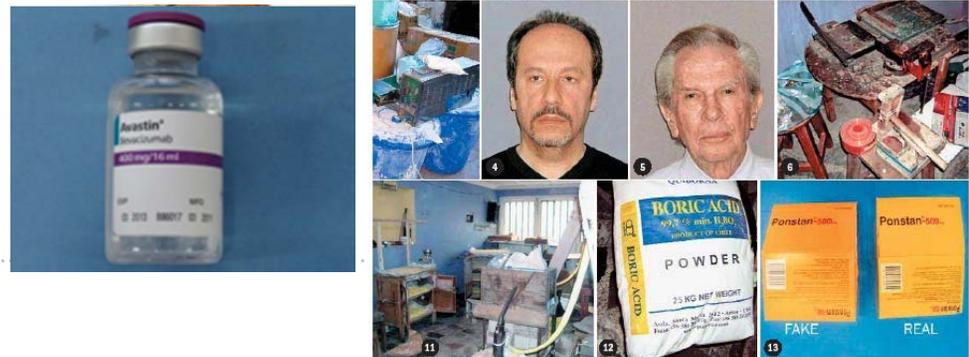
Counterfeit



Diversion



Theft



# WHY SERIALIZATION / TRACK & TRACE?

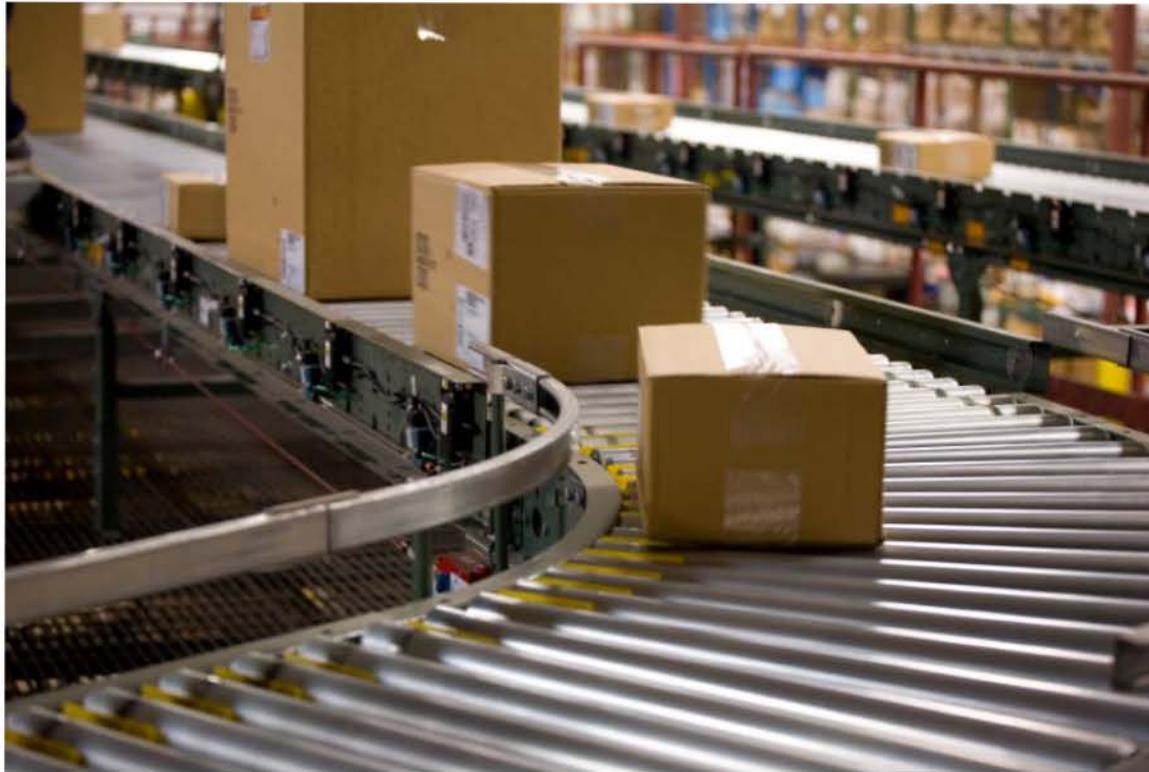
Find the counterfeit product:



# SERIALIZATION / TRACK & TRACE

## THE CHALLENGE IS:

---



# SERIALIZATION / TRACK & TRACE

## WHAT ARE THE ISSUES?

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**This amounts to an order of magnitude change in accuracy.**

**Will the solution cost more than problem?**

**Protect the supply chain without stopping the supply chain!**

**Provide visibility without also providing unfair business advantage.**

**Better the devil you know than the devil you don't.**

---



# TRACK & TRACE STANDARDS AND USES

# WHAT CAN WE DO WITH TRACK & TRACE STANDARDS?

A Lot!



## Examples:

- Forward Logistics
- Reverse Logistics
  - Recalls
  - Returns
  - Withdrawals
- Shrink/Loss Recovery
  - Pharmacy Theft
  - Cargo Theft
- Cold Chain
- Chargebacks
- Rebates
- Customs clearance
- Diversion



- Vendor Managed Inventory
- Investigations
- Perfect Order
- Infection Control
- Patient Flow
- Dispensing Errors
- Operating room turns
- Pharma co-vigilance
- Waste stream management



# THE STANDARDS AT THE CORE OF TRACK & TRACE

	<u>Example</u>	<u>Standard</u>
<b>EPCIS</b>	<b>Who</b>	Ship-From Ship-To Buyer Seller
	<b>What</b>	Products Logistics Units Assets Relationships
	<b>Where</b>	Postal Locations Warehouses Floors, Rooms
	<b>When</b>	Time & Date
	<b>Why</b>	Commissioning Packing Shipping Receiving Dispensing
		<b>GLN</b>
		<b>GTIN SSCC GRAI, GIAI GSRN</b>
		<b>GLN</b>
		<b>Business Step</b>

# WHAT CAN WE DO WITH TRACK & TRACE STANDARDS?

## Pedigree Data (showing Master Data)

Product

### GTIN Item Pedigree Report from Simulation - Secure

Product: Small case of 6 Prod 01, 100ct bottles 50 mg      Lot Number: 54  
 GTIN: 10398765129454      Serial Number: 1      Lot Expiration: 6/23/2013  
 NDC: 9876512945      Strength: 50 MG  
 Description: Small case of 6 bottles of Prod 01      Dosage Form: Tablet

Certification

Order #	Business Location	Day / Time	License #	Business Step / Disposition	Trans. Type	Shipped To / Shipped From	Pedigree Certificate (GSIN)
1	Wholesaler 000 160 North 1st Street Sacramento CA 95811	1/1/2011 3:00:00 PM		commissioning active			
2	Wholesaler 000 160 North 1st Street Sacramento CA 95811	1/1/2011 4:15:00 PM		shipping in_transit	PO 501	Pharmacy 001 5528 North 1st Street Fresno CA 93710	0398765129454
3	Pharmacy 001 5528 North 1st Street Fresno CA 93710	1/1/2011 12:30:00 PM		receiving sellable_not_accessible	PO 501	Wholesaler 000 160 North 1st Street Sacramento CA 95811	0849661290078

Ownership

Ownership

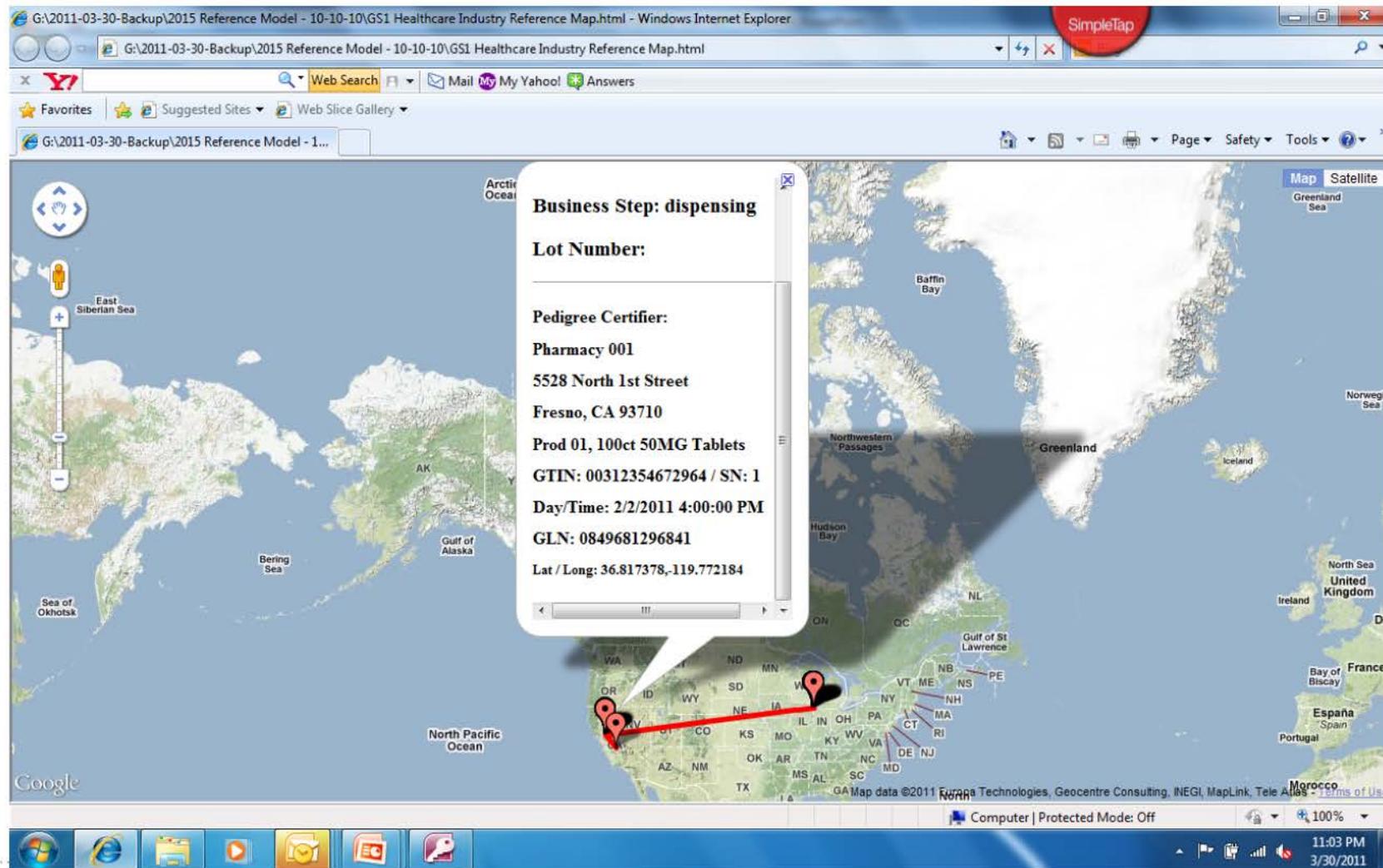
Pedigree

Monday, April 11, 2011

Page 1 of 1

# WHAT CAN WE DO WITH TRACK & TRACE STANDARDS?

## Visibility data rendered via Google Maps



# WHAT CAN WE DO WITH TRACK & TRACE STANDARDS?

Visibility, Traceability, Track & Trace



© GSI US™ 2012



# ANTI-COUNTERFEIT CONSIDERATIONS

# ANTI-COUNTERFEIT CONSIDERATIONS

## INFORMATION SECURITY

---

Criminals will Counterfeit:



Your Products

Your Packaging

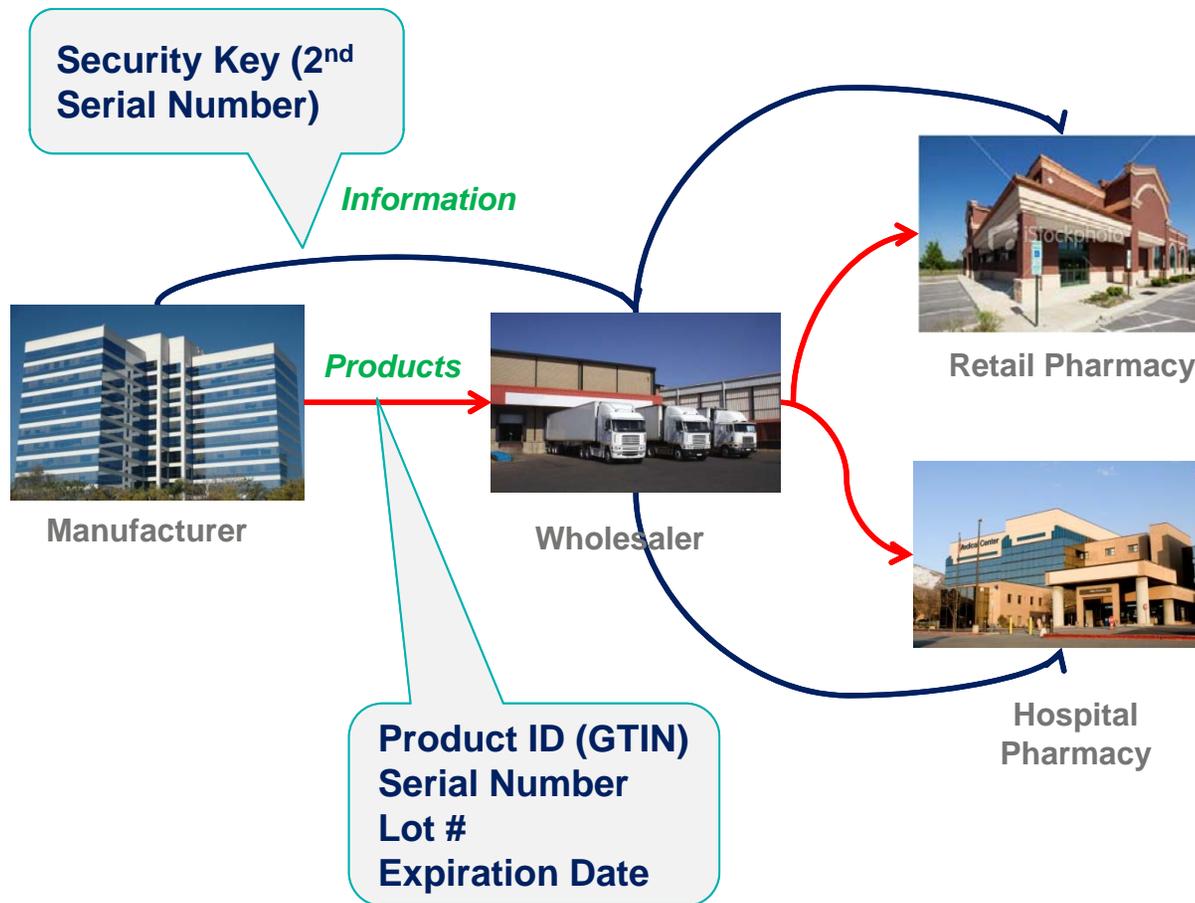
Your Pedigrees

Your Websites

Your Authentication Portals

# ANTI-COUNTERFEIT CONSIDERATIONS

## SPLIT SECURITY: PACKAGING & INFORMATION



- ### U.S. Pharmaceutical Supply Chain Partners
- Contract Manufacturer
  - Solid Dose Manufacturing
  - Biological Products
  - Generic Drug Manufacturer
  - National Wholesaler
  - Regional Wholesaler
  - Specialty Wholesaler
  - 3PL
  - Returns Processor
  - Repackager
  - Kitter
  - Hospital Pharmacy
  - Chain Pharmacy
  - Independent Pharmacy

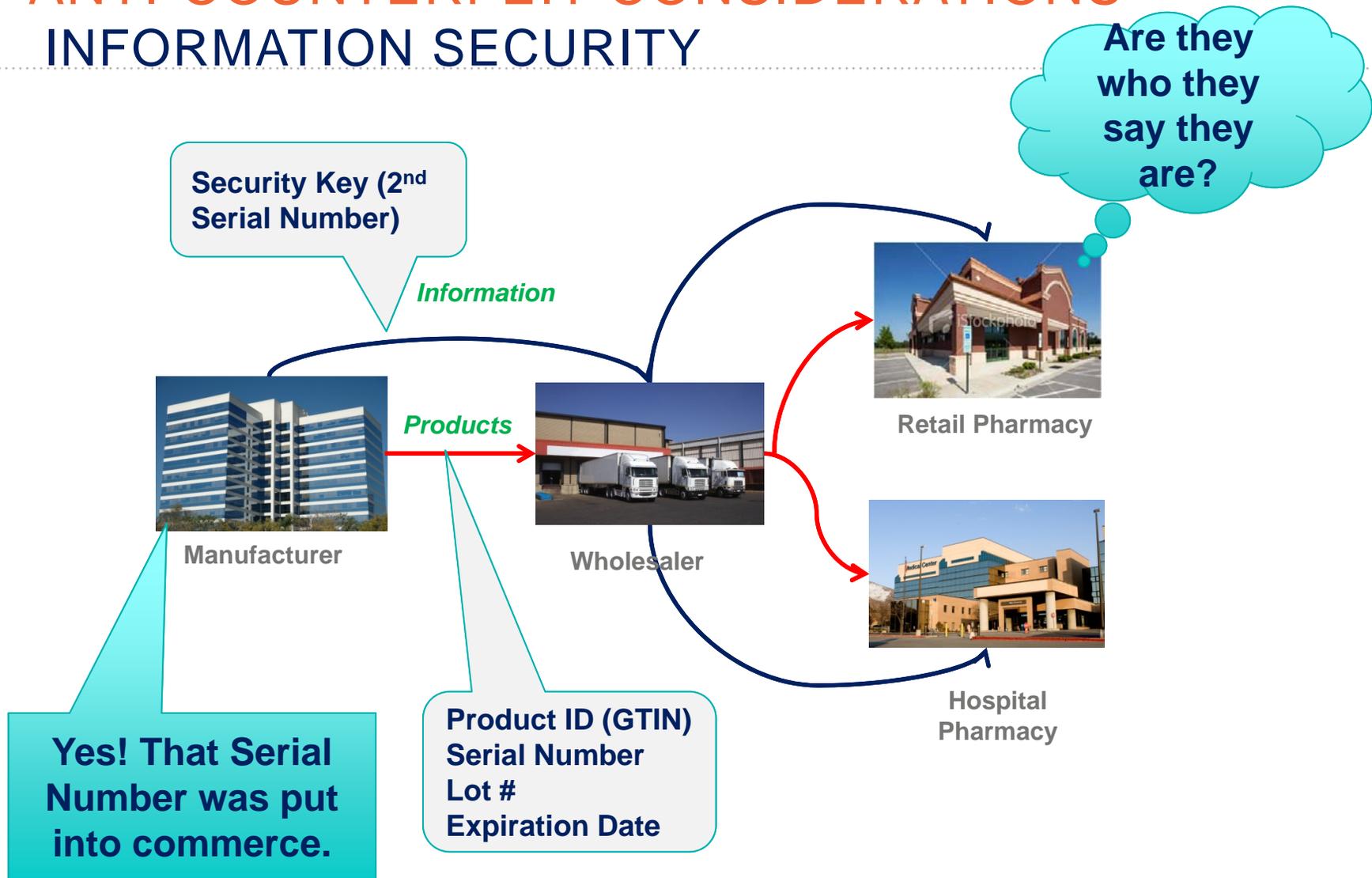
# ANTI-COUNTERFEIT CONSIDERATIONS

## INFORMATION SECURITY



# ANTI-COUNTERFEIT CONSIDERATIONS

## INFORMATION SECURITY



# ANTI-COUNTERFEIT CONSIDERATIONS

## INFORMATION SECURITY

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- **Verify information about the product or logistics item?**
  - Was the Product ID / Serial Number put into commerce?
- **Verify who is asking about the product or providing information about the:**
  - Legitimate company in the supply chain?
  - Have they actually had possession / ownership of the item they are asking about?
- **Verify who is answering my questions:**
  - Legitimate company in the supply chain?
  - Are they who they say they are?
  - Can I trust the answer to my question?

### U.S. Pharmaceutical Supply Chain Partners

Contract Manufacturer  
Solid Dose Manufacturing  
Biological Products  
Generic Drug Manufacturer  
National Wholesaler  
Regional Wholesaler  
Specialty Wholesaler  
3PL  
Returns Processor  
Repackager  
Kitter  
Hospital Pharmacy  
Chain Pharmacy  
Independent Pharmacy

**Thief**  
**Diverter**  
**Counterfeiter**

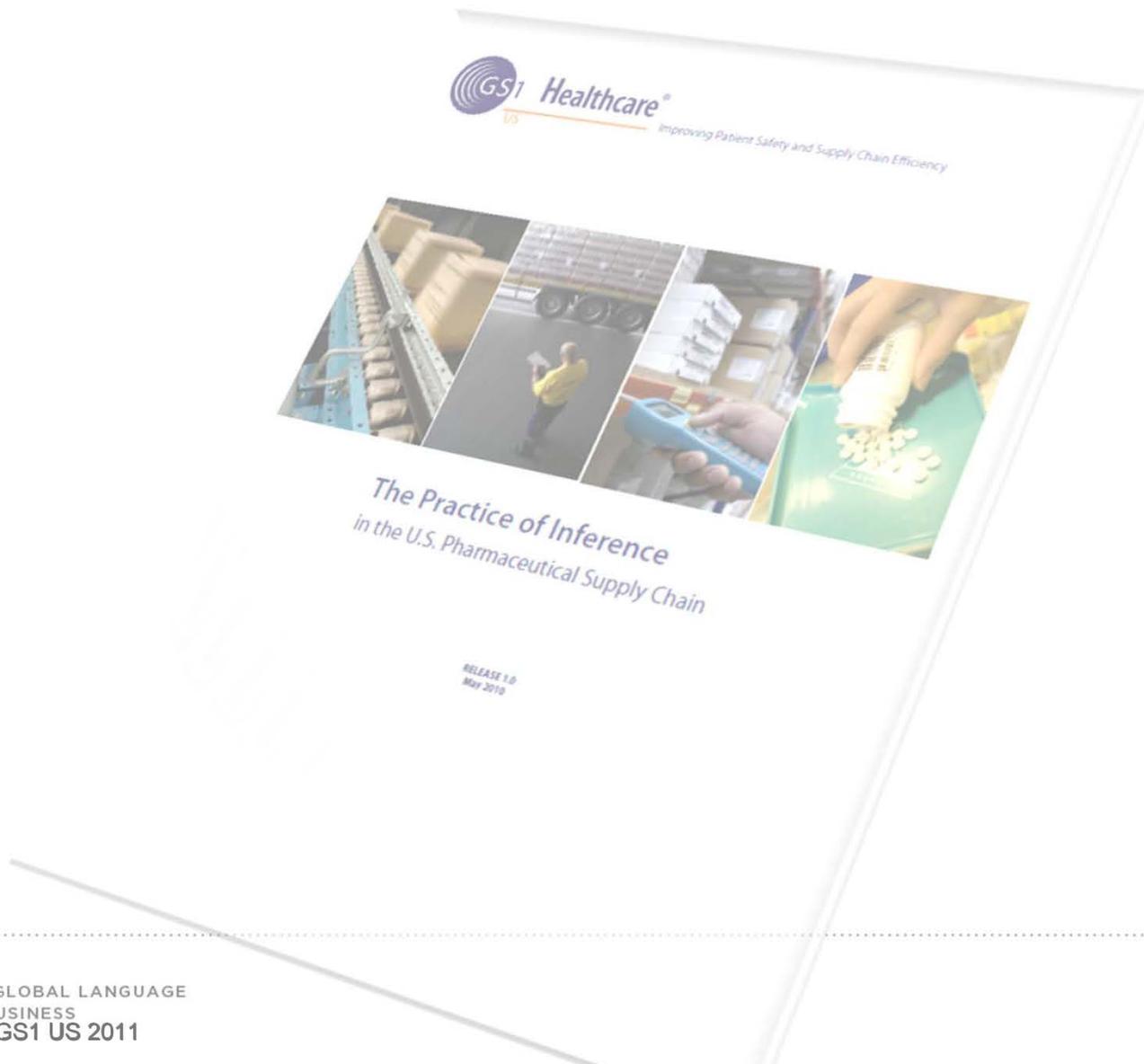


# STANDARDS ACTIVITIES IN THE U.S.

IMPLEMENTATION SUPPORT

# STANDARDS ACTIVITIES WITHIN THE U.S. INFERENCE

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# 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>																
Code letter: J																
<b>Normal Inspection:</b>										<b>Reduced Inspection (1):</b> the probabilities of acceptance accompanied by continuation of reduced inspection. <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.						
<b>Parameters of sampling plan:</b> sample size (n): 80 Acceptance number (c): 2																
<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>2. Average Outgoing Quality (AOQ):</b> Calculates the average percentage of nonconforming items after inspection, <u>in the long run</u> . Please check in the "Model assumptions" tab for more information on how the AOQ is calculated.						
<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 - Reduced inspection is considered desirable by the responsible authority; and - The total number of nonconforming items found in the preceding 10 (or more) shipments is sufficiently low. To check																

# SECURE SUPPLY CHAIN TASK FORCE IMPLEMENTATION GUIDE



## 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

# TRACEABILITY PILOTS TASK FORCE

## PILOT PANEL CALLS

Date	Topics
5/16/2012	Pharmacy/Clinic roundtable
5/30/2012	Master Data Management
6/13/2012	Implementation Challenges
6/27/2012	Bar code quality and readability
7/11/2012	Company Governance – Managing Traceability
7/25/2012	Implementation Guideline
8/8/2012	Physical vs Virtual Accountability
8/22/2012	RFID Bar Code Interoperability - GS1 Guideline Translations between different formats
9/5/2012	Inference and Aggregation

# STANDARDS ACTIVITIES WITHIN THE U.S.

## CLOSING THOUGHTS ON TRACK & TRACE INFORMATION

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For given regulatory requirements, business rules, data set and architecture:

### Counterfeits:

1. How are counterfeits detected?
2. How are counterfeits traced back to the questionable source?

### Other business benefits:

1. Given a specific scenario, what exactly do we know from the T&T information gathered?

# CONTACT INFORMATION

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CORPORATE HEADQUARTERS  
Princeton Pike Corporate Center  
1009 Lenox Drive, Suite 202  
Lawrenceville, NJ 08648 USA

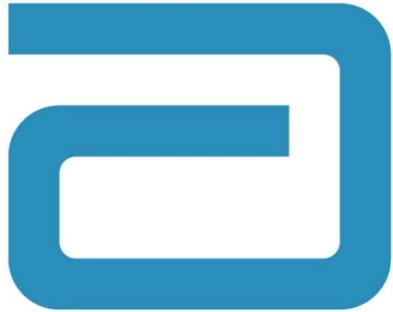
**T** +1 609.947.2720

**E** rceleste@GS1US.org

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

Connect with the GS1 US community on





## Abbott Today

A global, broad-based health care company

91,000 employees around the world

2011 sales: \$38.9 billion

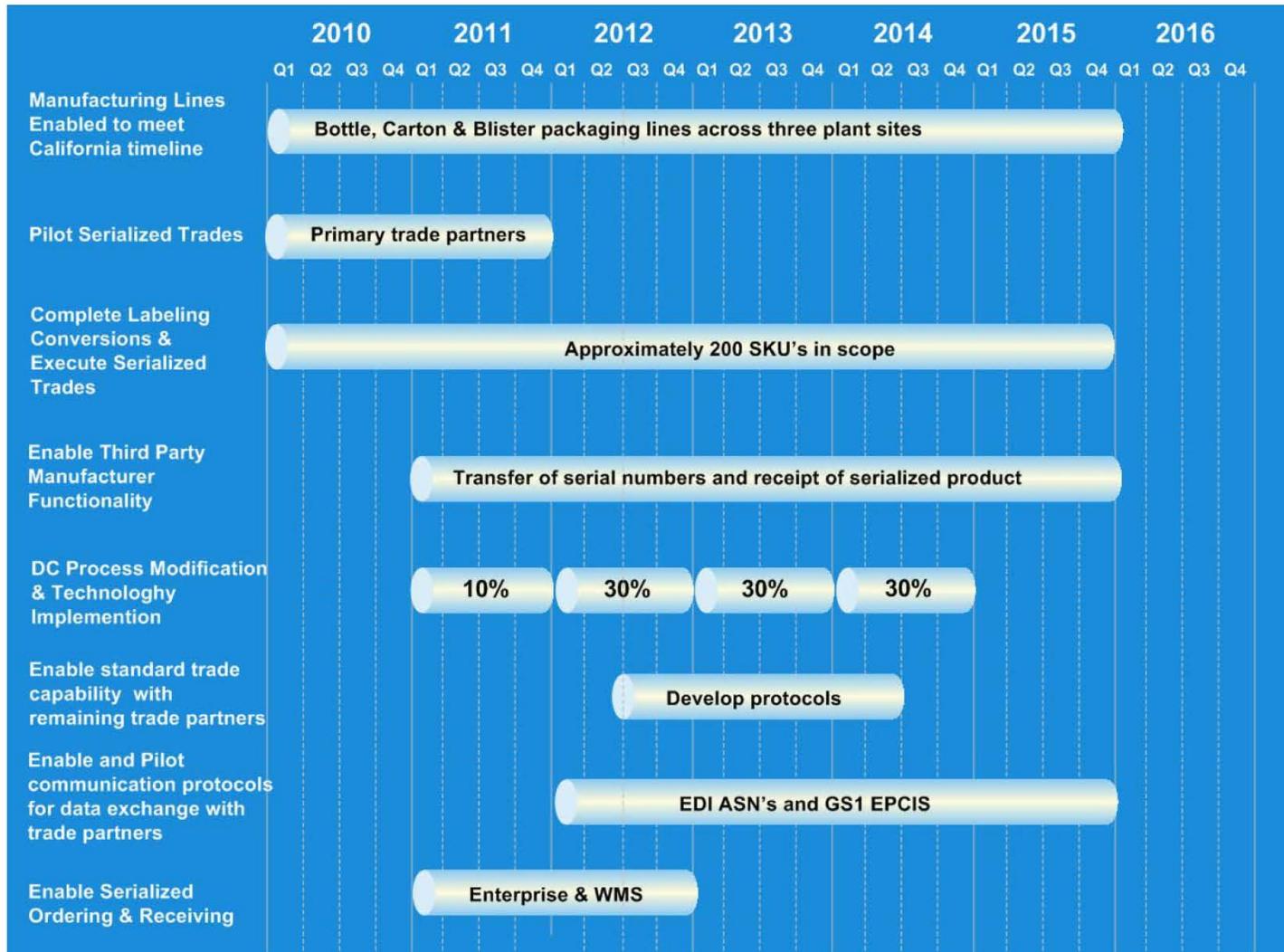


## Track and Trace – Pilot History

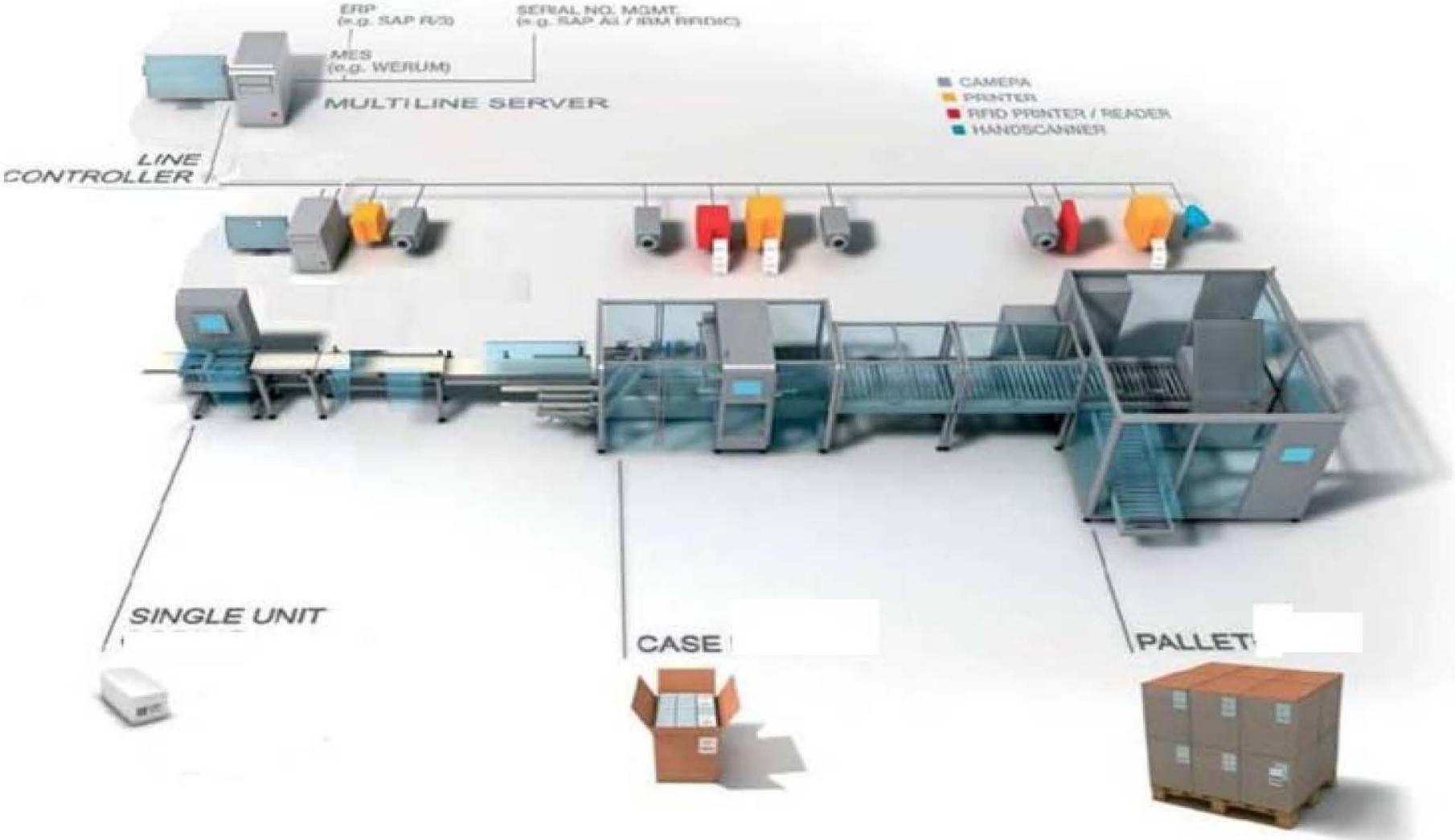
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- 2004 - Participant in industry pilot “Jumpstart”
- 2007 – Develop a ‘Proof of Concept, to meet ePedigree requirements of the California Board of Pharmacy, as interpreted
  - Engaged industry leading consultant
  - Serial Number generator/manager
  - Document Pedigree Management Solution ePedigree tool (since removed)
- 2007-2008 Pilot B, TriCor
  - RFID at unit level
  - Aggregated as demonstrated at CABoP
  - Conveyor solution implemented in distribution center (since removed)
  - Software platform implemented in DC (since replaced)
- 2009 Pilot C, Humira
  - Installed technology on packaging line to serialize and aggregate
  - Installed new software platform with in DC with handheld scanning technology
- 2010 – 2012 Three Pilots w/ Three Distributors
  - Continuous trade with Cardinal Health (Humira Syringe)
  - Limited small scale pilot w/ HD Smith Trade (Humira Syringe)
  - McKesson Trade (Humira Pen)

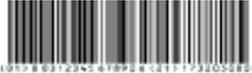
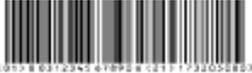
# Track & Trace LRP Timeline – US Market



# Line Schematic



# Product Packaging Levels

Packaging Level	Carrier/Encoding	Data Carrier Example	Data encoded
Item	2D/GS1 Data Matrix		GTIN+Serial Number
	1D/e.g. UPC-A		GTIN
Case (Full)	RFID/EPC GEN 2 UHF		GTIN +Serial Number
	1D/GS1-128		GTIN + Serial Number
Case (Partial/Mixed)	RFID/EPC GEN 2 UHF		SSCC
	1D/GS1-128		SSCC
Pallet (Full/Partial)	RFID/EPC GEN 2 UHF		SSCC
	1D/GS1-128		SSCC

# Establishing Parent Child Relationship - Cartons



# Distribution Conveyor

*This pilot equipment was purchased, installed, for pilot POC*

*Since then has been disassembled and removed from operations*

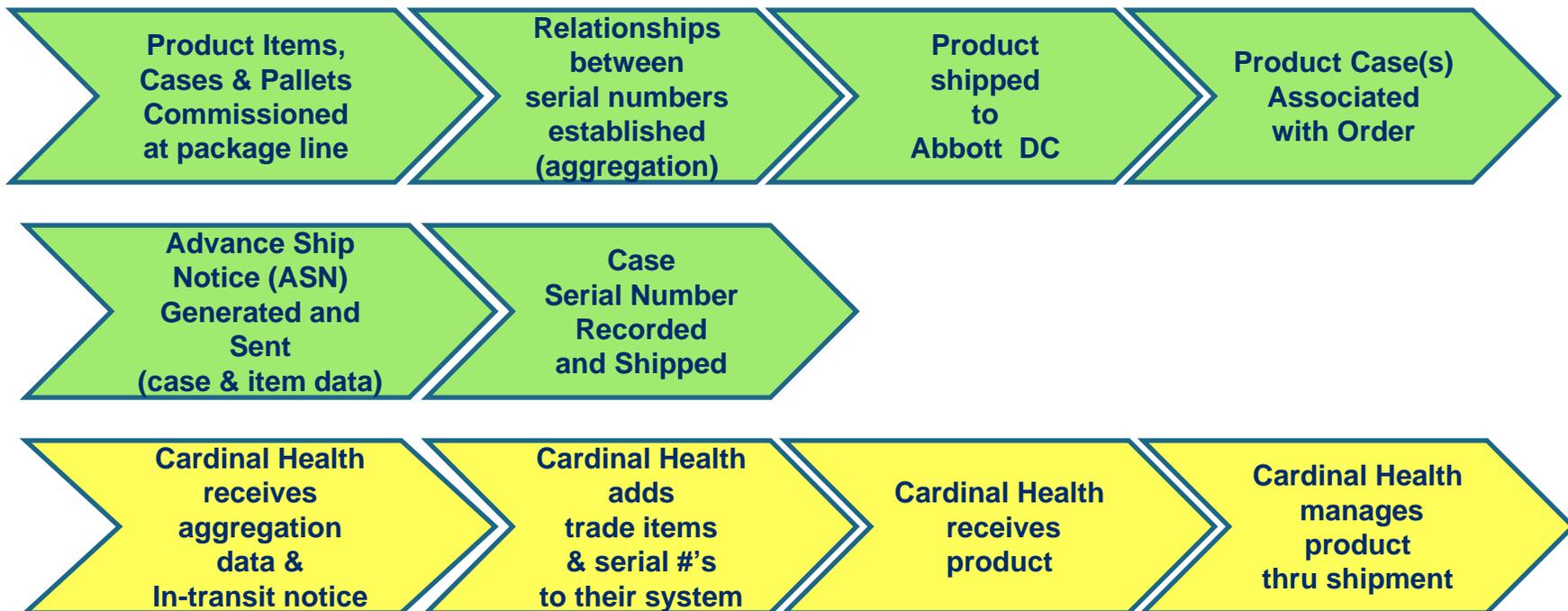


# Early Pilot Trade Learning

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- **Consultant expertise and vendor solutions are not mature**
- **Data Carrier**
  - RFID technology is complex and expensive
- **DPMS ePedigree worked but problematic**
  - Large data files
  - Duplicates data
  - Does not properly leverage master data
  - Communicates extraneous data when pedigrees are split
- **Advance Ship Notices not accepted / utilized by all trade partners**
- **Trade Process**
  - Aligned industry interpretation of acceptable trade model does not exist
  - Trade based on aggregation data creates risks when exceptions occur invalidating the certification of shipped items

# Abbott / Cardinal Health Pilot – High Level Process



- Both organizations are gaining knowledge
- Processes are very complex
- Systems being developed
- Exception handling requires effort from both teams

# Abbott Pilot Experiences

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## Lessons Learned Summary

Issues were found in four general categories: Serialization, Aggregation, Vendor and Process

Most prevalent were Serialization issues, but the most difficult to resolve are related to Aggregation

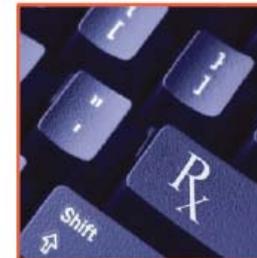


Pilot Report

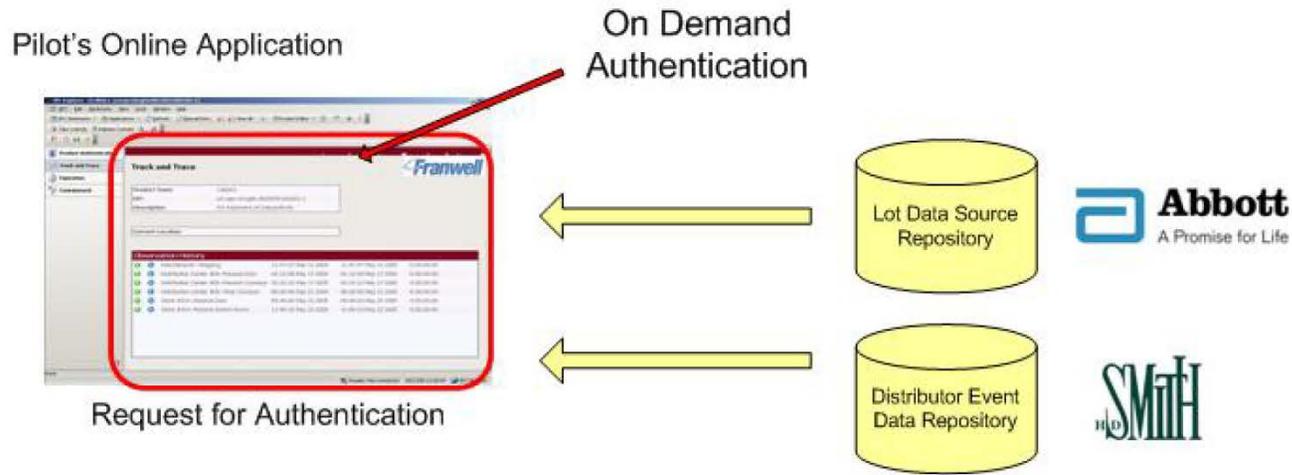
## Lessons Learned About Serialization

*Using GS1 Standards*

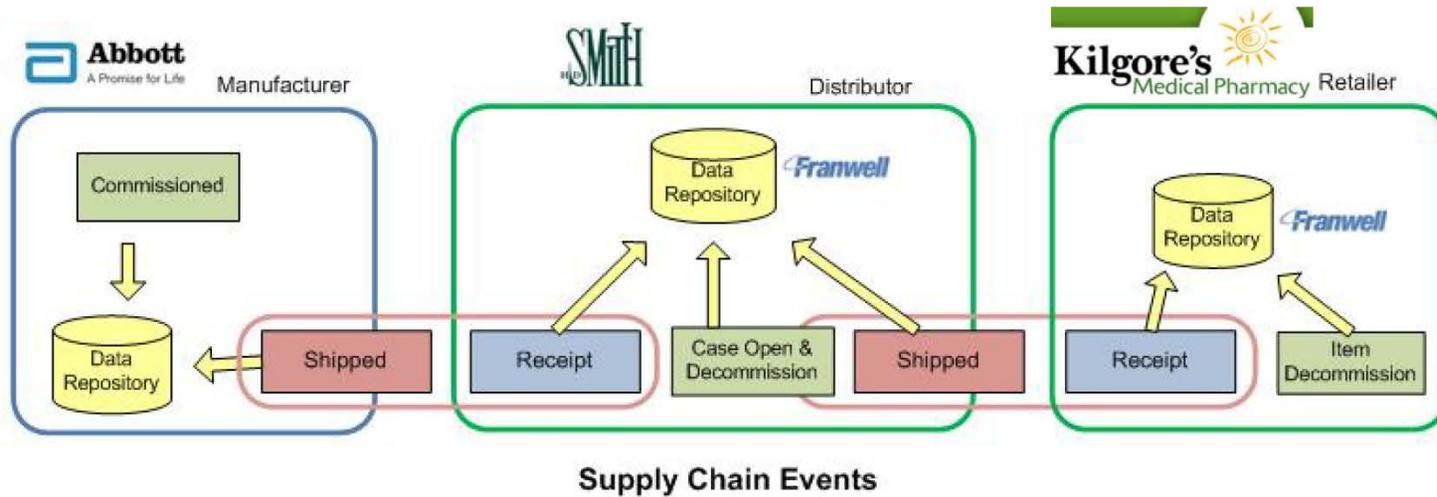
Experiences of a Pharmaceutical Manufacturer



# POC Pilot – Abbott & H.D. Smith – January, 2010



## Chain of Custody

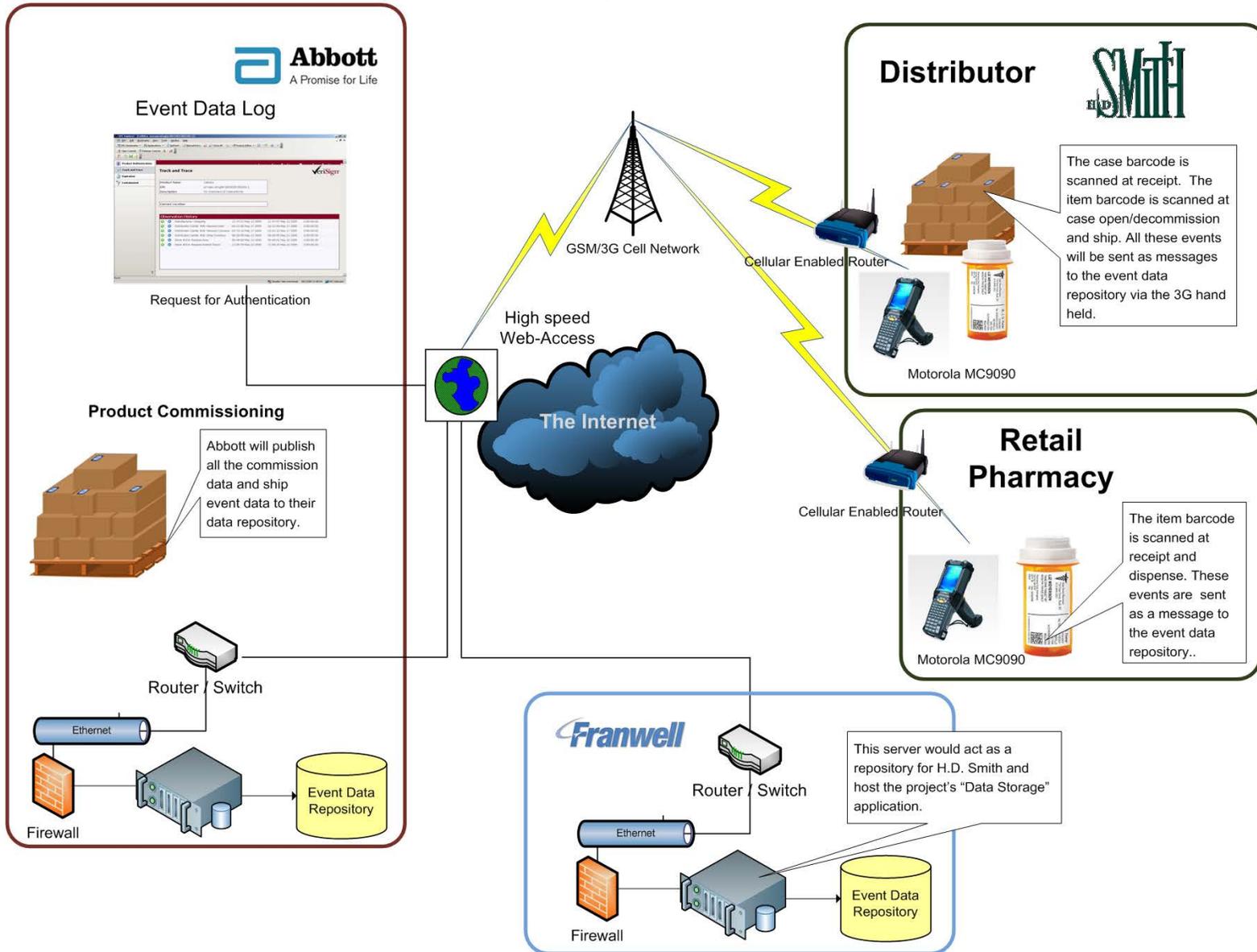


# Abbott-HD Smith Pilot Trades

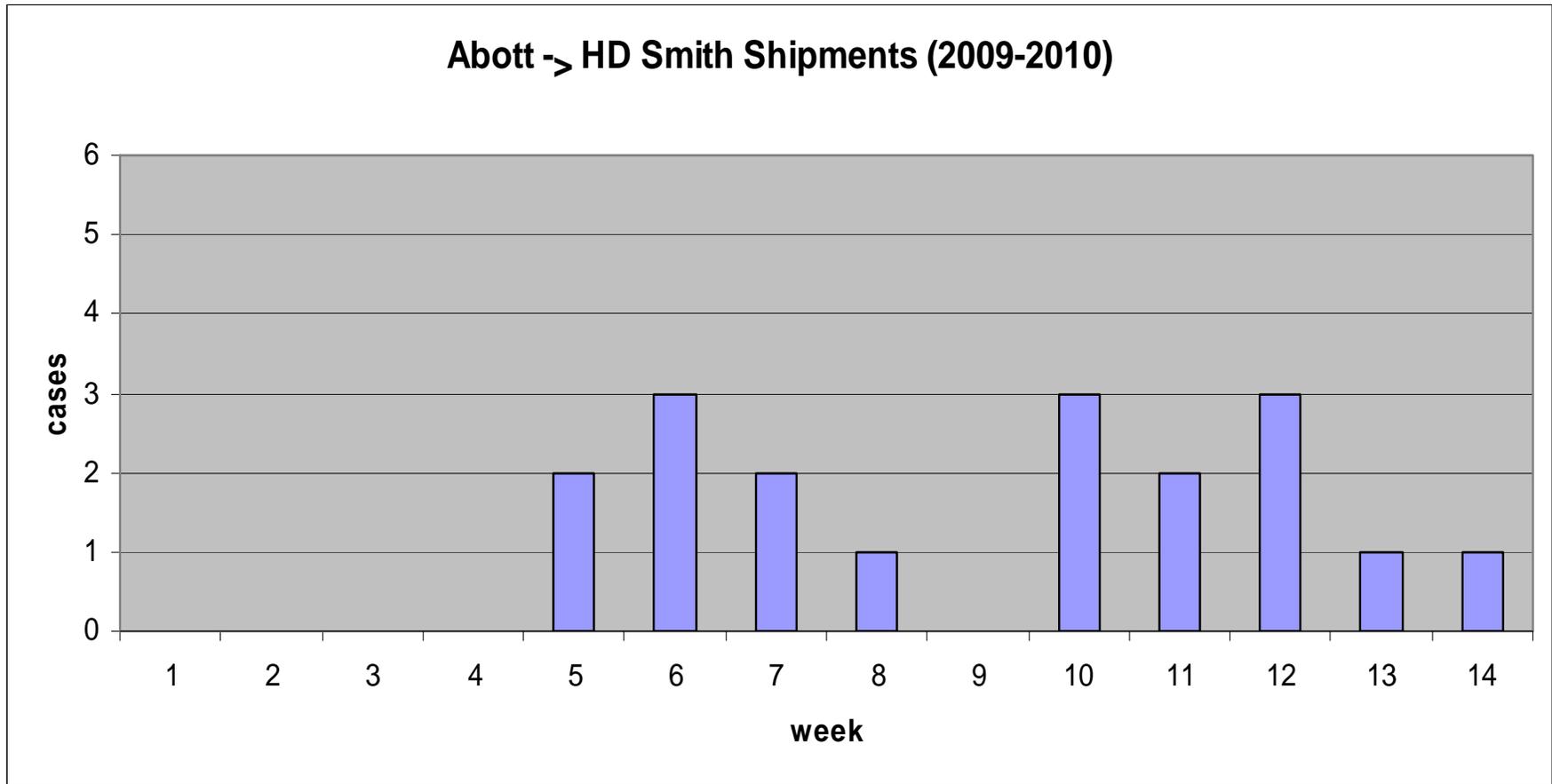
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- 1 HD Smith Distribution Center
- 2 Pharmacies (Kilgores, Complete Care)
- 14 weeks of trades
- Orders placed via EDI
- Serialized ASN sent via email (not EDI)
  - **Aggregated hierarchies not provided by Abbott**
- Quantities: 1-4 Cases per week
- Product scanned when shipped from Abbott's DC
- Product scanned when received/shipped @ HD Smith DC
- Product scanned when received/dispensed @ HD Smith Pharmacy

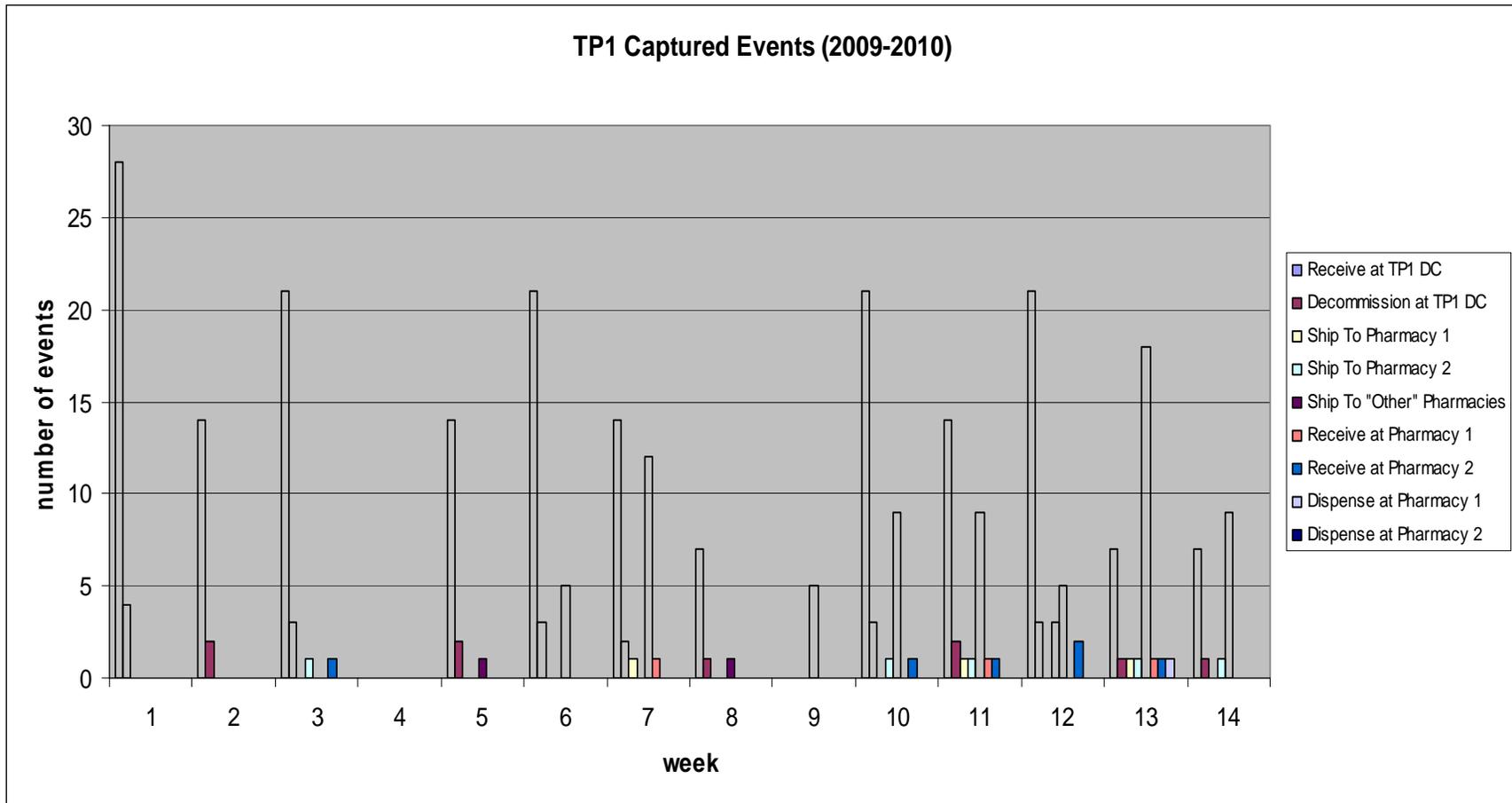
# HD Smith Pilot Topology using Cell and/or 802.11 infrastructure



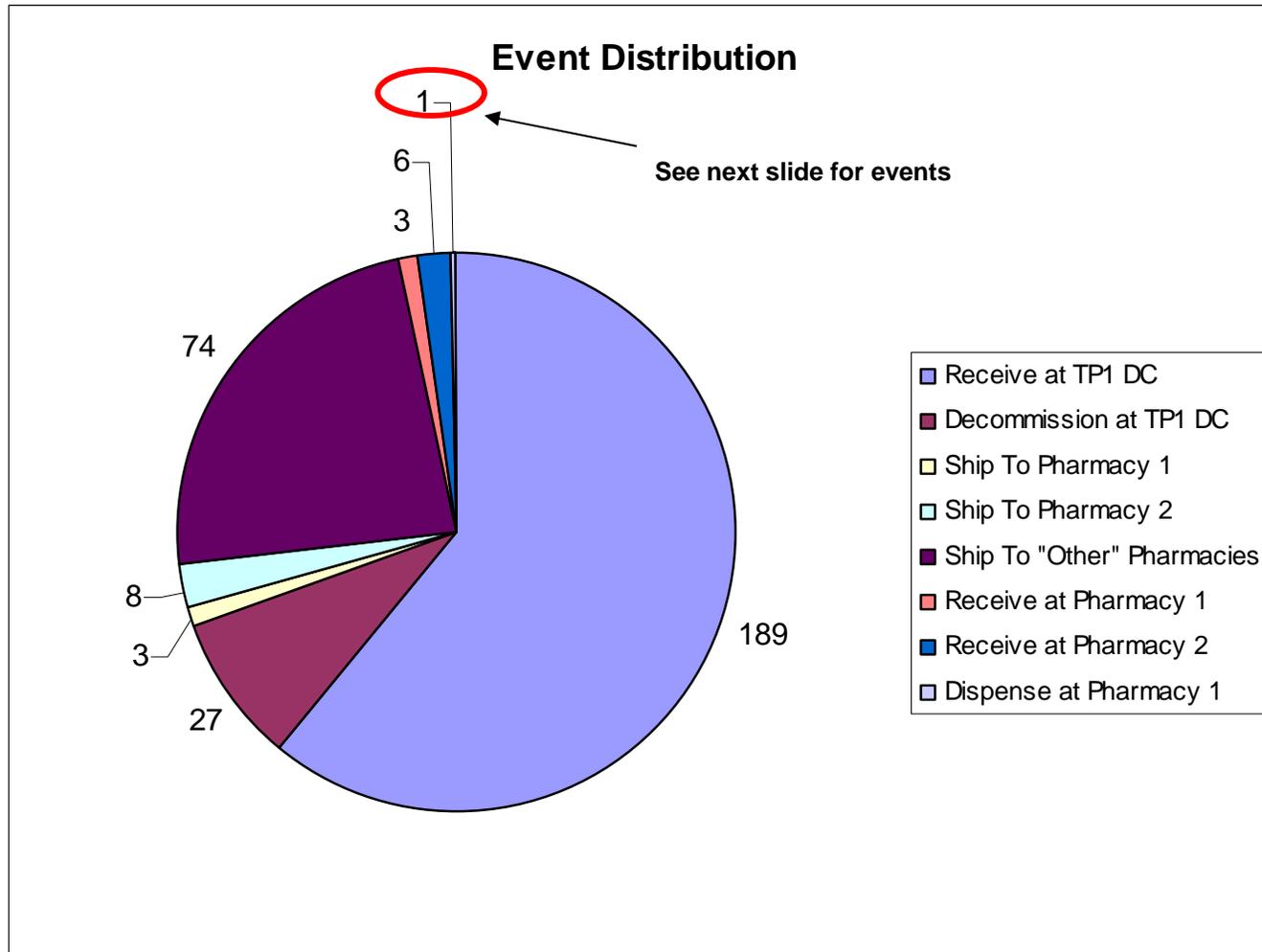
# Humira TnT Pilot Metrics – HD Smith



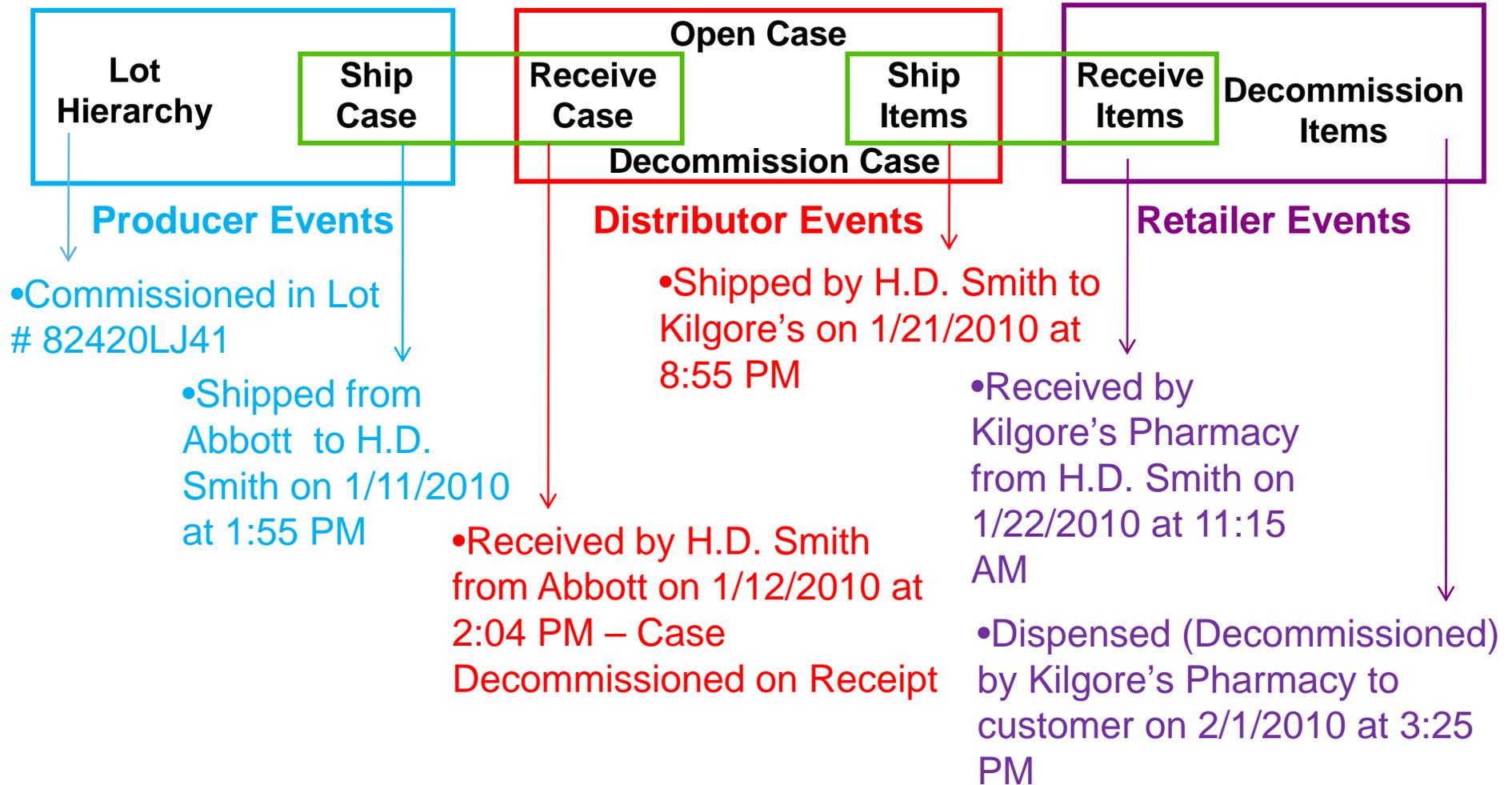
# Humira TnT Pilot Metrics – HD Smith



# Humira TnT Pilot Metrics – HD Smith



# The chain of events for Item 010030074379902621100000128047



# Abbott/HD Smith Pilot: End-To-End Visibility



**Object Event:** ADD  
**TIME:** 30 Oct 17:50  
**EPC:** SGTIN (item)  
**Biz Loc:** Abbott Manuf.  
 Plant/Line  
**BIZ STEP:** commissioning  
**DISP:** active  
**EXT:** Lot 78376LJ40

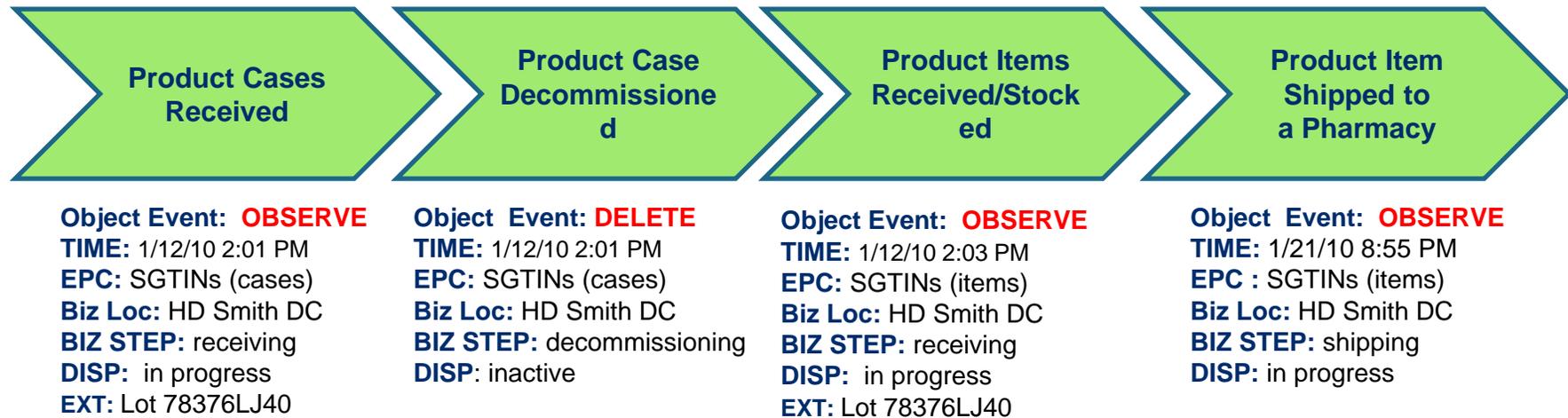
**Object Event:** ADD  
**TIME:** 30 Oct 18:30  
**EPC:** SGTIN (case)  
**Biz Loc:** Abbott Manuf.  
 Plant/Line  
**BIZ STEP:** commissioning  
**DISP:** active  
**EXT:** Lot 78376LJ40

**Aggregation Event:** ADD  
**TIME:** 30 OCT 18:30  
**Parent EPC:** SGTIN  
 (case)  
**Child EPCs:** SGTINs  
 (cartons)  
**Biz Loc:** Abbott Manuf  
 Plant/Line  
**BIZ STEP:** packing  
**DISP:** in progress

**Object Event:** OBSERVE  
**TIME:** 1/11/10 10:15 AM  
**EPC :** SGTINs (cases & items)  
**Biz Loc:** Abbott DC/Shipping  
 Station  
**BIZ STEP:** picking  
**DISP:** in progress  
**EXT:** Lot 78376LJ40

Item Serial #: 010030074379902621100000128047  
 Case Serial #: 013030074379902721100000113194

# Abbott/HD Smith Pilot: End-To-End Visibility



Item Serial #: 010030074379902621100000128047  
Case Serial #: 013030074379902721100000113194

# Abbott/HD Smith Pilot: End-To-End Visibility

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Item Serial #: 010030074379902621100000128047  
Case Serial #: 013030074379902721100000113194

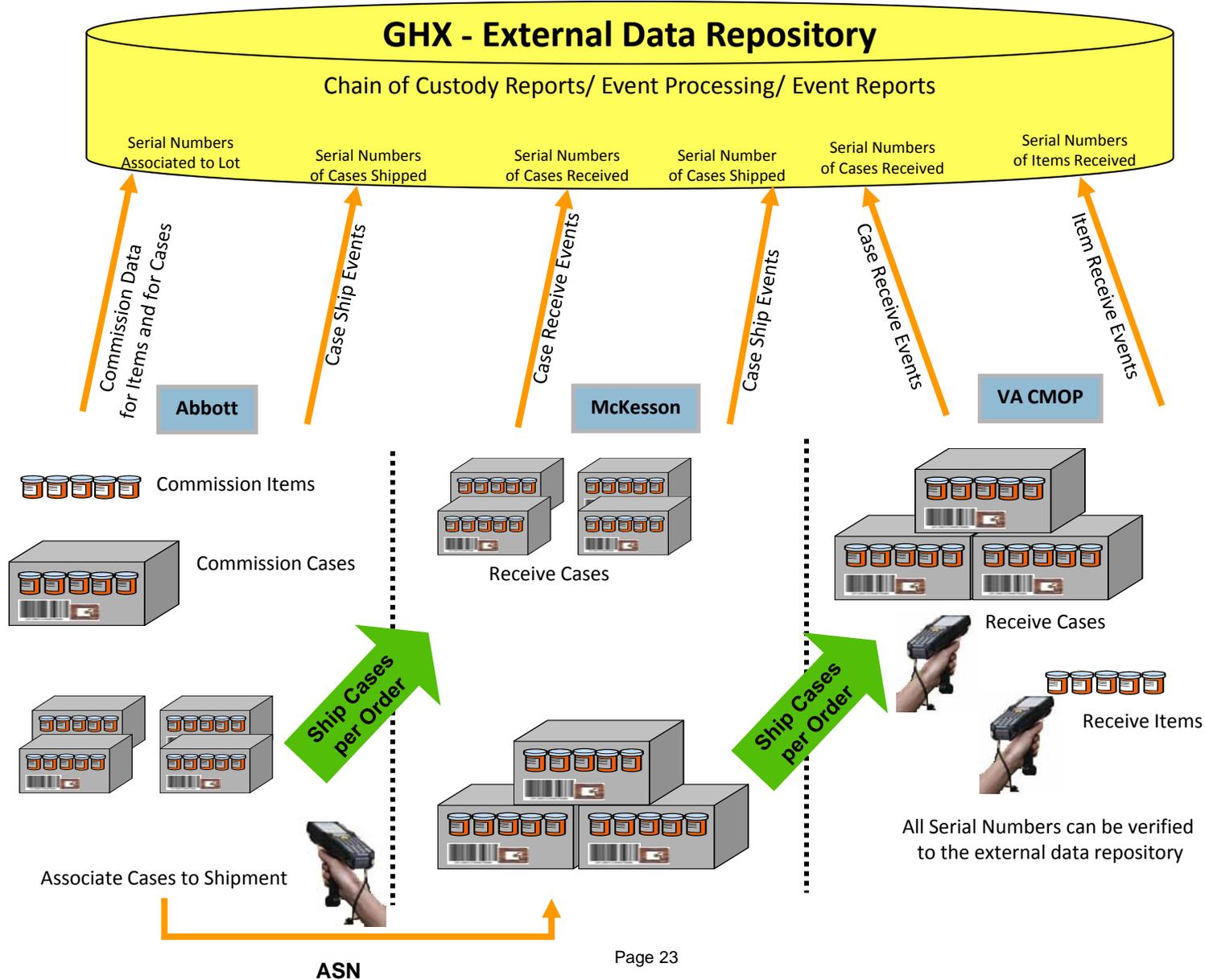
# Abbott/HD Smith Pilot: Chain of Custody

BUS STEP	BUS LOCATION	Serial Number	TIME STAMP
SHIP	ABBOTT DC	010030074379902621100000024844	12/7/10 10:15 AM
RECEIVE	HD SMITH WHLSE DC	010030074379902621100000024844	12/8/09 2:06 PM
SHIP	KILGOES MED PHCY	010030074379902621100000024844	12/22/09 8:32 PM
RECEIVE	KILGOES MED PHCY	010030074379902621100000024844	12/23/09 9:38 AM
SHIP	ABBOTT DC	010030074379902621100000128047	1/11/10 10:15 AM
RECEIVE	HD SMITH WHLSE DC	010030074379902621100000128047	1/12/10 2:03 PM
SHIP	KILGOES MED PHCY	010030074379902621100000128047	1/21/10 8:55 PM
RECEIVE	KILGOES MED PHCY	010030074379902621100000128047	1/22/10 11:31 AM
DECOMMISSION	KILGOES MED PHCY	010030074379902621100000128047	2/1/10 3:26 PM
SHIP	ABBOTT DC	010030074379902621100000129191	1/18/10 10:15 AM
RECEIVE	HD SMITH WHLSE DC	010030074379902621100000129191	1/19/10 12:18 PM
SHIP	KILGOES MED PHCY	010030074379902621100000129191	2/1/10 9:43 PM
RECEIVE	KILGOES MED PHCY	010030074379902621100000129191	2/2/10 9:46 AM

# Abbott/HD Smith Pilot: Chain of Custody

BUS STEP	BUS LOCATION	Serial Number	TIME STAMP
SHIP	ABBOTT DC	010030074379902621100000064407	11/9/09 10:15 AM
RECEIVE	HD SMITH WHLSE DC	010030074379902621100000064407	11/10/09 11:58 AM
SHIP	COMPLETECARE PHARMACY	010030074379902621100000064407	11/25/09 10:29 AM
RECEIVE	COMPLETECARE PHARMACY	010030074379902621100000064407	11/25/09 10:54 AM
SHIP	ABBOTT DC	010030074379902621100000128356	1/11/10 10:15 AM
RECEIVE	HD SMITH WHLSE DC	010030074379902621100000128356	1/12/10 2:03 PM
SHIP	COMPLETECARE PHARMACY	010030074379902621100000128356	1/25/10 11:39 PM
RECEIVE	COMPLETECARE PHARMACY	010030074379902621100000128356	1/26/10 10:36 AM
SHIP	ABBOTT DC	010030074379902621100000128432	1/11/10 10:15 AM
RECEIVE	HD SMITH WHLSE DC	010030074379902621100000128432	1/12/10 2:03 PM
SHIP	COMPLETECARE PHARMACY	010030074379902621100000128432	1/27/10 10:47 PM
RECEIVE	COMPLETECARE PHARMACY	010030074379902621100000128432	1/28/10 10:35 AM
SHIP	ABBOTT DC	010030074379902621100000129200	1/25/10 10:15 AM
RECEIVE	HD SMITH WHLSE DC	010030074379902621100000129200	1/26/10 12:26 PM
SHIP	COMPLETECARE PHARMACY	010030074379902621100000129200	2/3/10 12:14 AM
RECEIVE	COMPLETECARE PHARMACY	010030074379902621100000129200	2/4/10 3:07 PM

# Humira Pen Pilot – May 2012



# Abbott Posts Commissioned Serial Numbers by Lot



## Data Capture - Commission

Read Point

Biz Location

Scan Here

Date  YYYY-MM-DD

Time  HH:mm:ss (24 hour format)

Time Zone

Batch/Lot Number

Expiration Date  YYYY-MM-DD

[Commission](#) [Aggregation](#) [Ship](#) [Check](#) [Receive](#) [Disaggregation](#)



**Serial Numbers created for:**  
**Lot # 132172E**  
**15 pallets**  
**3,292 cases**  
**19,753 saleable items**  
**Total = 23,060**

05/14/2012 6:55:41 PM COMMISSIONING SGLN 030074.000000.0

**Business Step:** commissioning  
**Disposition:** active  
**Container Qty:** 7  
**Child Product Numbers:** sgtin 030074.3433902.100000003932  
sgtin 030074.0433902.100000063627  
sgtin 030074.0433902.100000063628  
sgtin 030074.0433902.100000063629  
sgtin 030074.0433902.100000063630  
sgtin 030074.0433902.100000063631  
sgtin 030074.0433902.100000063632

# Abbott Creates Relationships Between Serial Numbers



dleeAsEmployeeOfAbbott [LOGOUT](#)

## Data Capture - Aggregation

Read Point

Biz Location

Scan Parent Here

Scan Children Here

Date  YYYY-MM-DD

Time  HH:mm:ss (24 hour format)

Time Zone

[Commission](#) [Aggregation](#) [Ship](#) [Check](#) [Receive](#) [Disaggregation](#)

05/15/2012 6:01:32 PM AGGREGATION SGLN 030074.000000.0

**Business Step:** Aggregation  
**Disposition:** in\_progress  
**Parent Product Number:** sgtin 030074.3433902.100000003932  
**Container Qty:** 6  
**Child Product Numbers:** sgtin 030074.0433902.100000063627  
sgtin 030074.0433902.100000063628  
sgtin 030074.0433902.100000063629  
sgtin 030074.0433902.100000063630  
sgtin 030074.0433902.100000063631  
sgtin 030074.0433902.100000063632

# Abbott Posts Certifiable Ship Data



dleeAsEmployeeOfAbbott [LOGOUT](#)

## Data Capture - Ship

Sold From Party	Abbott Pharmaceutical Products
Ship From Location	Abbott Pharmaceutical Products
Sold To Party	0010939999000 - McKesson Financial Center
Ship To Location	0010939182000 - McKesson Sacramento
Read Point	Abbott Pharmaceutical Products
Biz Location	Abbott Pharmaceutical Products
Scan Here	(01) 30300744339024 (21) 100000003932

Date	2012-05-15	YYYY-MM-DD
Time	18:07:29	HH:mm:ss (24 hour format)
Time Zone	Central	
Related PO Number	8182869993	required
Related Invoice Number		optional
	<input type="button" value="Generate Shipping Event"/>	



05/15/2012 6:07:29 PM SHIPPING SGLN 030074.000000.0

**Business Step:** shipping  
**Disposition:** in\_transit  
**Container Qty:** 1  
**Child Product Numbers:** sgtin 030074.3433902.100000003932  
**Transactions:** undefined 8182869993

[Commission](#) [Aggregation](#) [Ship](#) [Check](#) [Receive](#) [Disaggregation](#)

# Distributor Receives Shipment Identifier



EmployeeOfMcKesson

## Data Capture - Check Case

Read Point

Biz Location

Scan Case

(01) 30300744339024 (21) 100000003932

[Commission](#) [Aggregation](#) [Ship](#) [Check](#) [Receive](#) [Disaggregation](#)

Distributor Checks Case for Consistency Before Receipt

# Distributor Receives Case – Closes Chain of Custody



EmployeeOfMcKesson

## Data Capture - Receive Case

Read Point

Biz Location

Case SGTIN

Case Status Consistent ✓

Scan Items

Date  YYYY-MM-DD

Time  HH:mm:ss (24 hour format)

Time Zone

Related PO Number  optional

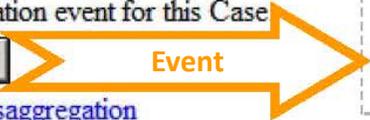
Related Invoice Number  optional

Disaggregation?  Also create Disaggregation event for this Case

[Commission Aggregation](#) [Ship Check Receive](#) [Disaggregation](#)

2012-05-16T23:53:05.366Z 2012-05-16T23:53:05.366Z RECEIVING SGLN 0010939.18211.0

**Business Step:** receiving  
**Disposition:** in\_progress  
**Container Qty:** 1  
**Child Product Numbers:** sgtin 030074.3433902.100000003932  
**Transactions:** po 8182869993



# Distributor Posts Certifiable Ship Data



EmployeeOfMcKesson

## Data Capture - Ship

Sold From Party	McKesson Financial Center	
Ship From Location	McKesson Sacramento	
Sold To Party	4703713051710 - Point of Receive 1	
Ship To Location	4703713051710 - Point of Receive 1	
Read Point	McKesson Sacramento	
Biz Location	McKesson Sacramento	
Scan Here	(01) 30300744339024 (21) 100000003932	
Date	2012-05-18	YYYY-MM-DD
Time	14:23:09	HH:mm:ss (24 hour format)
Time Zone	Pacific	
Related PO Number	C25018HPEN18	required
Related Invoice Number		optional
	Generate Shipping Event	Event

05/18/2012 2:23:09 PM SHIPPING SGLN 0010939.18200.0  
**Business Step:** shipping  
**Disposition:** in\_transit  
**Container Qty:** 1  
**Child Product Numbers:** sgtin 030074.3433902.100000003932  
**Transactions:** undefined C25018HPEN18

[Commission Aggregation](#) [Ship](#) [Check](#) [Receive](#) [Disaggregation](#)

# VA Receives Shipment Identifier



EmployeeOfVA [LOGOUT](#)

## Data Capture - Check Case

Read Point

Biz Location

Scan Case

VA Check Case for Consistency Before Receipt

[Commission](#) [Aggregation](#) [Ship](#) [Check](#) [Receive](#) [Disaggregation](#)

# VA Receives Case – Closes Chain of Custody



EmployeeOfVA

## Data Capture - Receive Case

Read Point

Biz Location

Case SGTIN urn:epc:id:sgtin:030074.3433902.100000003932

Case Status **Consistent** ✓

Scan Items

(01) 00300744339024 (21) 100000063627
(01) 00300744339024 (21) 100000063628
(01) 00300744339024 (21) 100000063629
(01) 00300744339024 (21) 100000063630
(01) 00300744339024 (21) 100000063631
(01) 00300744339024 (21) 100000063632

Date  YYYY-MM-DD

Time  HH:mm:ss (24 hour format)

Time Zone

Related PO Number  optional

Related Invoice Number  optional

Disaggregation?  Also create Disaggregation event for this Case

**Event**

[Commission Aggregation](#) [Ship](#) [Check](#) [Receive](#) [Disaggregation](#)

05/22/2012 12:36:49 PM RECEIVING SGLN 47037130.5171.0

**Business Step:** receiving  
**Disposition:** in\_progress  
**Container Qty:** 1  
**Child Product Numbers:** sgtin 030074.3433902.100000003932

---

05/22/2012 12:36:49 PM DISAGGREGATION SGLN 47037130.5171.0

**Business Step:** Disaggregation  
**Disposition:** in\_progress  
**Parent Product Number:** sgtin 030074.3433902.100000003932  
**Container Qty:** 6  
**Child Product Numbers:** sgtin 030074.0433902.100000063627  
sgtin 030074.0433902.100000063631  
sgtin 030074.0433902.100000063628  
sgtin 030074.0433902.100000063632  
sgtin 030074.0433902.100000063629  
sgtin 030074.0433902.100000063630

## Welcome!

Use the tools below to create events and run reports.

### Run a Report

Select the report you would like to run and fill in any corresponding fields.

**Product History**    **Product Number**

**Custody Report**

**Lot Report**

**Run Report**

### Submit a Custody Check

Submit a custody check by filling in the Product Number, Business Step, and Location to the right.

**Product Number**

**Location**

-- Select Business Step -- ▾

**Submit Check**

### Submit a Recall

[ Content ]

**Lot Number**

**Submit a Recall**

### Create An Event

Create events or upload event documents for up to five Product Numbers at once. Start by selecting the type of event you would like to upload.

**Upload Event Document**

## Product History

Product Number	Date	Event Sequence State	Location	Business Step	Disposition
sgtin 030074.3433902.100000003932	05/22/2012	Consistent	sgln 47037130.5171.0	Disaggregation	in_progress

### Drug Information

ID: **0074433902**  
 Brand Name: **Humira Pen**  
 Generic Name: **Adalimumab**  
 Label Name: **HUMAN PRESCRIPTION DRUG**  
 Package Description: **2 KIT in 1 CARTON**  
 Package Size:  
 Drug Strength: **0.8 mL**  
 Package Quantity:  
 Drug Form: **SYRINGE**  
 Classification: **TNF Blocker**

### Chain of Custody

<a href="#">commissioning</a>	05/14/2012 6:55:41 PM	sgln 030074.000000.0
<a href="#">Aggregation</a>	05/15/2012 6:01:32 PM	sgln 030074.000000.0
<a href="#">shipping</a>	05/15/2012 6:07:29 PM	sgln 030074.000000.0
<a href="#">Custody Check</a>	2012-05-15T23:02:10.909Z 2012-05-15T23:02:10.909Z	Good
<a href="#">Custody Check</a>	2012-05-16T14:06:03.587Z 2012-05-16T14:06:03.587Z	Good
<a href="#">Custody Check</a>	2012-05-16T16:08:31.506Z 2012-05-16T16:08:31.506Z	Good
<a href="#">Custody Check</a>	2012-05-16T16:16:50.870Z 2012-05-16T16:16:50.870Z	Good
<a href="#">Custody Check</a>	2012-05-16T16:19:20.686Z 2012-05-16T16:19:20.686Z	Good
<a href="#">Custody Check</a>	2012-05-16T16:23:36.426Z 2012-05-16T16:23:36.426Z	Good
<a href="#">Custody Check</a>	2012-05-16T16:29:12.886Z 2012-05-16T16:29:12.886Z	Good
<a href="#">Custody Check</a>	2012-05-16T17:43:37.986Z 2012-05-16T17:43:37.986Z	Good
<a href="#">Custody Check</a>	2012-05-16T18:59:12.216Z 2012-05-16T18:59:12.216Z	Good
<a href="#">receiving</a>	2012-05-16T23:53:05.366Z 2012-05-16T23:53:05.366Z	sgln 0010939.18211.0
<a href="#">shipping</a>	05/18/2012 2:23:09 PM	sgln 0010939.18200.0
<a href="#">receiving</a>	05/22/2012 12:36:49 PM	sgln 47037130.5171.0
<a href="#">Disaggregation</a>	05/22/2012 12:36:49 PM	sgln 47037130.5171.0
<a href="#">Custody Check</a>	2012-05-22T16:36:49.701Z 2012-05-22T16:36:49.701Z	Good
<a href="#">Custody Check</a>	2012-05-25T14:34:27.216Z 2012-05-25T14:34:27.216Z	Good
<a href="#">Custody Check</a>	2012-05-25T19:18:08.844Z 2012-05-25T19:18:08.844Z	Good

## Custody Report

Product Number	Date	Event Sequence State	Location	Business Step	Disposition
sgtin 030074.3433902.100000003932	05/14/2012	Consistent	sgln 030074.000000.0	shipping	in_transit

### Drug Information

ID: **0074433902**  
Brand Name: **Humira Pen Case**  
Generic Name: **Adalimumab**  
Label Name: **HUMAN PRESCRIPTION DRUG**  
Package Description: **6 CARTON in 1 CASE**  
Package Size:  
Drug Strength: **0.8 mL**  
Package Quantity:  
Drug Form: **SYRINGE**  
Classification: **TNF Blocker**

### Custody Checks

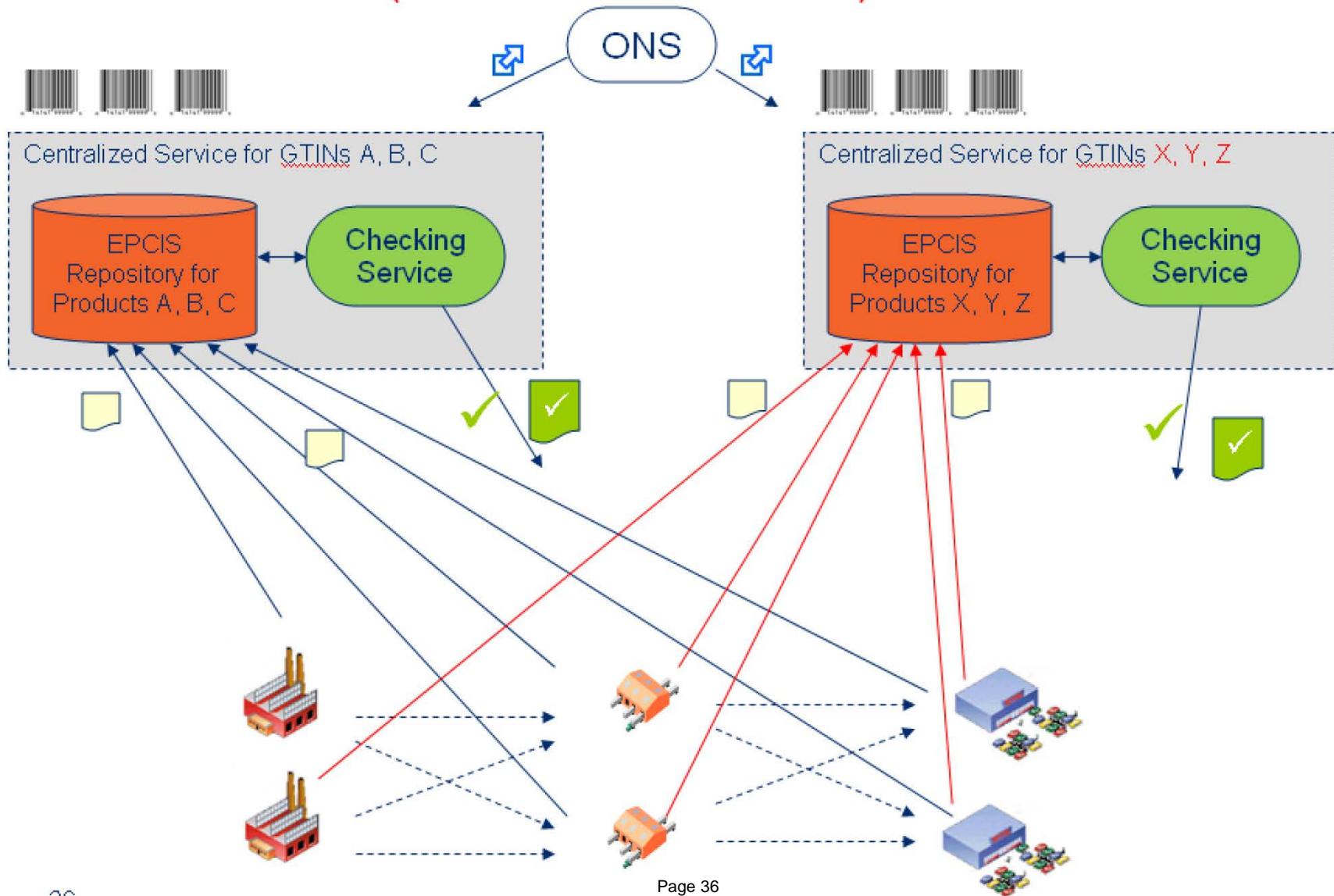
<a href="#">n/a</a>	2012-05-15T23:02:10.909Z	sgln 030074.000000.0
<a href="#">n/a</a>	2012-05-16T14:06:03.587Z	sgln 030074.000000.0
<a href="#">n/a</a>	2012-05-16T16:08:31.506Z	sgln 030074.000000.0



		Avoid delays to receiving / shipping operations			Data ownership and confidentiality		Data availability			Improvements over DPMS			
		Shipping party pre-advises receiving party of EPCs to be received, enabling receiving party to perform pedigree data check before goods arrive	Checking report is available to shipping party and can be transmitted to receiving party (to remove the need for them to gather data and perform check)	Checking procedure can be optimized to remember the time window for which checking has already been performed for that SGTIN (may speed up checking)	Each party independently decides where to store the data they contribute to the pedigree information trail	Ability to limit access to upstream-only and visibility granted only to parties within individual supply chain path of each SGTIN	All pedigree data for a specific SGTIN can be found in a single location	No need for receiving party to gather event data (because all concise summary reports (whitelists) of prior checks are pushed to the receiving party)	Enforceable contracts in place with all relevant repositories to ensure access to all required data for a specific SGTIN	Only need to transmit and store concise checking receipts (verified whitelists of EPCs with complete & consistent pedigree) from upstream parties	Ability to outsource checking burden	Ability to quickly/cheaply do forward tracking (subject to access control policies allowing for downstream visibility)	
Centralized	Centralized with checking service	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	
	Semi-centralized (per GTIN) with checking service	Y	Y	Y	only brand owner decides	Y	Y	Y	Y	Y	Y	Y	
Distributed + push of links	Distributed with push of links	Y	local checking applications may be used	N	Y	Y	N	N	N	N	local checking applications may be used	N	
Distributed	Distributed	Y		N	Y	Y	N	N	N	N		N	N
	Distributed with Discovery Services	Y		N	Y	Y	N	N	N	N		N	Y
	Distributed with Discovery Services and Checking Service	Y	Y	Y	Y	Y	N	Y	N	Y	Y	Y	



# Semi-centralized model [per GTIN] (architectural model)



# Aggregate and Inference

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## Inference

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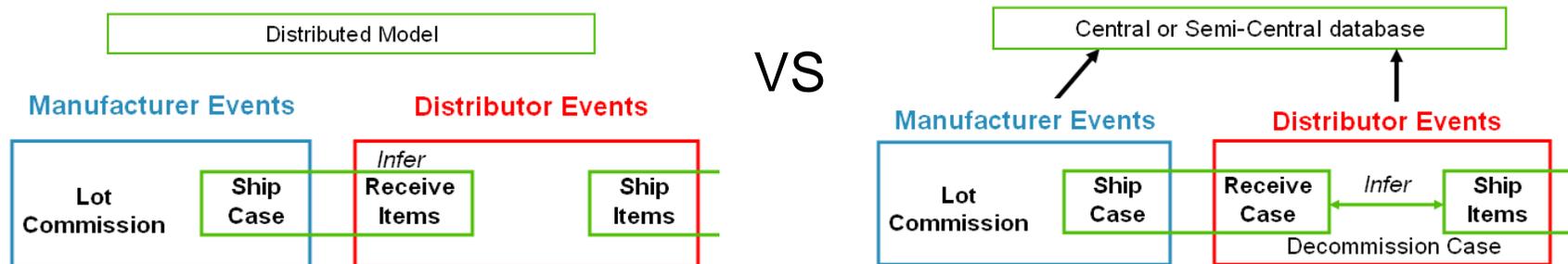
- ❑ Board will need to establish regulations to allow
- ❑ Allows a unique identifier to be applied to a case, pallet or other “aggregate” without individually reading each serialized unit
- ❑ Specifies intent that Mfgs, wholesalers and pharmacies distribute and receive electronic pedigrees, and verify and validate pedigrees at the unit level except where efficiency and safety can be secured through inference

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Inference can be applied by association of items to the logistical units that were received in a secure trade. (case or pallet of cases)

All packaging levels are serialized and can be verified back to commission data.

# Model Comparisons



- The DPMS Distributed model is dependant on certification of inferred items
- Inference in a Semi-Central model occurs within a companies four walls
- Consider that one case label error would have created multiple aggregation exceptions that could impact multiple trade partners
  - If case A is wrong then likely case B & C are wrong
  - Who received case B & C?
  - Is a recall necessary?
  - Am I in control of my process?

# Key Concepts & Terminology (2)

FOR DISCUSSION ONLY

## Interoperability

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

## Authentication

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

## Data Management

- provides standardized mechanisms that supply chain participants use to capture, store, protect, and utilize track-and-trace data to facilitate authentication and interoperability. These mechanisms may include information for ensuring compliance of and accountability for established processes, as well as corrective action if these processes are not followed.

## Track-and-trace data

- Any information collected about each package from the point of manufacture to the point of dispense or destruction

## Pedigree

- Distribution history of a drug package

## Accountability

- When a person or entity has to report, explain, justify, or be responsible for effectively takes custody or ownership of a package

## Status

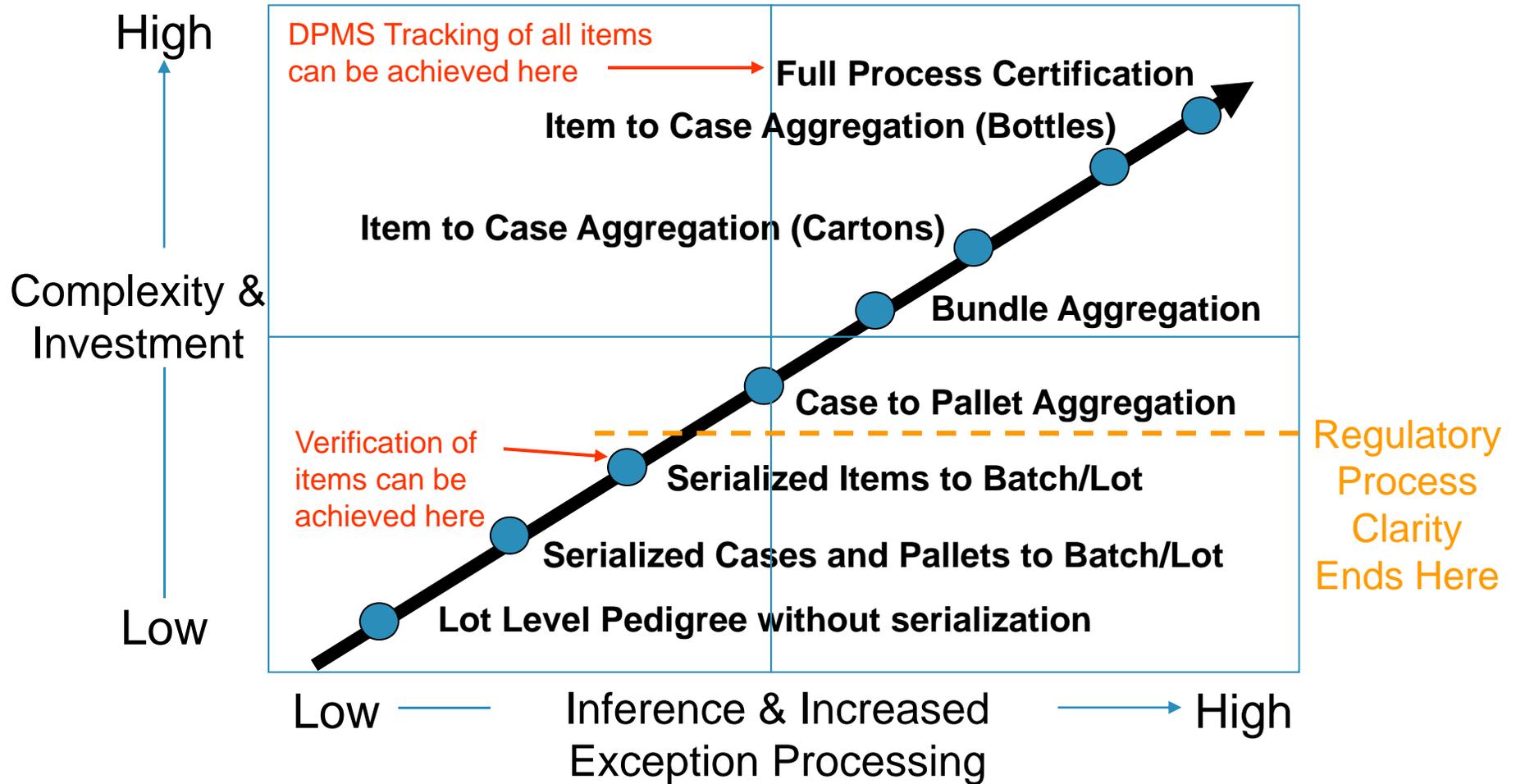
- The description of the disposition of the package as it moves through the supply chain (e.g., recall in process, in transit, destroyed, dispense, stolen, etc.)



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

# Trade Model Considerations

Segregated databases require 100% accuracy to facilitate Inference



# Desired Industry Implementation Approach

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## **Abbott supports a phased approach to enable the market for serialization**

- We believe this reduces overall operational risk and cost, allows technology providers to mature, and creates an environment where a logical overall solution can emerge enabling all stakeholders in the supply chain to achieve meaningful participation to protect the patient.

### **Phase 1**

- Attain finished goods manufacturing capability to serialize every item, case and pallet within a specific homogenous packaged lot
- Develop accurate case to pallet aggregation at manufacturing
- Attain at distribution facilities the ability to accurately aggregate a mixed case (non-homogenous) of serialized items
- Utilize a central or semi-central database to enable downstream Authentication, Trace capabilities and Pedigree reporting

### **Phase 2**

- Attain at manufacturing the ability to accurately identify relationships (aggregation) of items within a homogenous packaged lot as practicable to improve business processes
- Work with Industry to improve accuracy in an industry developed Track & Trace system
- Support development of business rules for decommission of serial numbers

## **Abbott desires definition and acceptance of an industry trade model**

# Thank you

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# Attachment 8



**California State Board of Pharmacy**

1625 N. Market Blvd, N219, Sacramento, CA 95834  
Phone: (916) 574-7900  
Fax: (916) 574-8618  
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
GOVERNOR EDMUND G. BROWN JR.

June 17, 2012

Sent via email to:

Kathleen Laird ([Kathleen\\_Laird@help.senate.gov](mailto:Kathleen_Laird@help.senate.gov))

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Subject: Enhancing Pharmaceutical Distribution Integrity Act of 2012  
Comments of the California State Board of Pharmacy

Dear Ms. Laird, Ms. Stuntz, Mr. Edattel and Mr. Patel:

On behalf of the California State Board of Pharmacy, we are submitting the following comments on amendments to add the Pharmaceutical Distribution Integrity Act into the Federal Food, Drug and Cosmetic Act. Thank you for providing this additional opportunity to provide our comments, which are being made on a draft released and dated 6/16/12.

First, just a short reminder about our history with establishing requirements for supply chain integrity. The board has been working for more than nine years on requirements to secure the supply chain against counterfeit, adulterated and other unfit medications being dispensed to patients. Our law has been on the books, in basically its present form, since 2004. That year, the FDA's Counterfeit Drug Task Force was assured by the industry that it would be feasible to have an RFID-based infrastructure for e-pedigree/track-and-trace in place and operational by 2007. Based on that commitment, our law was first supposed to take effect in 2007 and now will take effect on a staggered basis from 2015 through mid-2017. It was postponed three times at the request of members of the supply chain that indicated that with a bit more time, they would be able to fully comply with California's law. This was most obviously and directly done in the "readiness letters" that were submitted to the Board during 2007 and early 2008, wherein members of the industry said that a Board decision to delay implementation from 2009 to 2011 was necessary and justified because although it would not be possible for them to be ready for implementation in 2009, they would be ready by 2011. The same logic was repeated in the 2008 legislative negotiations that led to the current implementation timeline (and explains why Senator Ridley-Thomas insisted on listing the companies who agreed, essentially, that this would be the last such extension of time to comply).

We believe there are several fundamental features that are crucial to a successful supply chain security infrastructure. These include:

- The e-pedigree/track-and-trace infrastructure should require participation by all supply chain participants, i.e., manufacturers, repackagers, wholesalers and dispensers should be required to both receive and be capable of passing electronic pedigree data, and comparing that data to products received. This is crucial not only to early detection and interdiction of any counterfeits, substandard, adulterated, or other suspicious products, but also to effective operation of the recall (and returns) system, and avoidance of diversion.
- The e-pedigree/track-and-trace infrastructure should require that each transaction be verified/validated at both ends, i.e., that the shipping/selling party should certify that the product it is shipping/selling is authentic and matches verified e-pedigree data it is transmitting, and that the receiving party should certify that the product it is receiving matches the verified e-

pedigree data received along with the product, and that the SNIs are verified/validated. Again this is important to detect substandard drugs at their entry into the supply chain.

- The system should be built and implemented using interoperable, non-proprietary formats and transmission protocols.
- The e-pedigree/track-and-trace infrastructure should serialize products to the unit (saleable package) level, and track product at that level.
- However, with respect to "tracking at the unit level," while we expect that trading partners will be certifying and authenticating to the unit level, we acknowledge that full unit-level certification and tracking would impose logistical hurdles (e.g., having to open every box and scan each bottle) that may not be feasible or advisable. As such, California's law provides for possible use of inference and thus of some use of aggregation. What exactly this means and how it would be employed is something that we are still figuring out and negotiating in California at the current time. But in theory it should be possible to allow members of the industry to "certify" the contents of an aggregate container (for instance, a case of 48 bottles) for purposes of passing that container (unopened) to its trading partner (without scanning the bottles inside), by allowing that entity to scan an aggregate numerical identifier (e.g., an SNI or similar serial number on the case), and to "infer" that the contents of the case are what were promised by the prior trading partner that packed the case and affixed the case-level identifier. However, the circumstances under which this kind of inference based on aggregation will be allowed still need to be determined.

With respect to the pending federal legislation (which we will reference below as RxTEC):

- ISSUE: In Phase II, the current RxTEC proposal would permit the FDA to propose regulations to require unit level serialization by all members of the supply chain through a negotiated rulemaking process no earlier than 10.5 years after enactment. Implementation of any regulations, once adopted, would thus be even longer.

Unfortunately, we do not believe that the current draft of the proposed legislation would establish a system meeting any of these essential criteria to protect the supply chain. It certainly would not do so immediately, and any chance for improvement above the system set forth in Phase I of the legislation would have to wait for far more than 10 years, and would have to somehow emerge from a very uncertain and unpredictable negotiated rulemaking by the FDA.

We cannot help but recall that under similar circumstances, under the PDMA, the FDA was likewise tasked with rulemaking on pedigree matters. That rulemaking took over 12 years to emerge, and was never fully implemented, and here we stand approximately 25 years after enactment of the PDMA and that law has never had its intended effect. For this reason as well as several others that we will outline below, we cannot support the current draft of the proposed legislation, and instead urge passage of something that would by a date certain guarantee the system we described above.

Meanwhile, the system described in Phase I of the current draft would be far less robust and secure than the system attributes we describe above. Among other things, the proposed law does not require that any participant in the supply chain track products at the unit level, does not require that even lot-level tracking be verified and validated at each distribution point (only upon request, not as a routine matter), does nothing to secure the integrity of returns, and does not require any verification or passage of data by dispensers. In numerous ways, we believe that the system as described in Phase I does not contain attributes necessary to interdict the counterfeits and other substandard products that we know are in the supply chain.

We again respectfully request reconsideration and substantial shortening of the timeline proposed in RxTEC by which the FDA would be able to initiate future regulations requiring track and trace systems that include the specific parameters identified by the board above. We also request that instead of

proposing regulations in a negotiated rulemaking, the FDA be directed to develop regulations for implementation within a substantially earlier timeframe and by a date certain.

The board also has additional serious issues with other areas of RxTEC:

- ISSUE: Section 12089: Uniform National Policy. This section would provide that . . . no state or political subdivision of a state may establish or continue in effect any requirement for manufacturers, repackagers, wholesale distributors or dispensers, as defined in section 581 of the Federal Food, Drug, and Cosmetic Act, with respect to identifying each prior sale, purchase or trade of prescription drugs (including requirements for paper or electronic pedigree systems of for tracking and tracking drugs throughout the distribution system) which is different from, or in addition to, any requirement of subchapter H of chapter V of the Federal Food, Drug and Cosmetic Act.

This section is very broad and would not only preempt California's pedigree laws, but would quite possibly also have the far greater effect of preempting California's as well as all other states' laws related to records that track acquisition and distribution of prescription drugs -- including normal inspection/regulatory laws that permit this board and other regulators to request and review invoices, packing slips, etc. If the board loses the ability to conduct investigations using all paper or other records that identify sales, purchases, or trades, the board will essentially lose everything it needs to regulate licensees generally.

- ISSUE: Section 1207(b) and (c)(3) Federal Licensing Standards for 3PLs. This section requires a 3PL to be licensed as a wholesaler by the state in which the company is located; however, section (c)(3) directs that a state may only enforce federal requirements -- it cannot enforce any state requirements.

As the licensing authority and regulator, the state should be able to establish state-specific requirements for the operations of the businesses and not be specifically precluded from doing so. We have no objection to setting minimum national standards, but the regulating state must remain able to respond to issues more locally and immediately to protect its citizens.

- ISSUE: Each of the sections for repackagers (section 582(b)(3)(E)(iii)), wholesalers (582(c)(3)(E)(iii)), and dispensers (582(d)(3)(E)(iii)) directs the destruction of confirmed illegitimate products unless the Secretary allows the product to reenter the supply chain. We strongly disagree with these provisions because destruction of the illegitimate product will inhibit any type of possible investigation that would occur into what compromise occurred, how it occurred, and perhaps where it occurred.

The ability to examine and assay a compromised product is integral to identifying the underlying problem. If members of the supply chain destroy suspect product too soon, it will make it even more difficult to assess what might have occurred to cause a compromise in a drug product.

- ISSUE: Section 582(a)(2)(d): This section permits manufacturers to check the RxTEC data for a case or product that is being returned to the supply chain for distribution.

The board cautions that some members of the supply chain are "recycling" manufacturers' containers and to be careful with the reentry practice authorized by this section. For example, the board is discovering pharmacies with hundreds of empty manufacturers' containers on their premises. These containers are being refilled -- illegally -- with medication from skilled nursing facilities and other unknown sources. RxTEC envisions that returned containers with valid RxTEC data carriers would be safe to reenter the supply chain; the board suggests extreme caution with this practice. (See attached pictures.)

- ISSUE: Section 582(g): Requires that all information required by this section be retained for two years from the date of creation. This requirement would mean that the data required by RxTEC to track lot, serial number, and expiration date (plus other items involving a transaction) would only be kept for two years.

The expiration date of drug products may exceed two years. Thus products in the supply chain more than two years potentially would not have even RxTEC data available to confirm their origin.

- ISSUE: Sections 582(a)(1)(B1), 582(b)(1)(d1) and 582(c)(1)(D1): permit returns from members of the supply chain only if they are licensed with the appropriate entities. The board cautions that the fact that a business or individual is appropriately licensed is no guarantee that the entity is operating legally, nor that the drugs it may return are not adulterated or counterfeited. As a state regulator over 130,000 licensees, we spend the bulk of our budget enforcing provisions against licensees. However, the board does note that buying from unlicensed sources is even riskier, because the entity would not be in a position to buy or trade drugs from legitimate entities.
- ISSUE: Section 582 (b)(1)(H)(ix)(III): Requires that repackagers receive a statement from the previous trading partner that such trading partner did not knowingly and intentionally ship an illegitimate product. The board notes that this statement is of little value in reality. In media coverage of the February 2012 Avastin counterfeit drugs episode (where a number of physicians bought an "Avastin" which actually had no active ingredient), one of the principals in the investigation stated that he did know the drug was counterfeit. Such statements are of little value to patients who receive drugs with no therapeutic ingredients.
- There are various anomalies or inconsistencies among the provisions as well. For example, repackagers do not have to obtain RxTEC data until four years after enactment of the act. However, repackagers are required to secure RxTEC data from wholesalers, who have five years to comply with the RxTEC provisions.

Also, pharmacies sometimes sell limited or small quantities of prescription drugs to other pharmacies, especially in emergency situations, yet section 582(d)(1)(A) does not include other pharmacies as a purchasing source of medication for pharmacies.

In closing, if enacted, this proposal will have substantial impacts on the distributing and dispensing of prescription drugs in the USA. We respectfully suggest wider review over a longer period of time for these provisions to be vetted to prevent against unintentional consequences that could jeopardize product and patient safety.

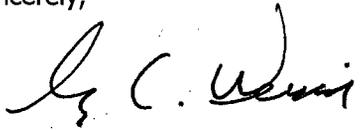
But most importantly, we again assert our opposition to the current proposal for Phase I and the construction and timeline of a possible, proposed Phase II. We desire federal legislation at the earliest possible time to require e-pedigree/track and tracing of prescription drugs for all entities that own the drug product as it ships through the supply chain to patients. We believe that nothing less will protect the safety of our drug supply and public health. The FDA needs to be specifically charged with this purpose and given a defined and substantially shorter timeframe to develop the requirements.

As additional background to these comments, we are also attaching one letter we mailed to several members of Congress providing our comments on a prior version of RxTEC. These comments are still relevant. We also are attaching pictures illustrating hundreds of empty manufacturers' containers in a pharmacy discovered during an investigation in California. Regrettably this is not the only pharmacy

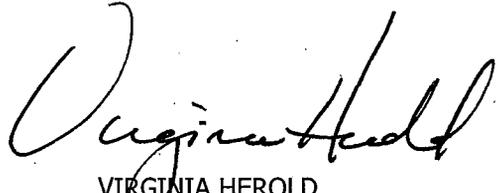
performing such practices have we have discovered. However, this is the type of compromised product that is so difficult to detect under existing laws and would remain equally difficult under proposed Phase I of RxTEC.

We commend all the individuals involved in the hard work put forth on this subject. Thank you for again considering our remarks. If you have questions, please do not hesitate to contact either of us at (916) 574-7911.

Sincerely,



STAN WEISSER, RPh  
President, California State Board of Pharmacy



VIRGINIA HEROLD  
Executive Officer

Attachments: Letter to Senator Harkin,  
Photos

# Attachment 9

# 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	638	2492
Closed	413	450	485	743	2091
Pending (at the end of quarter)	1772	1849	1944	1941	1941

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

Compliance Team	537	584	449	410	410
Drug Diversion/Fraud	226	318	297	276	276
Probation/PRP	101	119	132	87	87
Routine Inspection	33	85	266	260	260
Mediation/Enforcement **	64	82	146	214	214
Criminal Conviction	561	661	613	642	642

**Application Investigations**

Received	217	379	286	207	1089
Closed					
Approved	135	137	156	196	624
Denied	18	27	22	45	112
Total ***	243	224	269	297	1033
Pending (at the end of quarter)	209	363	409	305	409

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

LOAs Issued	20	21	29	77	147
Citations Issued	239	127	236	383	985
Citations Closed	273	190	215	234	912
Total Fines Collected ****	\$319,115.00	\$198,405.00	\$408,751.76	\$333,370.30	\$1,259,642.06

\* 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 6/30/2012 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	74	273
Pleadings Filed	61	56	48	66	231
<b>Pending</b>					
Pre-accusation	194	175	129	194	194
Post Accusation	279	265	248	224	224
Total*	533	515	438	461	461
<b>Closed</b>					

**Revocation**

Pharmacist	2	4	2	3	11
Intern Pharmacist	0	1	0	0	1
Pharmacy Technician	16	28	27	27	98
Designated Representative	1	0	0	1	2
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	1	1

**Revocation, stayed; suspension/probation**

Pharmacist	2	3	4	8	17
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	1	1	3
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0

**Revocation, stayed; probation**

Pharmacist	3	5	3	7	18
Intern Pharmacist	0	0	1	0	1
Pharmacy Technician	6	5	6	6	23
Designated Representative	0	0	0	1	1
Wholesaler	0	0	0	1	1
Pharmacy	3	3	2	7	14

**Surrender/Voluntary Surrender**

Pharmacist	0	3	5	4	12
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	7	8	9	8	32
Designated Representative	0	0	1	1	2
Wholesaler	0	0	0	1	1
Pharmacy	0	1	0	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	0	1
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	0	0	1	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Cost Recovery Requested**	\$88,205.00	\$279,912.20	\$215,489.00	\$674,685.00	\$1,258,291.20
Cost Recovery Collected**	\$77,917.99	\$65,379.59	\$133,920.99	\$192,499.99	\$469,718.56

\* This figure includes Citation Appeals

\*\* This figure includes administrative penalties

### Probation Statistics

#### Licenses on Probation

Pharmacist	111	110	130	131	131
Intern Pharmacist	5	3	5	4	4
Pharmacy Technician	31	35	42	50	50
Designated Representative	2	2	3	2	2
Pharmacy	18	20	25	27	27
Wholesaler	2	3	4	4	4
Probation Office Conferences	17	40	31	53	141
Probation Site Inspections	73	67	60	74	274
Probationers Referred to AG for non-compliance	2	1	0	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 June 30, 2012.

# SB 1441 – Program Statistics

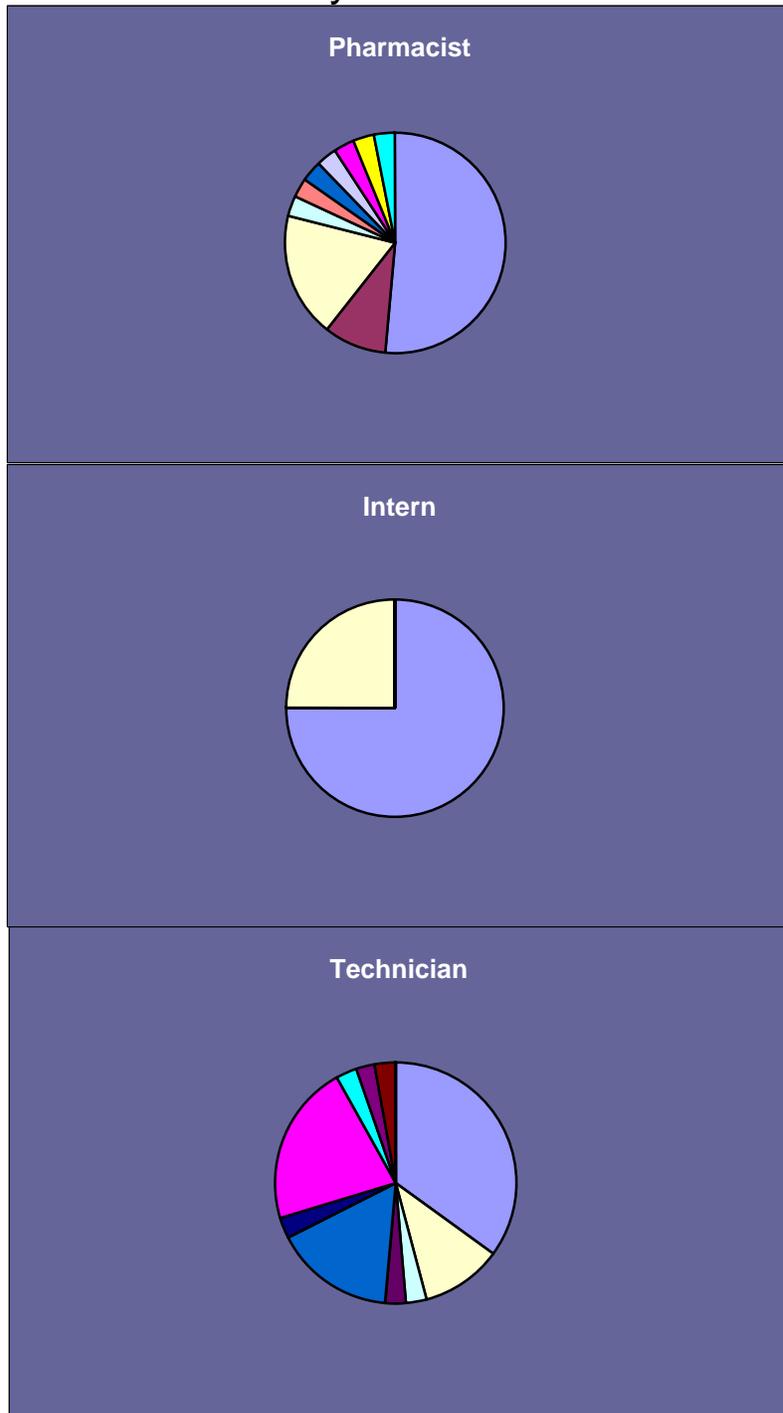
Pharmacist Recovery Program (PRP)

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 11/12
PRP Self-Referrals	3	0	1	2	6
PRP Board Referrals	2	0	2	2	6
PRP Under Investigation	3	5	1	3	12
PRP In Lieu Of	1	0	0	0	1
PRP Intakes	9	5	4	7	25
<b>New Probationers</b>	9	9	12	22	52
Pharmacists	2	3	5	10	20
Interns	0	0	1	0	1
Technicians	7	6	6	12	31
<b>Total PRP Participants</b>	76	80	76	72	N/A
Contracts Reviewed	70	76	72	68	286
	0	0	0	0	0
Total Probationers	100	95	110	119	424
Inspections Completed	97	106	91	127	421
<b>Referrals to Treatment</b>					
Referrals to Treatment	4	3	0	4	11
Drug Test Ordered	967	1076	1054	1170	4267
Drug Tests Conducted	1185	1294	973	1015	4467
<b>Relapsed</b>					
Relapsed	5	4	7	13	29
<b>Major Violation Actions</b>					
Cease Practice/Suspension	8	7	8	10	33
Termination - PRP	3	2	4	5	14
Referral for Discipline	3	2	0	0	5
<b>Exit from PRP or Probation</b>					
Successful Completion	2	3	1	13	19
Termination - Probation	2	3	1	0	6
Voluntary Surrender	2	1	4	3	10
Surrender as a result of PTR	0	1	0	0	1
Public Risk	3	2	4	5	14
Non-compliance	19	11	13	25	68
Other	1	2	1	1	5
Number of Patients Harmed	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	1	17
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	3	3
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	3	13
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	2	6
Heroin	0	0	0	0	0
Cocaine	0	0	0	1	1
Methamphetamine	2	1	1	4	8
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	7	0	13

# 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



# Board of Pharmacy Enforcement Statistics Three Year Comparison Corrected

## Workload Statistics

Total 09/10

Total 10/11

Total 11/12

### Complaints/Investigations

Received	2347	2425	2492
Closed	3909	2572	2091
Pending (at the end of fiscal year)	1033	1324	1941

### Cases Under Investigation (by Team) at end of fiscal year\*

Compliance	574	450	410
Drug Diversion/Fraud	103	175	276
Probation/PRP	102	78	87
Routine Inspection (Est. FY 2011/12)			260
Mediation/Enforcement	77	75	214
Criminal Conviction	590	524	642

### Application Investigations

Received	847	798	1089
Closed			
Approved	558	538	624
Denied	100	136	112
Total**	769	1021	1033
Pending (at the end of quarter)	423	223	409

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

LOAs Issued	362	186	147
Issued	1827	1043	985
Abated	1466	1172	912
Total Fines Collected ***	\$1,333,140.00	\$1,173,552.00	\$1,259,642.06

\* This figure does not include cases that have been submitted to the supervisor.

\*\* This figure includes withdrawn applications.

\*\*\* Fines collected and reports in previous fiscal year.

# Board of Pharmacy Enforcement Statistics Three Year Comparison Corrected

## Workload Statistics

Total 09/10

Total 10/11

Total 11/12

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

	Total 09/10	Total 10/11	Total 11/12
Referred to AG's Office*	354	375	273
Pleadings Filed	272	305	231
Pending			
Pre-accusation	185	188	194
Post Accusation	281	257	224
Total *	433	520	461

### Closed\*\*

#### Revocation

Pharmacist	15	9	11
Intern Pharmacist	0	0	1
Pharmacy Technician	62	127	98
Designated Representative	1	0	2
Wholesaler	0	0	0
Pharmacy	2	0	1

#### Revocation, stayed; suspension/probation

Pharmacist	13	23	17
Intern Pharmacist	0	0	0
Pharmacy Technician	0	26	3
Designated Representative	0	0	0
Wholesaler	1	0	0
Pharmacy	3	0	0

#### Revocation, stayed; probation

Pharmacist	8	15	18
Intern Pharmacist	0	0	1
Pharmacy Technician	6	16	23
Designated Representative	0	1	1
Wholesaler	1	1	1
Pharmacy	2	9	16

#### Surrender/Voluntary Surrender

Pharmacist	9	8	12
Intern Pharmacist	0	0	0
Pharmacy Technician	16	35	32
Designated Representative	1	0	2
Wholesaler	0	0	1
Pharmacy	5	3	2

# Board of Pharmacy Enforcement Statistics Three Year Comparison Corrected

**Workload Statistics**

**Total 09/10**

**Total 10/11**

**Total 11/12**

<b>Public Reproval/Reprimand</b>			
Pharmacist	1	0	1
Intern Pharmacist	0	0	0
Pharmacy Technician	1	0	1
Designated Representative	0	0	0
Wholesaler	0	0	0
Pharmacy	0	0	0
Cost Recovery Requested	\$312,840.75	\$1,011,606.20	\$1,258,291.20
Cost Recovery Collected	\$335,420.58	\$422,530.21	\$469,718.56

\* This figure includes citation appeals

\*\* This figure includes cases withdrawn

\*\*\* This figure includes administrative penalties

# Board of Pharmacy Enforcement Statistics Three Year Comparison Corrected

## Workload Statistics

Total 09/10

Total 10/11

Total 11/12

### Probation Statistics

#### Licenses on Probation

Pharmacist	102	110	131
Intern Pharmacist	4	5	4
Pharmacy Technician	21	26	50
Designated Representative	1	2	2
Wholesaler	2	2	5
Pharmacy	7	17	27
Probation Office Conferences	105	141	147
Probation Site Inspections**	121	231	268
Probationers Referred to AG for non-compliance	13	9	3

As part of probation monitoring, the board requires licensees to appear before the lead 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.

### Pharmacists Recovery Program

#### Program Statistics

In lieu of discipline	1	2	1
In addition to probation	6	10	6
Closed, successful	11	5	9
Closed, non-compliant	4	3	1
Closed, other	14	1	5
Participants			
Board Mandated	56	56	55
Participants			
Under Investigation	21	14	14
Participants			
Self-Referral*	4	5	3
Treatment Contracts Reviewed	201	273	286

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, enforcement coordinator and lead inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

\* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

\*\*Some PRP Participant Inspections are included in the Probation Site Inspections total.

# Attachment 10

# 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	642	219	80	150	193	161
			34%	12%	23%	30%	
	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	406	45	62	88	211	306
			11%	15%	22%	52%	
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	563	331	86	58	88
Closed 4301 letters, license denials, withdrawn by Board	171	109	47	8	7
Cite and/or fine letter of admonishment	240	54	51	49	86
Attorney General's Office	74	18	8	17	31

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  Measure:	Manage enforcement activities for achievement of performance expectations.  Percentage compliance with program requirements.																																																																																																																																		
Tasks:	<p><b>1. Administer the Pharmacists Recovery Program.</b></p> <table border="1" data-bbox="367 254 1511 533"> <thead> <tr> <th></th> <th>Voluntary Participants</th> <th>Participants Mandated Into Program</th> <th>Noncompliant, Terminated From Program</th> <th>Successfully Completed Program</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>25</td> <td>51</td> <td>3</td> <td>1</td> </tr> <tr> <td>Qtr 2</td> <td>26</td> <td>55</td> <td>2</td> <td>1</td> </tr> <tr> <td>Qtr 3</td> <td>15</td> <td>61</td> <td>4</td> <td>0</td> </tr> <tr> <td>Qtr 4</td> <td>20</td> <td>52</td> <td>5</td> <td>7</td> </tr> </tbody> </table> <p><b>2. Administer the Probation Monitoring Program.</b></p> <table border="1" data-bbox="367 604 1235 909"> <thead> <tr> <th></th> <th>Qtr 1</th> <th>Qtr 2</th> <th>Qtr 3</th> <th>Qtr 4</th> </tr> </thead> <tbody> <tr> <td>Individuals</td> <td>151</td> <td>156</td> <td>180</td> <td>187</td> </tr> <tr> <td>Sites</td> <td>20</td> <td>24</td> <td>29</td> <td>31</td> </tr> <tr> <td>Tolled</td> <td>28</td> <td>27</td> <td>28</td> <td>27</td> </tr> <tr> <td>Inspections Conducted</td> <td>67</td> <td>66</td> <td>60</td> <td>74</td> </tr> <tr> <td>Successfully Completed</td> <td>4</td> <td>4</td> <td>2</td> <td>6</td> </tr> <tr> <td>Petitions to Revoke Filed</td> <td>3</td> <td>2</td> <td>0</td> <td>2</td> </tr> </tbody> </table> <p><b>3. Issue all citations and fines within 30 days.</b></p> <table border="1" data-bbox="367 980 1417 1373"> <thead> <tr> <th></th> <th><u>N</u></th> <th>30 days</th> <th>60 days</th> <th>90 days</th> <th>&gt; 90 days</th> <th><u>Average Days</u></th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>241</td> <td>141 59%</td> <td>90 37%</td> <td>9 4%</td> <td>1 .4%</td> <td>31</td> </tr> <tr> <td>Qtr 2</td> <td>128</td> <td>95 74%</td> <td>13 10%</td> <td>10 8%</td> <td>10 8%</td> <td>29</td> </tr> <tr> <td>Qtr 3</td> <td>240</td> <td>214 89%</td> <td>14 6%</td> <td>0 0%</td> <td>12 5%</td> <td>28</td> </tr> <tr> <td>Qtr 4</td> <td>391</td> <td>190 49%</td> <td>160 41%</td> <td>35 9%</td> <td>6 1%</td> <td>42</td> </tr> </tbody> </table> <p><b>4. Issue letters of admonishment within 30 days.</b></p> <table border="1" data-bbox="367 1457 1417 1845"> <thead> <tr> <th></th> <th><u>N</u></th> <th>30 days</th> <th>60 days</th> <th>90 days</th> <th>&gt; 90 days</th> <th><u>Average Days</u></th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>15</td> <td>10 67%</td> <td>5 33%</td> <td>0 0%</td> <td>0 0%</td> <td>25</td> </tr> <tr> <td>Qtr 2</td> <td>15</td> <td>12 80%</td> <td>1 7%</td> <td>2 13%</td> <td>0 0%</td> <td>24</td> </tr> <tr> <td>Qtr 3</td> <td>42</td> <td>39 93%</td> <td>1 2%</td> <td>0 0%</td> <td>2 5%</td> <td>27</td> </tr> <tr> <td>Qtr 4</td> <td>54</td> <td>37 69%</td> <td>11 20%</td> <td>6 11%</td> <td>0 0%</td> <td>26</td> </tr> </tbody> </table> <p>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).</p>		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	4	0	Qtr 4	20	52	5	7		Qtr 1	Qtr 2	Qtr 3	Qtr 4	Individuals	151	156	180	187	Sites	20	24	29	31	Tolled	28	27	28	27	Inspections Conducted	67	66	60	74	Successfully Completed	4	4	2	6	Petitions to Revoke Filed	3	2	0	2		<u>N</u>	30 days	60 days	90 days	> 90 days	<u>Average Days</u>	Qtr 1	241	141 59%	90 37%	9 4%	1 .4%	31	Qtr 2	128	95 74%	13 10%	10 8%	10 8%	29	Qtr 3	240	214 89%	14 6%	0 0%	12 5%	28	Qtr 4	391	190 49%	160 41%	35 9%	6 1%	42		<u>N</u>	30 days	60 days	90 days	> 90 days	<u>Average Days</u>	Qtr 1	15	10 67%	5 33%	0 0%	0 0%	25	Qtr 2	15	12 80%	1 7%	2 13%	0 0%	24	Qtr 3	42	39 93%	1 2%	0 0%	2 5%	27	Qtr 4	54	37 69%	11 20%	6 11%	0 0%	26
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**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	0	0	2

**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	0	0	2	2

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 283">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="370 283 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>485</td> <td>449</td> <td>5%</td> </tr> <tr> <td>Qtr 2</td> <td>581</td> <td>884</td> <td>9%</td> </tr> <tr> <td>Qtr 3</td> <td>348</td> <td>587</td> <td>6%</td> </tr> <tr> <td>Qtr 4</td> <td>290</td> <td>733</td> <td>7%</td> </tr> </tbody> </table> <p data-bbox="370 548 1414 611">2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.</p> <table border="1" data-bbox="370 611 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>Qtr 4</td> <td>64</td> <td>0</td> </tr> </tbody> </table> <p data-bbox="370 875 1471 907">3. Initiate investigations based upon violations discovered during routine inspections.</p> <table border="1" data-bbox="370 907 1479 1129"> <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>485</td> <td>60</td> <td>12%</td> </tr> <tr> <td>Qtr 2</td> <td>581</td> <td>46</td> <td>8%</td> </tr> <tr> <td>Qtr 3</td> <td>348</td> <td>31</td> <td>9%</td> </tr> <tr> <td>Qtr 4</td> <td>290</td> <td>31</td> <td>11%</td> </tr> </tbody> </table>		Number of Inspections	Aggregate Inspections This Cycle	Percent Complete	Qtr 1	485	449	5%	Qtr 2	581	884	9%	Qtr 3	348	587	6%	Qtr 4	290	733	7%		Number of Inspections	Number Inspected Late	Qtr 1	81	0	Qtr 2	85	0	Qtr 3	49	0	Qtr 4	64	0		Number of Inspections	Number of Investigations Opened	Percent Opened	Qtr 1	485	60	12%	Qtr 2	581	46	8%	Qtr 3	348	31	9%	Qtr 4	290	31	11%
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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 1646"> <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.*  
*4th Qtr 11/12: 19 reports submitted.*