California State Board of Pharmacy
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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

COMMITTEE MEMBERS ABSENT:
Tappan Zee, Public Member

LOCATION:
The Westgate Hotel
1055 Second Avenue
San Diego, CA 92101

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

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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 palates, 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 needs 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 very 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 discussion. 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 [1]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.

[1] 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

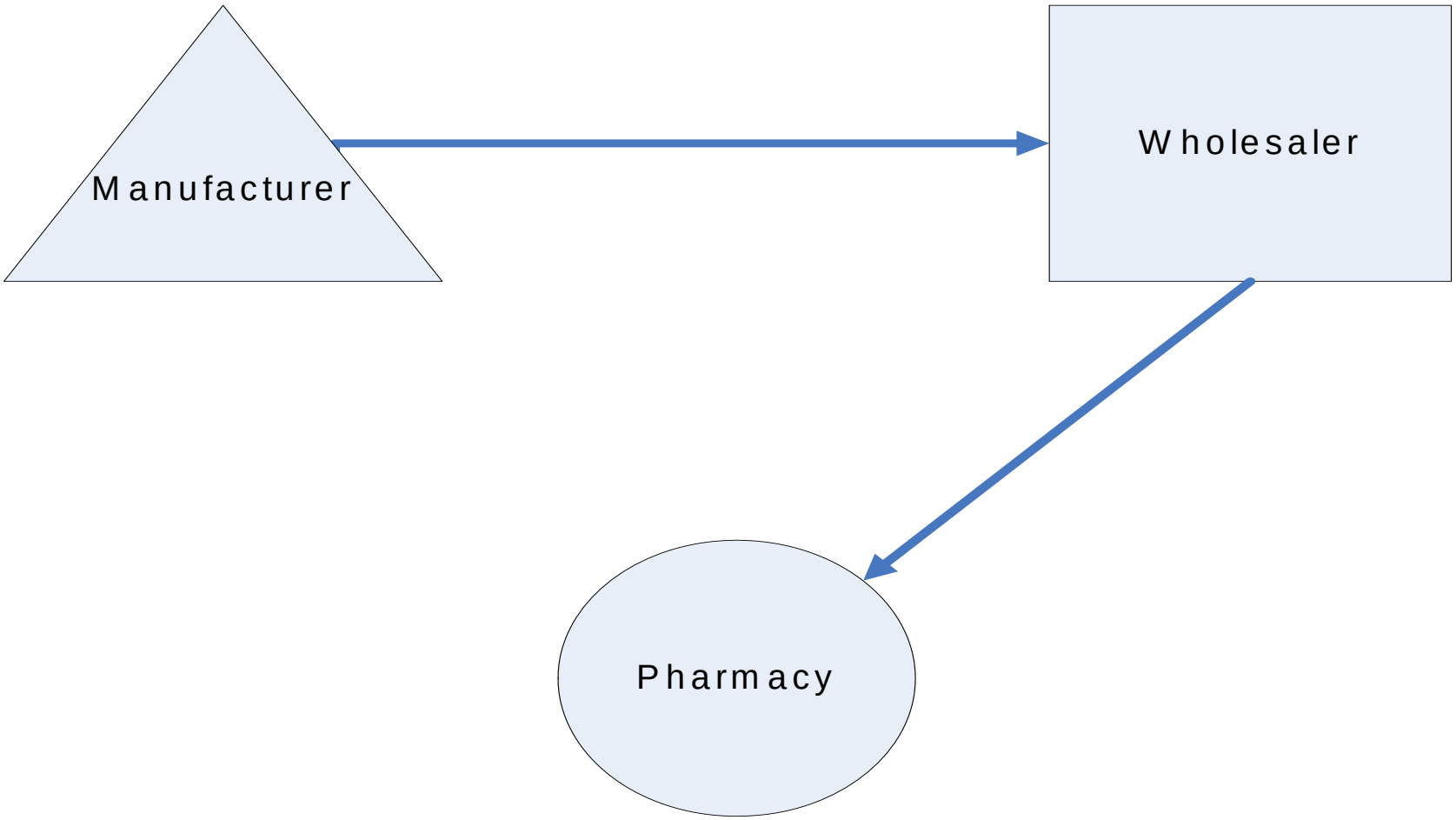
CA State Board of Pharmacy

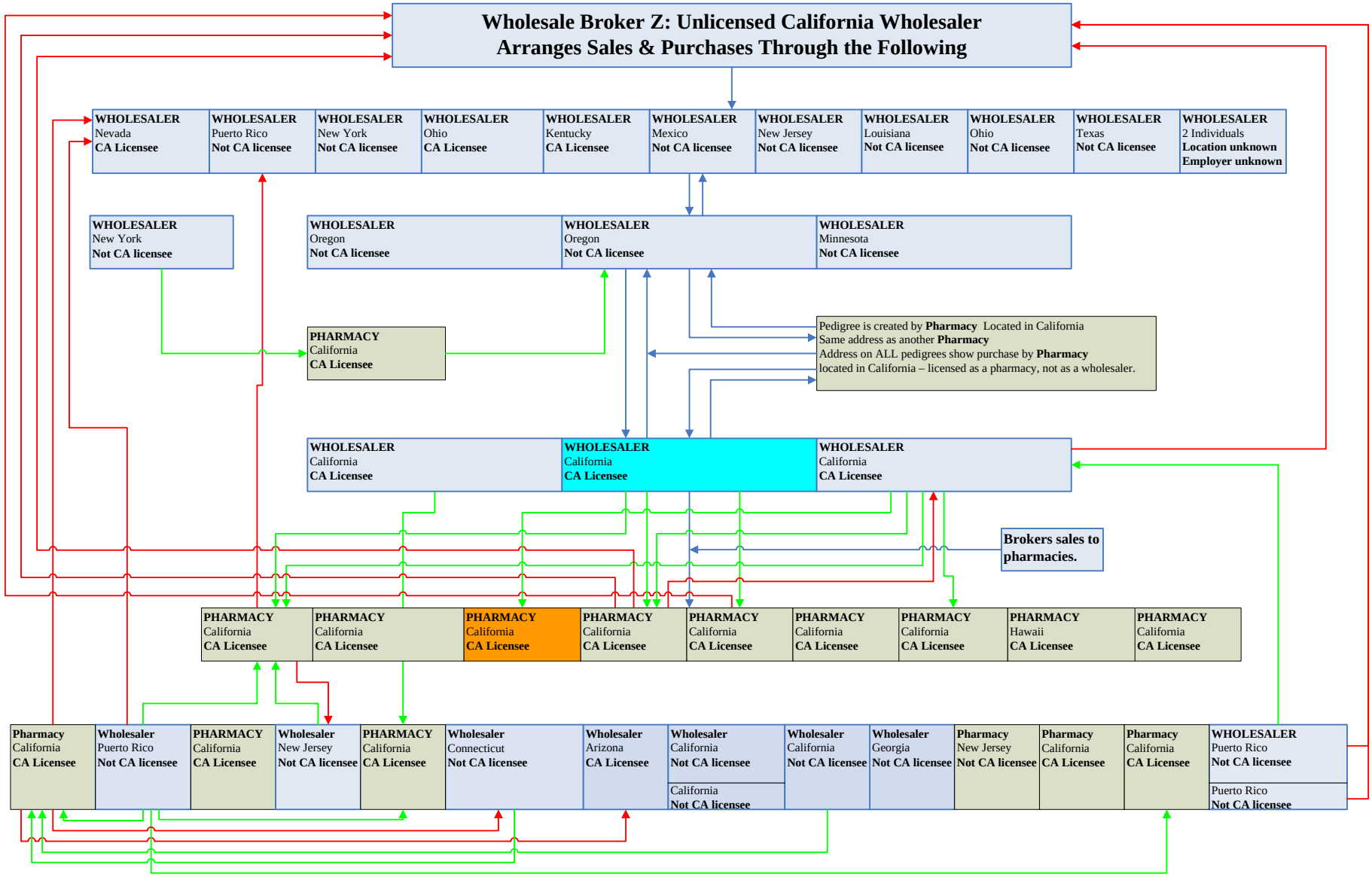
Statutory Mandate

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
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
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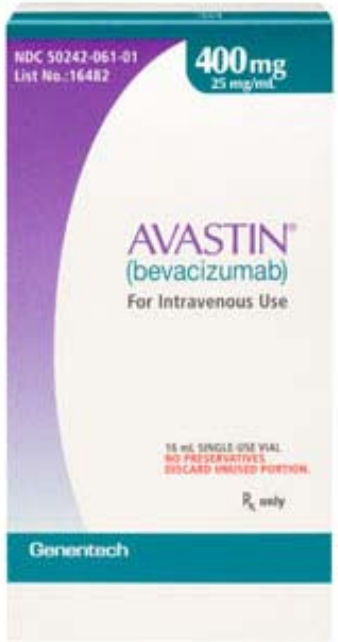
PHARMACY California CA Licensee
PHARMACY California CA Licensee
PHARMACY Hawaii CA Licensee
PHARMACY California CA Licensee
Pharmacy California CA Licensee
Wholesaler Puerto Rico Not CA licensee
PHARMACY California CA Licensee
Wholesaler New Jersey Not CA licensee
PHARMACY California CA Licensee
Wholesaler Connecticut Not CA licensee
Wholesaler Arizona CA Licensee
Wholesaler California Not CA licensee
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 Adderal 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

Drugs from “other” sources

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

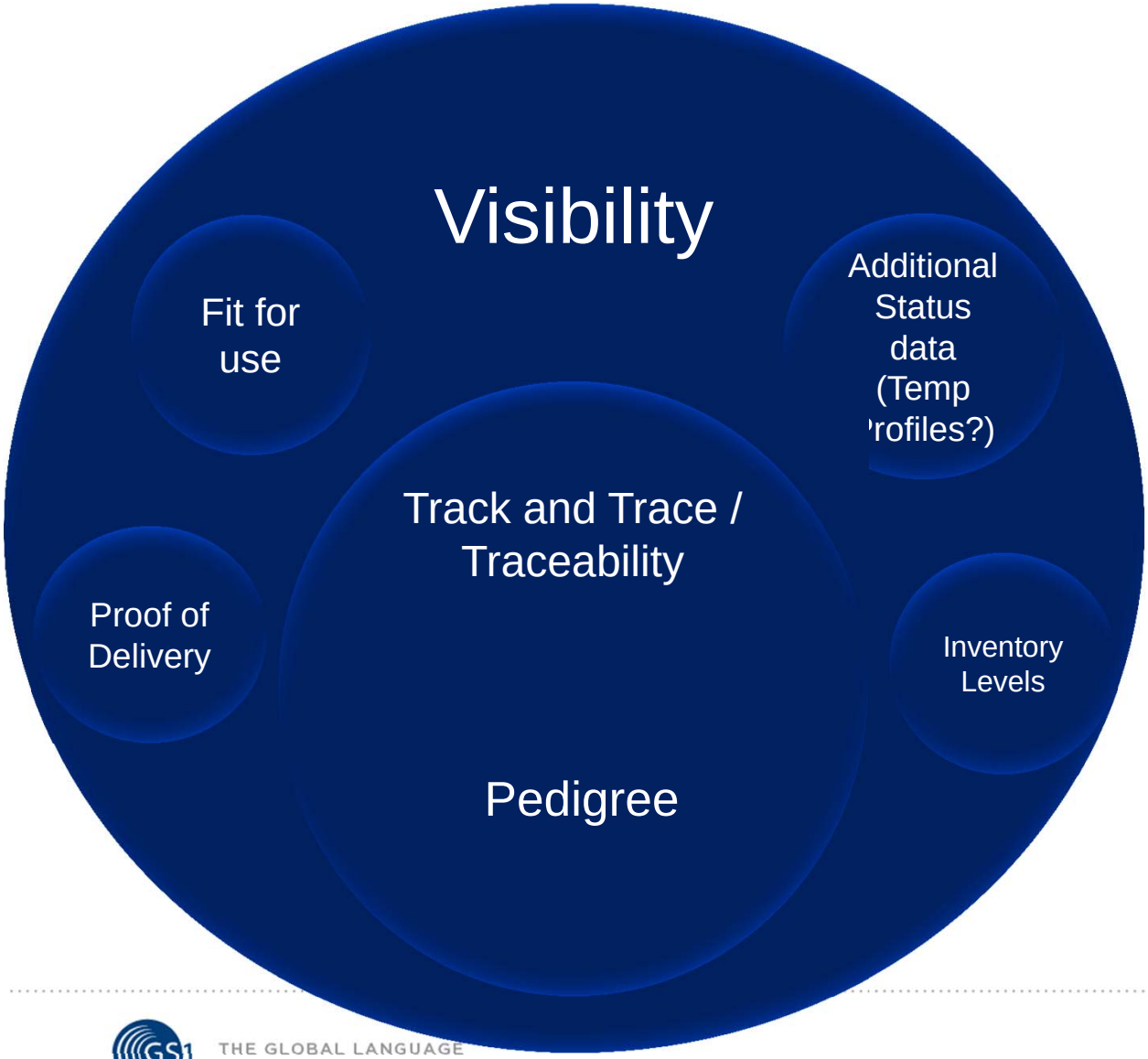
- Join our subscriber alert by going to www.pharmacy.ca.gov

THE GLOBAL LANGUAGE OF BUSINESS

CALIFORNIA BOARD OF PHARMACY ENFORCEMENT COMMITTEE

GS1 TRACK AND TRACE STANDARDS AND IMPLEMENTATION

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.

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VISIBILITY, TRACEABILITY, TRACK AND TRACE

WHO ARE USING GS1 STANDARDS FOR TRACK & TRACE?

Apparel

Sea Food

Fresh Foods

Food Service

Consumer Goods

Aerospace

Pharmaceuticals

Healthcare Providers

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SERIALIZATION AROUND THE WORLD

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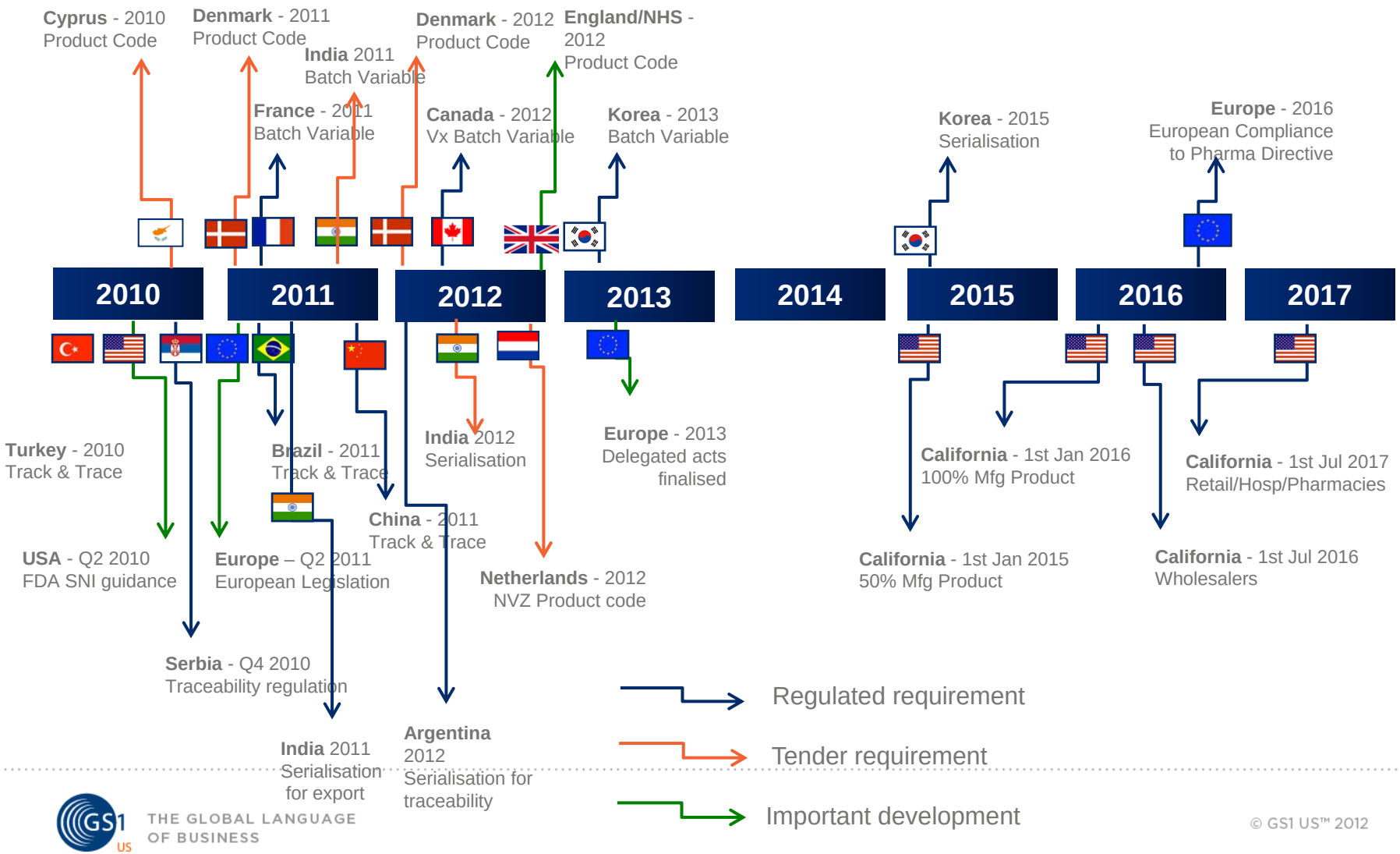
PHARMACEUTICALS

NEW CODING & SERIALISATION REQUIREMENTS



THE GLOBAL LANGUAGE OF BUSINESS

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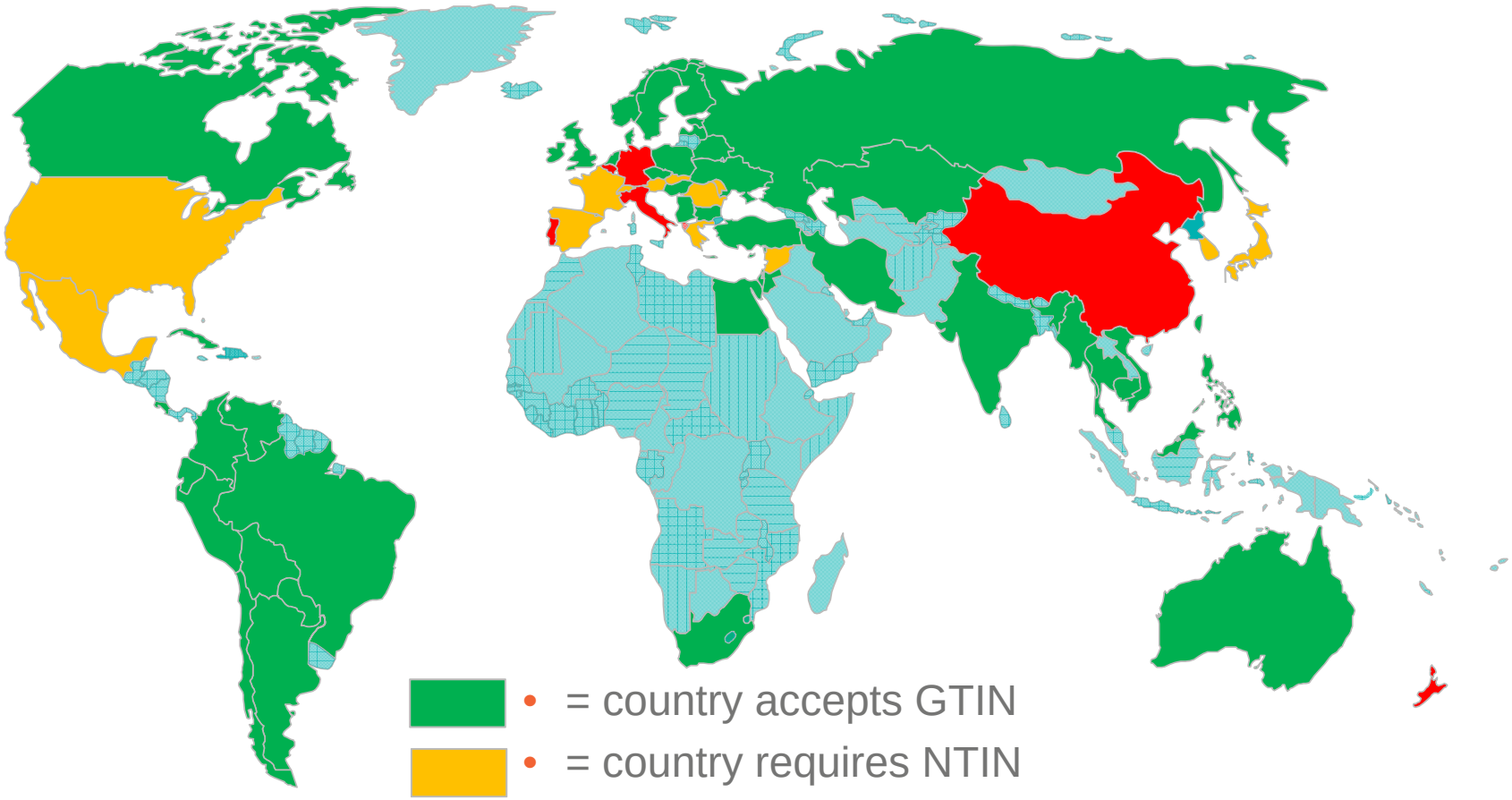
IDENTIFICATION OF PHARMACEUTICALS



- = country accepts GTIN
- = country requires NTIN
- = country requires national ID #
- = no input available

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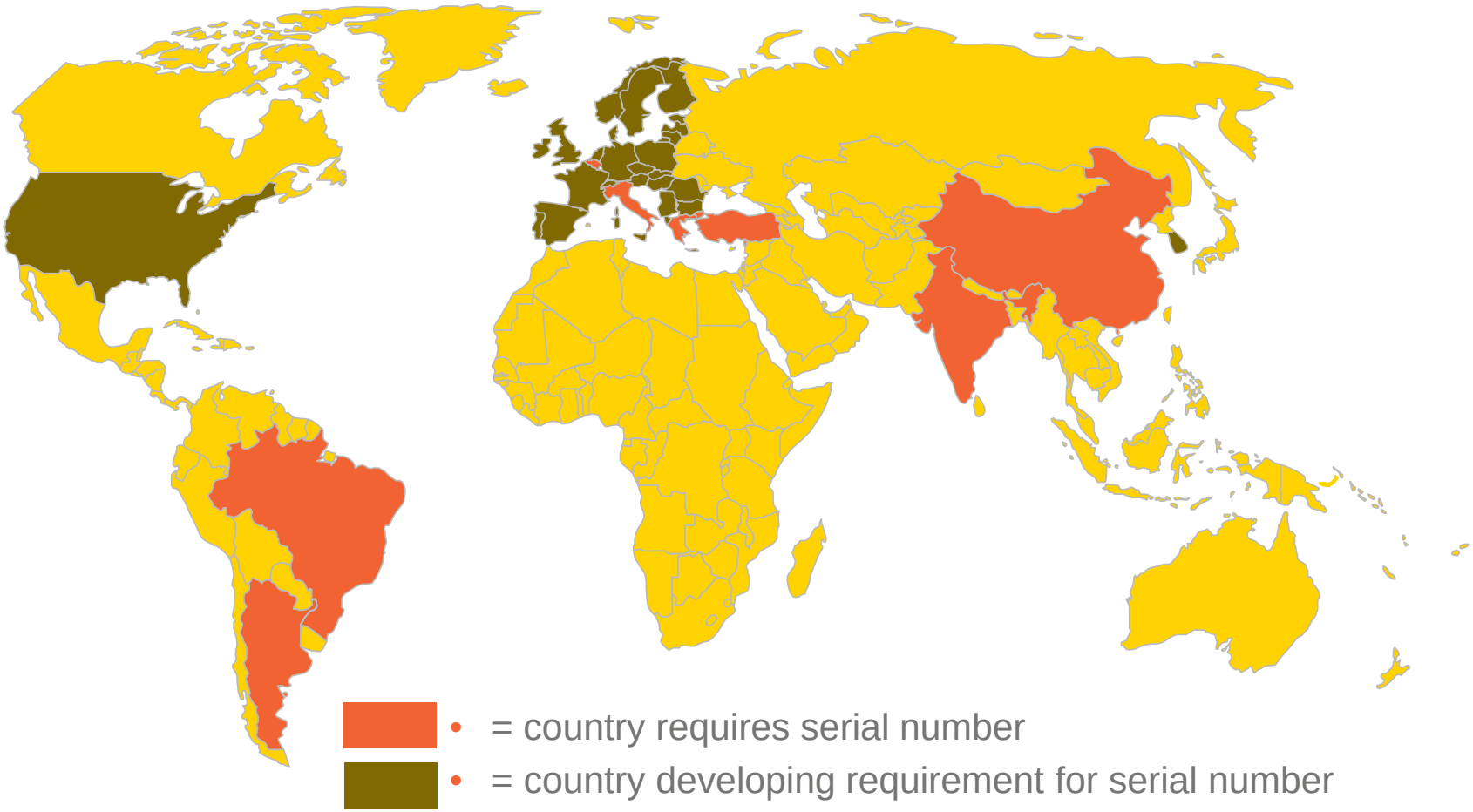
SERIALIZATION OF PHARMACEUTICALS



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DATAMATRIX ON PHARMACEUTICALS

Switzerland: SmartLog Pilot

Spain: Pilot

France: AFSSAPS regulation (2011)

Belgium: Pilot project unit dose marking

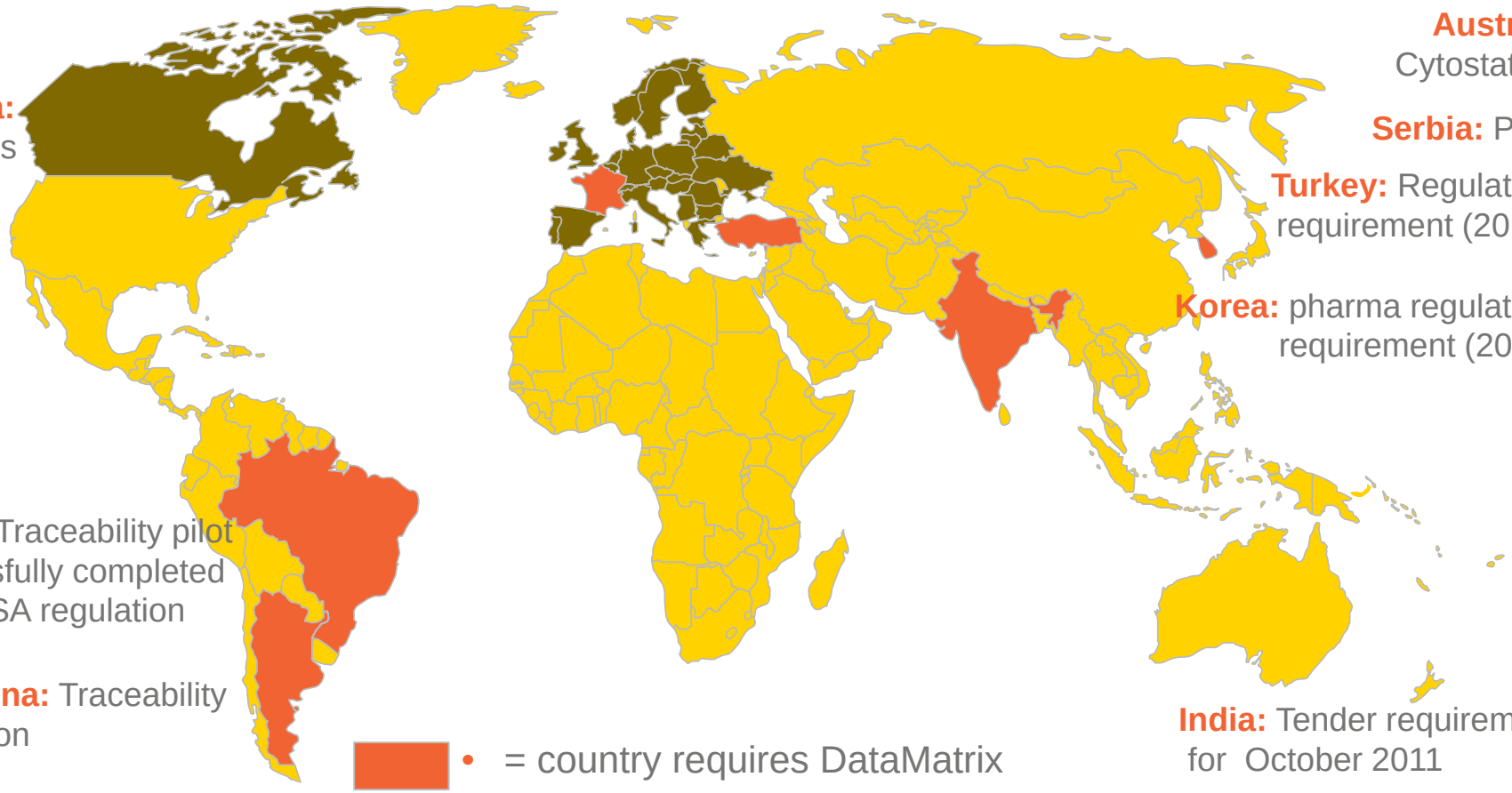
Austria: Cytostatics

Serbia: Pilot

Turkey: Regulatory requirement (2010)

Korea: pharma regulatory requirement (2011)

Canada: Vaccines



Brazil: Traceability pilot successfully completed – ANVISA regulation

Argentina: Traceability regulation

India: Tender requirement for October 2011

- = country requires DataMatrix
- = country using DataMatrix in pilots and/or developing requirement for DataMatrix

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WHY SERIALIZATION / TRACK & TRACE?

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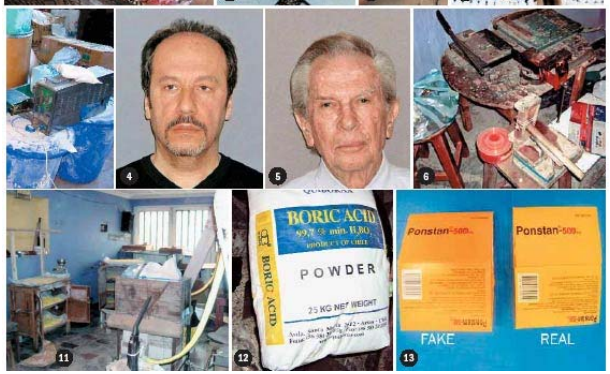
WHY SERIALIZATION / TRACK & TRACE?

Counterfeit

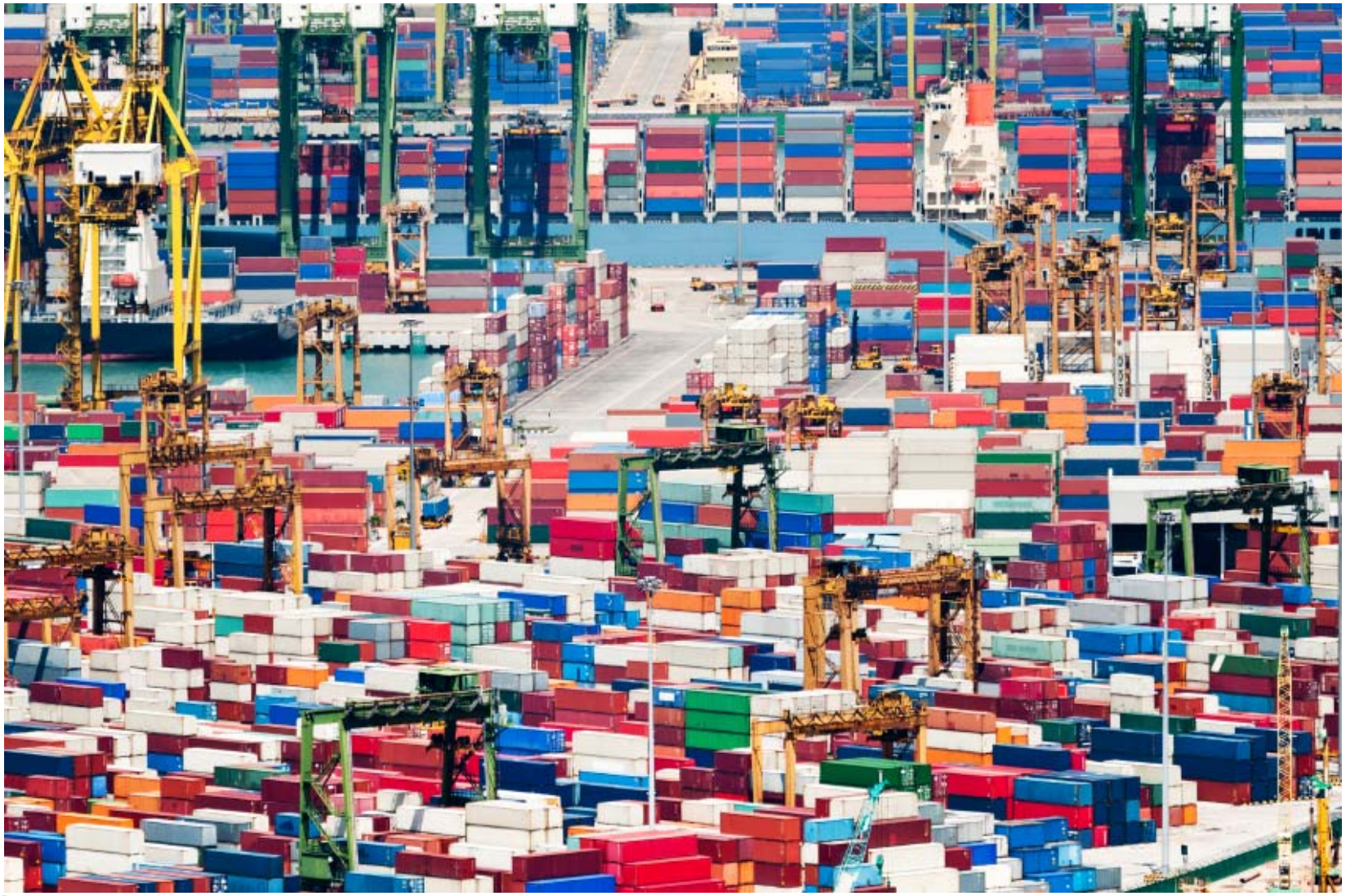
Diversion

Theft



WHY SERIALIZATION / TRACK & TRACE?

Find the counterfeit product:



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SERIALIZATION / TRACK & TRACE

THE CHALLENGE IS:

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SERIALIZATION / TRACK & TRACE

WHAT ARE THE ISSUES?

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.

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TRACK & TRACE STANDARDS AND USES

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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

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THE STANDARDS AT THE CORE OF TRACK & TRACE

EPCIS

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

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WHAT CAN WE DO WITH TRACK & TRACE STANDARDS?

Pedigree Data (showing Master Data)

Product

Certification

GTIN Item Pedigree Report from Simulation - Secure

Product: Small case of 6 Prod 01, 100ct bottles 50 mg
GTIN: 10398765129454 Serial Number: 1
NDC: 9876512945
Description: Small case of 6 bottles of Prod 01

Lot Number: 54
Lot Expiration: 6/23/2013
Strength: 50 MG
Dosage Form: Tablet

Row	Business Location	Day / Time	License #	Business Step / Disposition	Trans. Type / ID	Shipped To / Shipped From	Pedigree Certifier (GSRN)
1	Wholesaler 020 160 North 12th Street Sacramento CA 95811	2/1/2011 3:00:00 PM		commissioning active			
2	Wholesaler 020 160 North 12th Street Sacramento CA 95811	2/1/2011 4:15:00 PM		shipping in_transit	PO 521	Pharmacy 001 5528 North 1st Street Fresno CA 93710	03987651200120
3	Pharmacy 001 5528 North 1st Street Fresno CA 93710	2/2/2011 12:30:00 PM		receiving sellable_not_accessable	PO 521	Wholesaler 020 160 North 12th Street Sacramento CA 95811	0849681290078

Ownership

Ownership

Monday, April 11, 2011

Page 1 of 1

Pedigree

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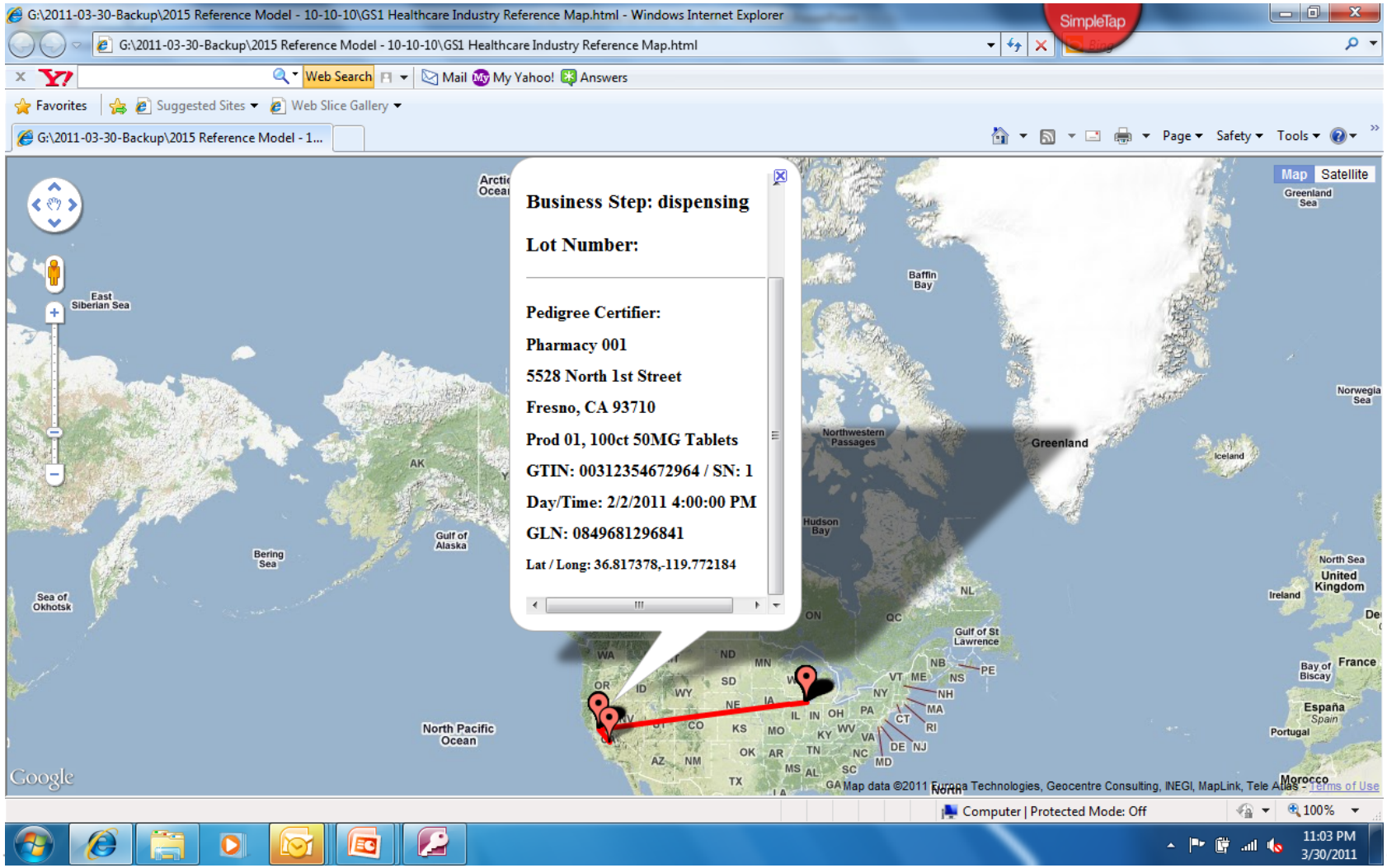
WHAT CAN WE DO WITH TRACK & TRACE STANDARDS?

Visibility data rendered via Google Maps



WHAT CAN WE DO WITH TRACK & TRACE STANDARDS?

Visibility, Traceability, Track & Trace

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ANTI-COUNTERFEIT CONSIDERATIONS

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ANTI-COUNTERFEIT CONSIDERATIONS
INFORMATION SECURITY

Criminals will Counterfeit:

Your Products

Your Packaging

Your Pedigrees

Your Websites

Your Authentication Portals

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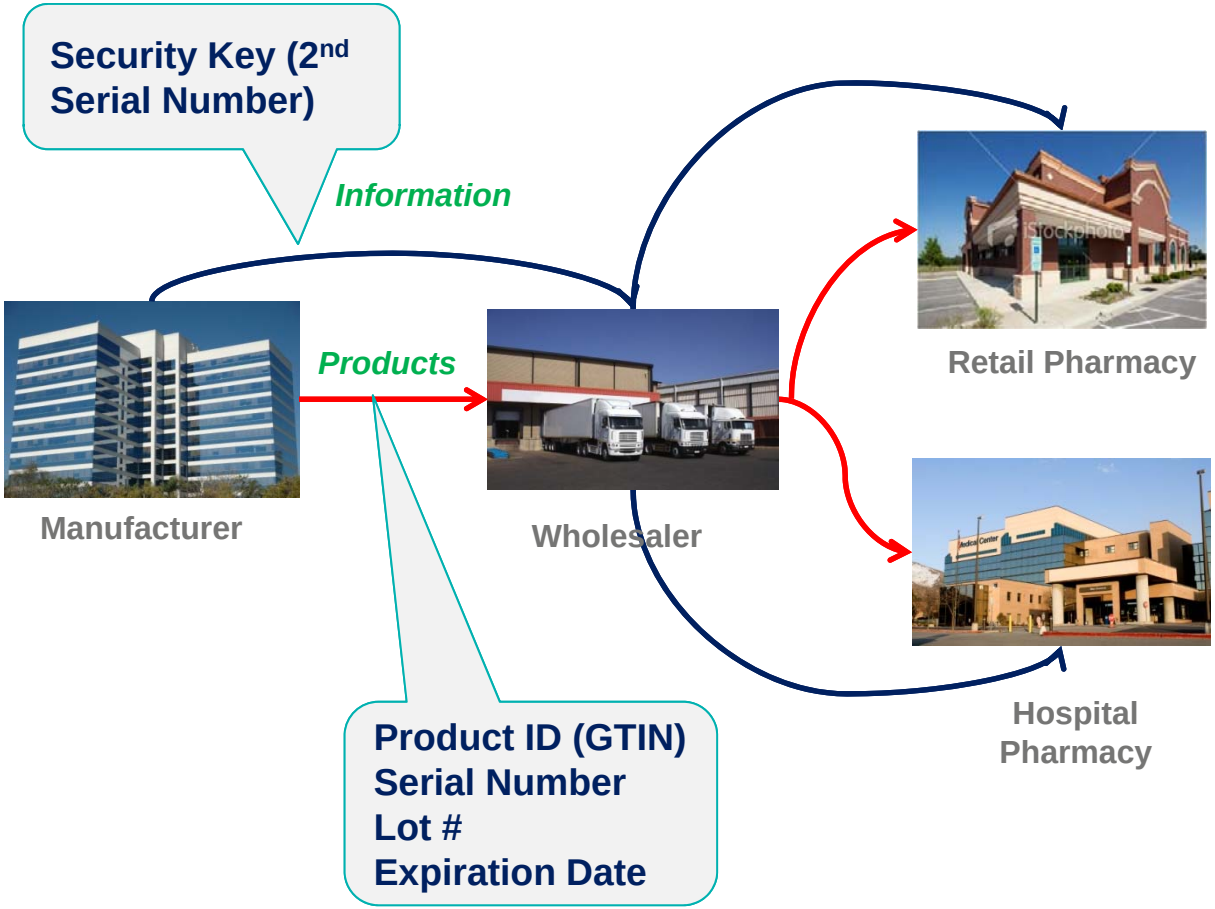
ANTI-COUNTERFEIT CONSIDERATIONS

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

Thief
Diverter
Counterfeiter

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ANTI-COUNTERFEIT CONSIDERATIONS

INFORMATION SECURITY

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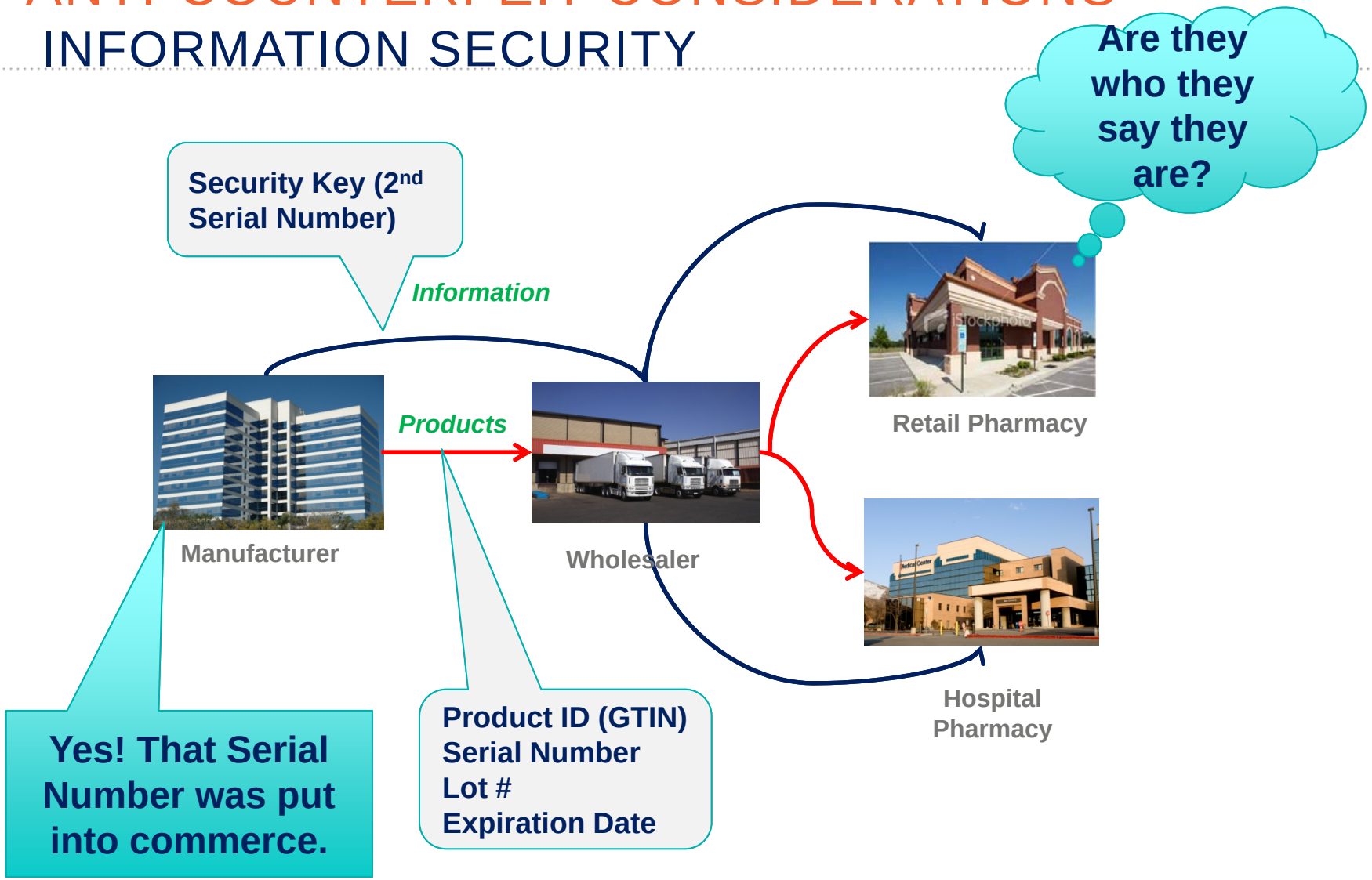
ANTI-COUNTERFEIT CONSIDERATIONS

INFORMATION SECURITY



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ANTI-COUNTERFEIT CONSIDERATIONS
INFORMATION SECURITY

- **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

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STANDARDS ACTIVITIES IN THE U.S.

IMPLEMENTATION SUPPORT

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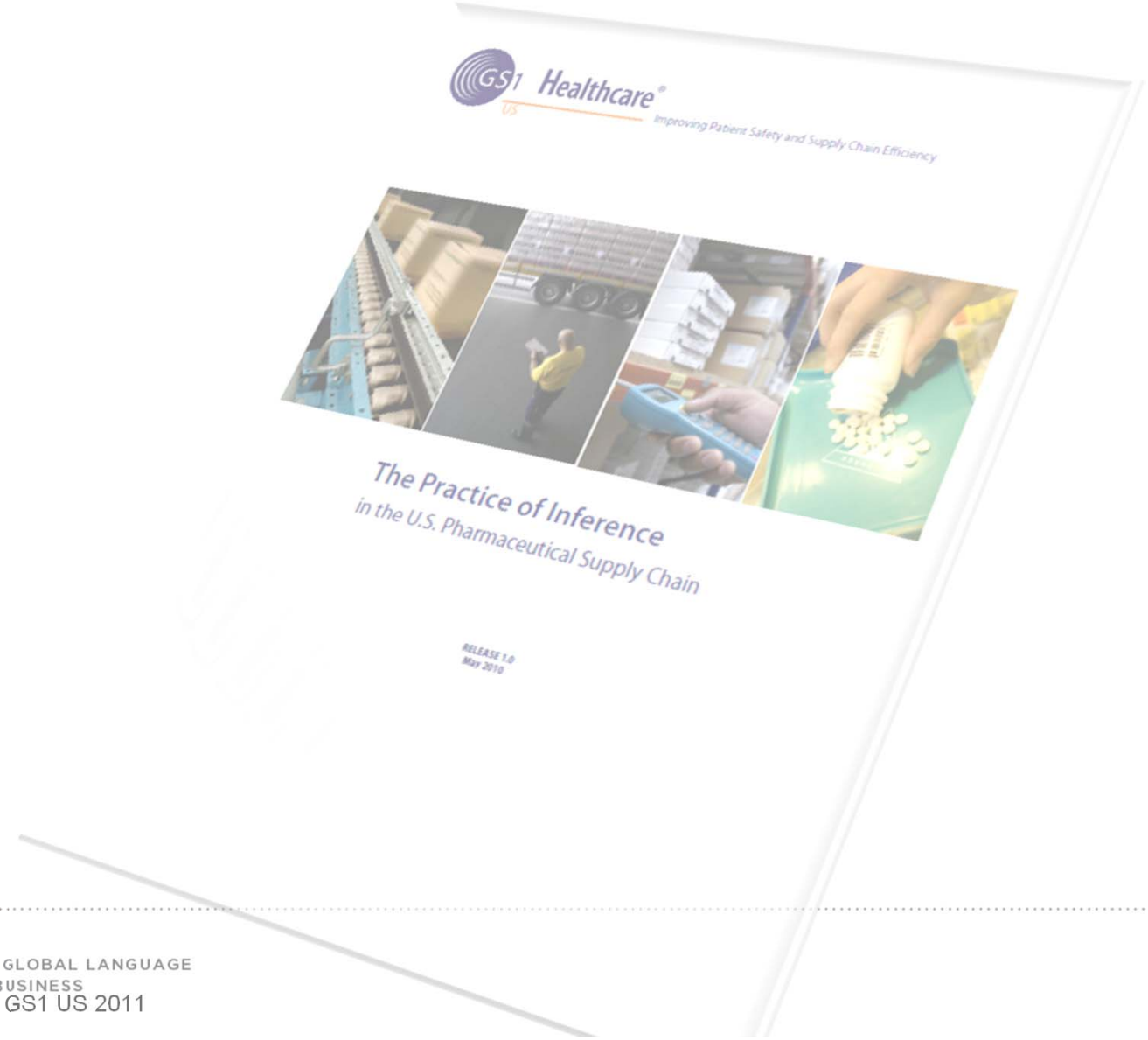
STANDARDS ACTIVITIES WITHIN THE U.S.

INFERENCE



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STANDARDS ACTIVITIES WITHIN THE U.S.

IMPLEMENTATION SUPPORT - **STATISTICAL SAMPLING MODEL**

THE GLOBAL LANGUAGE OF BUSINESS

STANFORD UNIVERSITY

Statistical Sampling Plan

Input required by users:

Size of shipment (in bottles):	1,000	bottles
Acceptable quality level (%):	1.000%	please select from the drop down list

Output:

Code letter: J

Normal Inspection:

Parameters of sampling plan:

sample size (n)	80
Accptance number (c)	2

Sample plan instructions:

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.

Switch to tightened inspection:

6. If 2 or more of the last 5 shipments from the same supplier have been rejected, switch to tightened inspection.

Switch to reduced inspection:

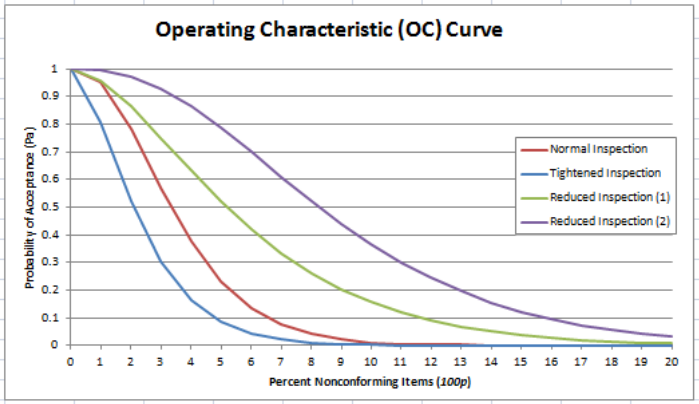
7. Switch to reduced inspection if ALL of the following conditions have been met:
   - It seems likely that the product to be inspected under reduced inspection will be produced and delivered to the receiving party under the same conditions that gave rise to the recent good quality history; and
   - 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

Quality Characteristics of the Selected Plan

1. Operating characteristic (OC) curve

Shows the ability of the plan to distinguish between good and bad shipments.

For any fraction nonconforming *p* , the OC curve shows the probability *Pa* that the shipment will be accepted.



Reduced Inspection (1): the probabilities of acceptance accompanied by continuation of reduced inspection.

Reduced Inspection (2): 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.

2. Average Outgoing Quality (AOQ):

Calculates the average percentage of nonconforming items after inspection, in the long run.

Please check in the "Model assumptions" tab for more information on how the AOQ is calculated.

Sampling Model | Instructions | Diagrams | Inspection resutls form | Model assumptions | Supporting tables

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SECURE SUPPLY CHAIN TASK FORCE

IMPLEMENTATION GUIDE

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

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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**

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STANDARDS ACTIVITIES WITHIN THE U.S.

CLOSING THOUGHTS ON TRACK & TRACE INFORMATION

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?

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www.GS1US.org

Connect with the GS1 US community on

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Abbott Today

A global, broad-based health care company

91,000 employees around the world

2011 sales: $38.9 billion

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Track and Trace – Pilot History

- *2*004 - 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)

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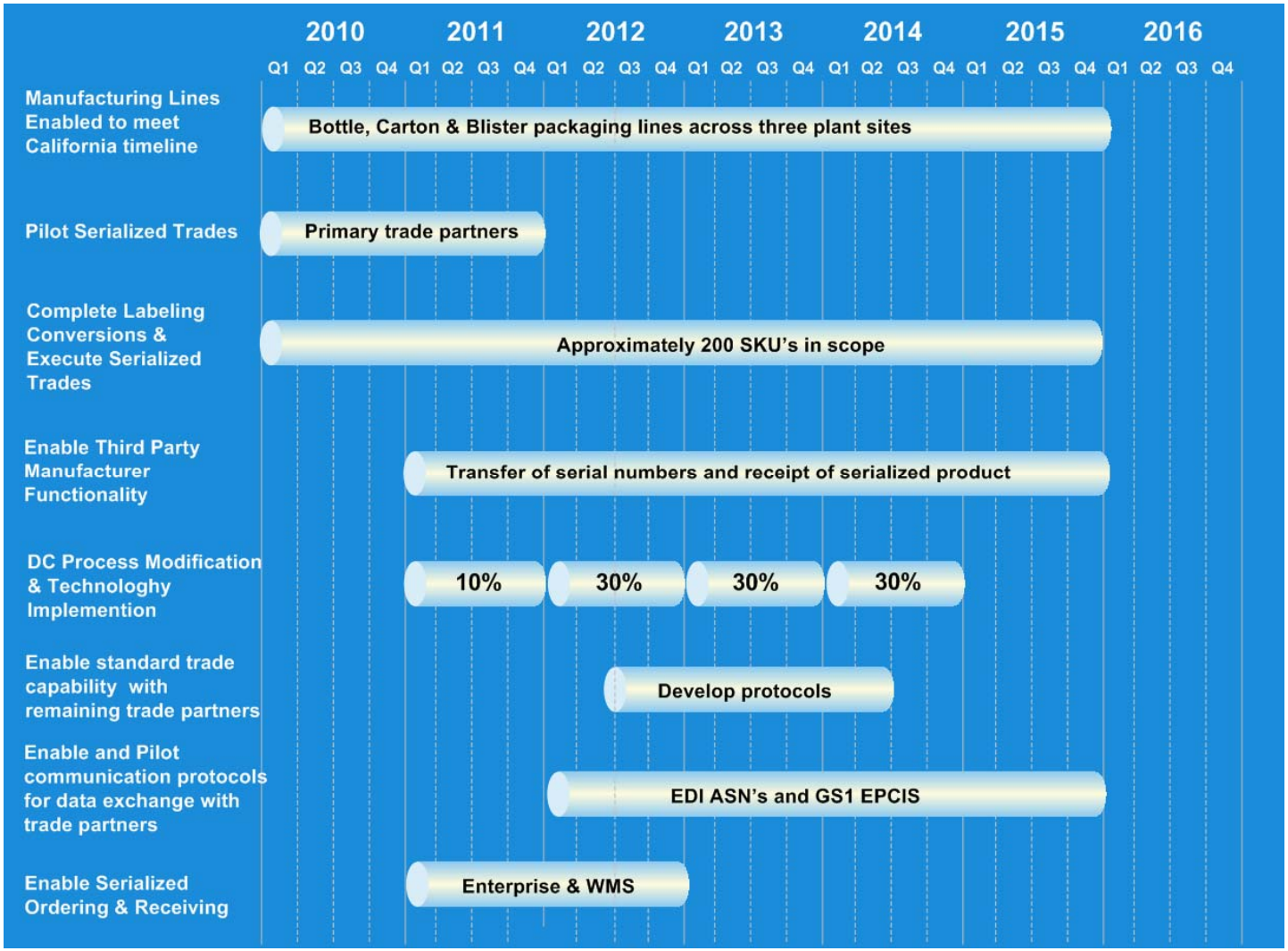
Track & Trace LRP Timeline – US Market



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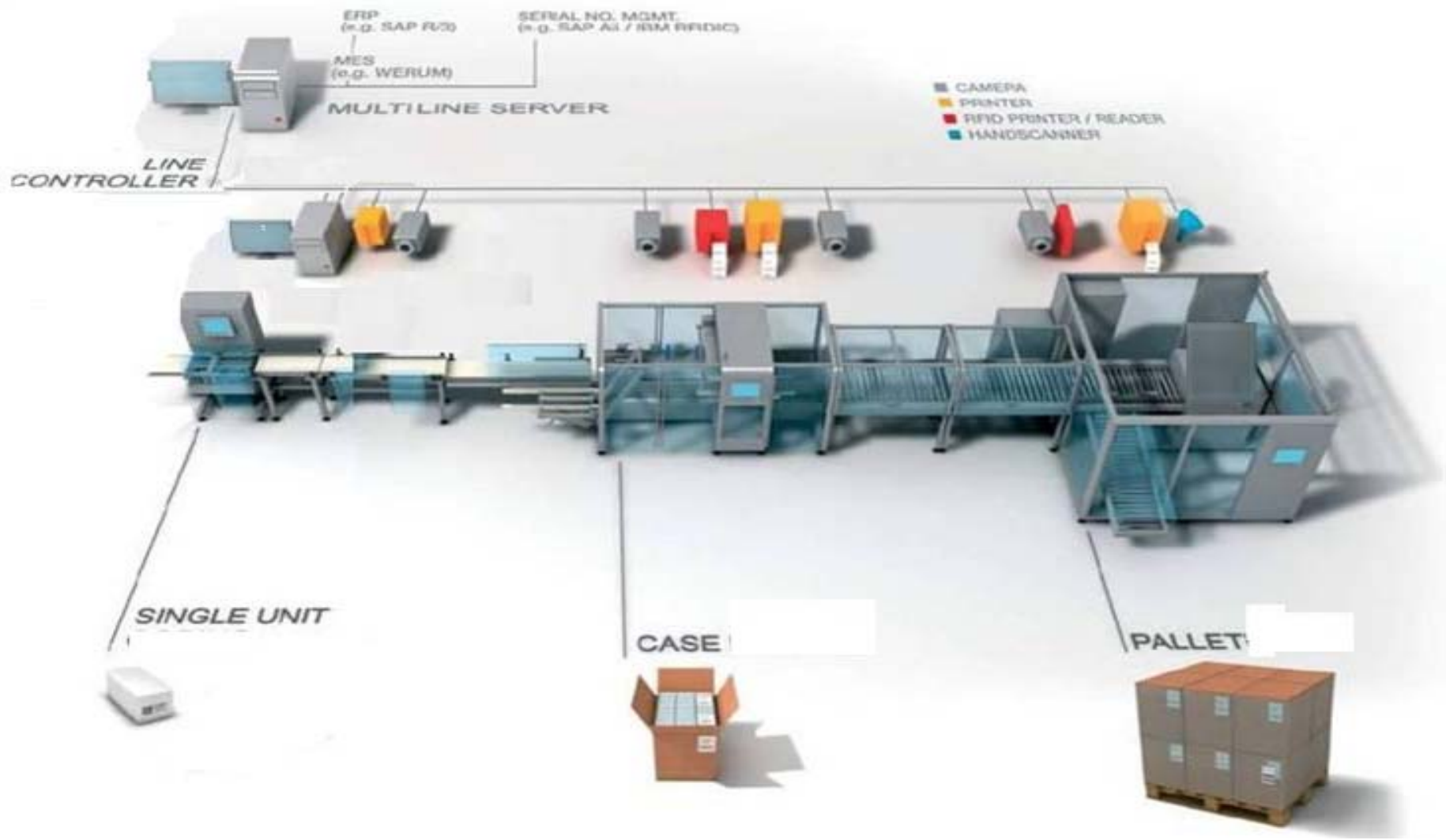
Line Schematic



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Product Packaging Levels

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

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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

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Early Pilot Trade Learning

- **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

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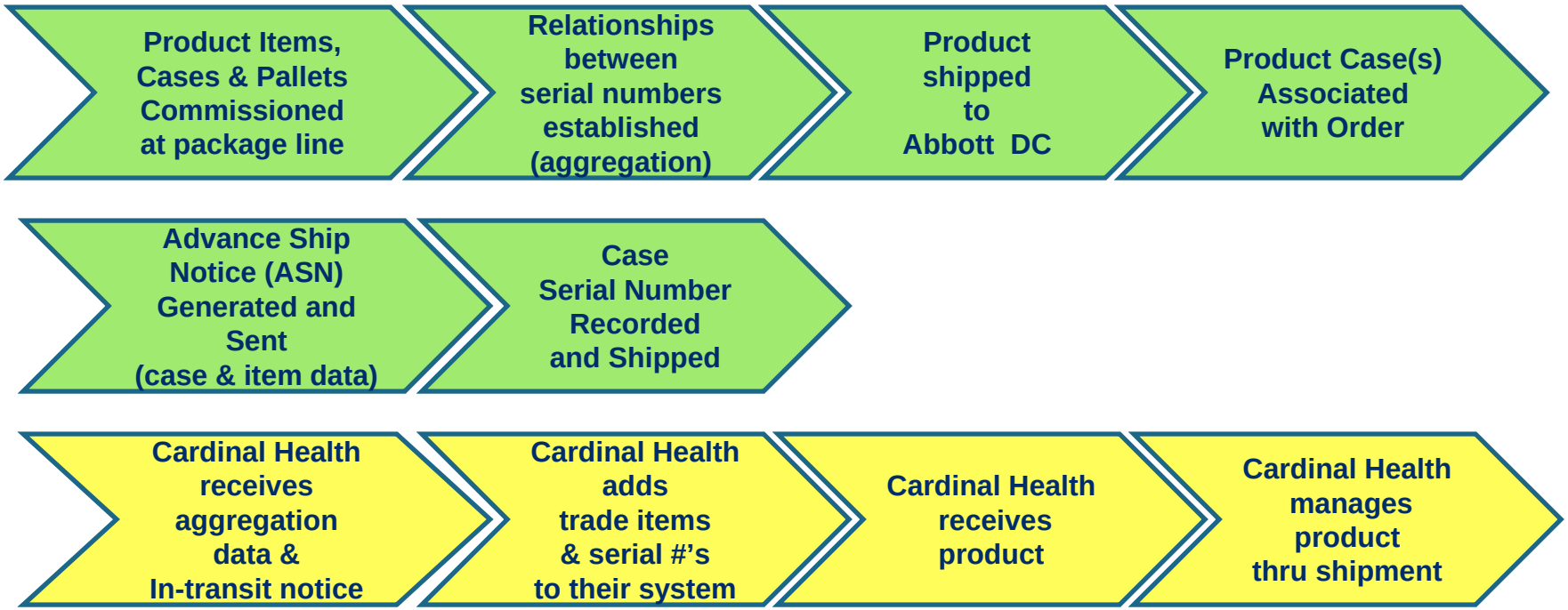
Abbott / Cardinal Health Pilot – High Level Process



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

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Abbott Pilot Experiences

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

GS1 Healthcare® US

Pilot **Report**

Lessons Learned About Serialization

Using GS1 Standards

Experiences of a Pharmaceutical Manufacturer

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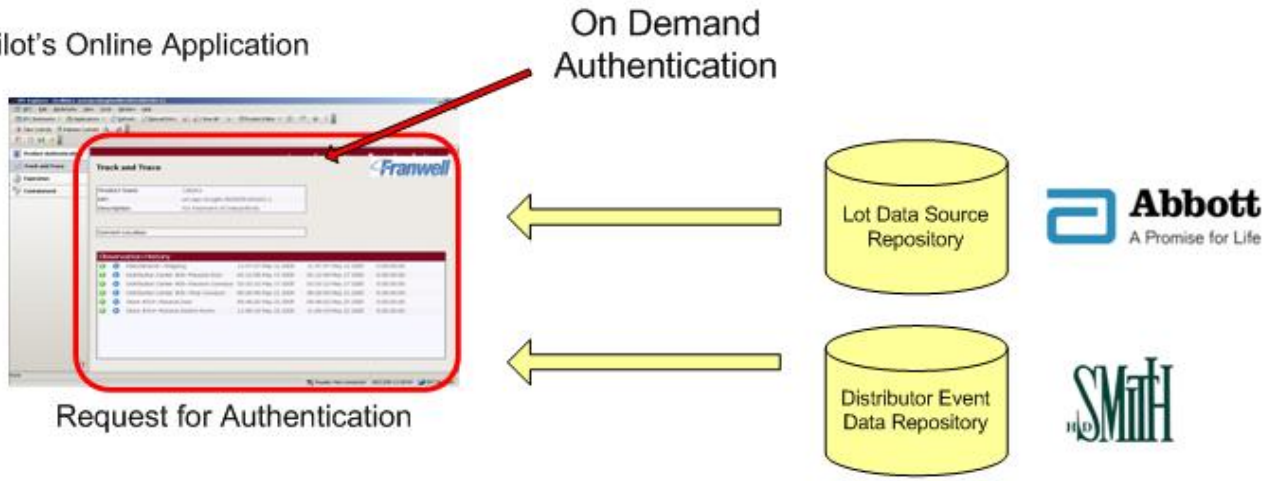
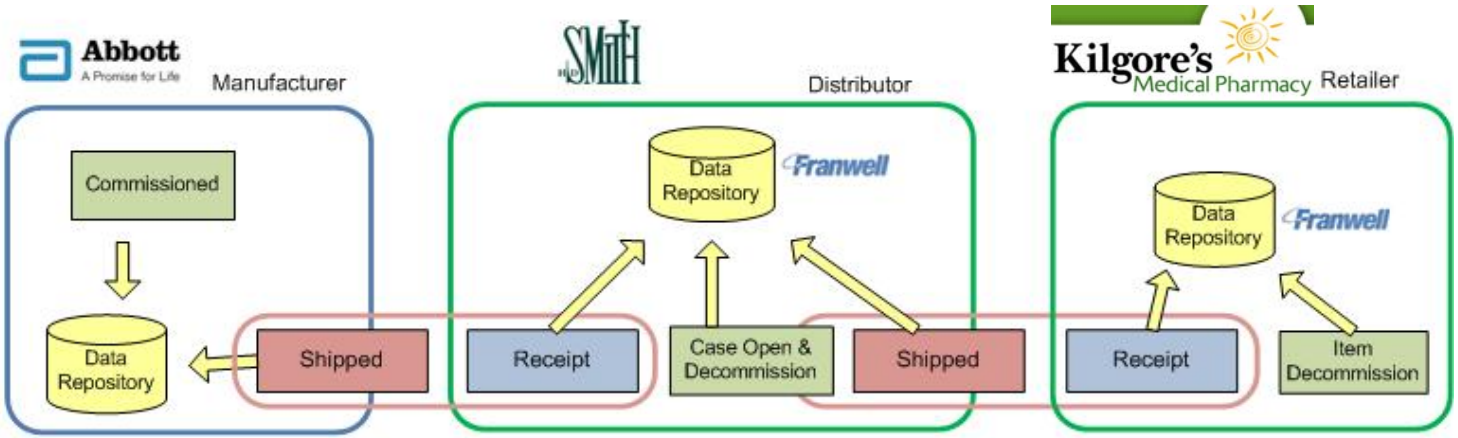
POC Pilot – Abbott & H.D. Smith – January, 2010



Chain of Custody



Supply Chain Events

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Abbott-HD Smith Pilot Trades

- 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

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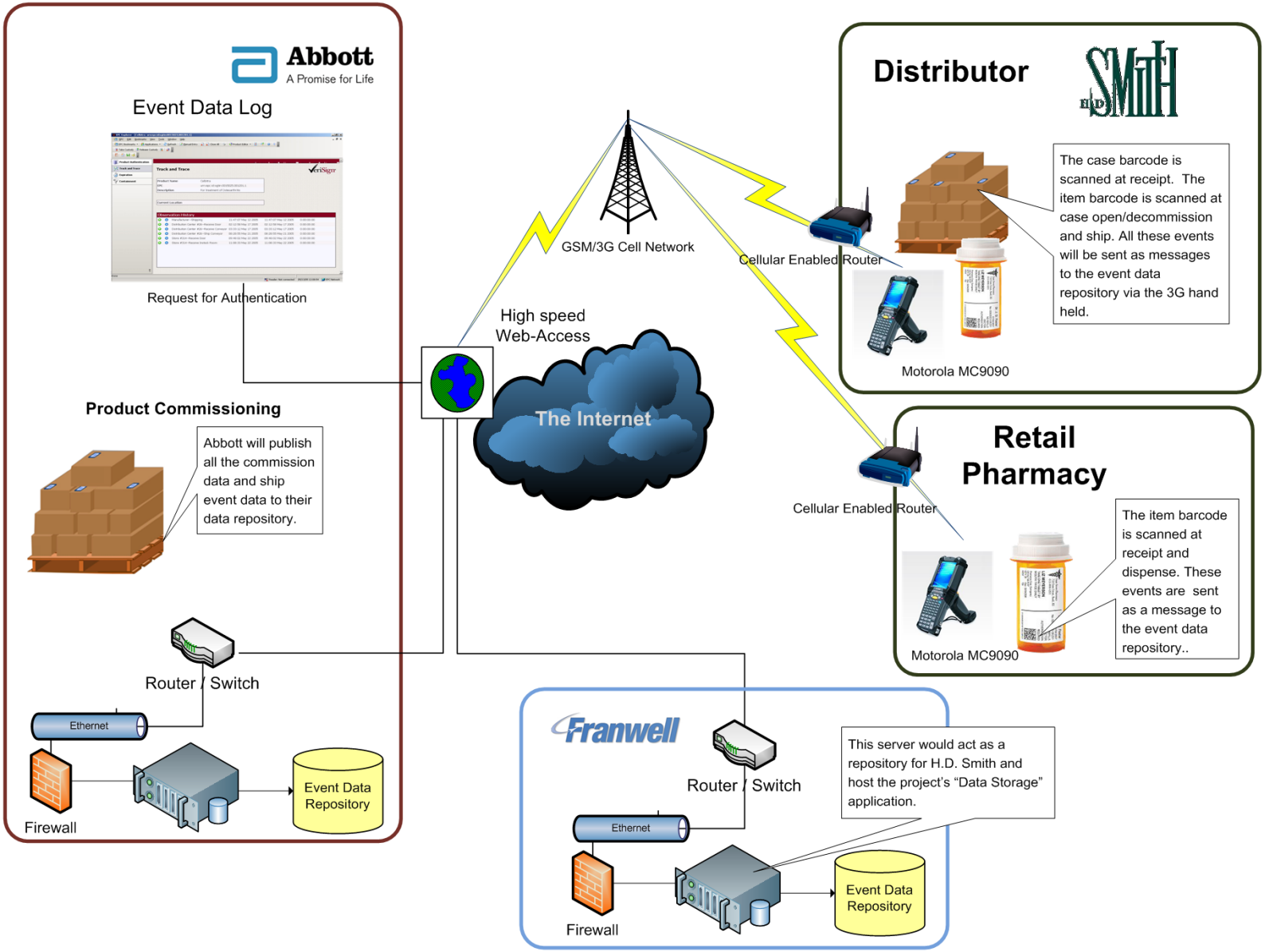
HD Smith Pilot Topology using Cell and/or 802.11 infrastructure



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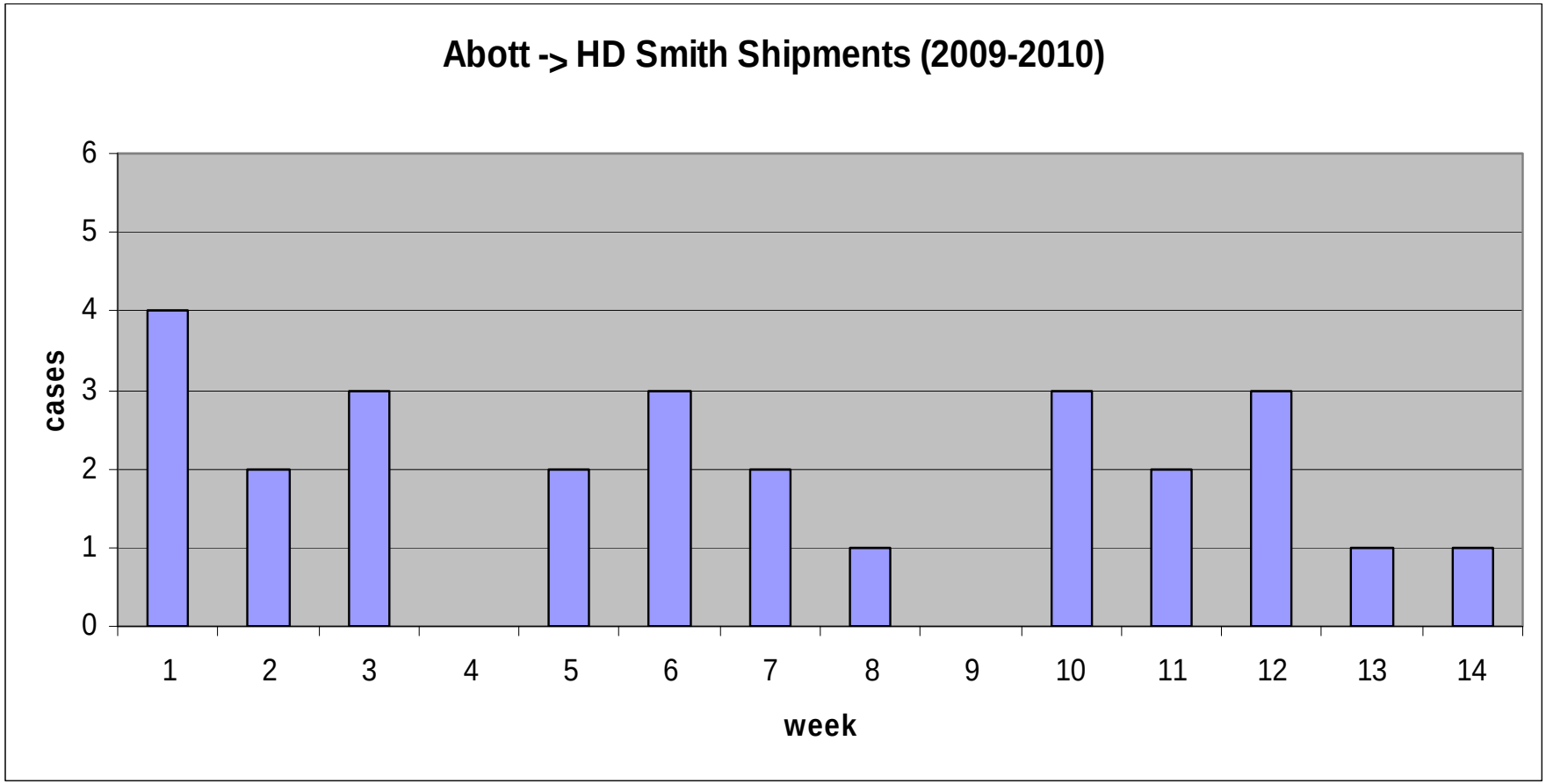
Humira TnT Pilot Metrics – HD Smith



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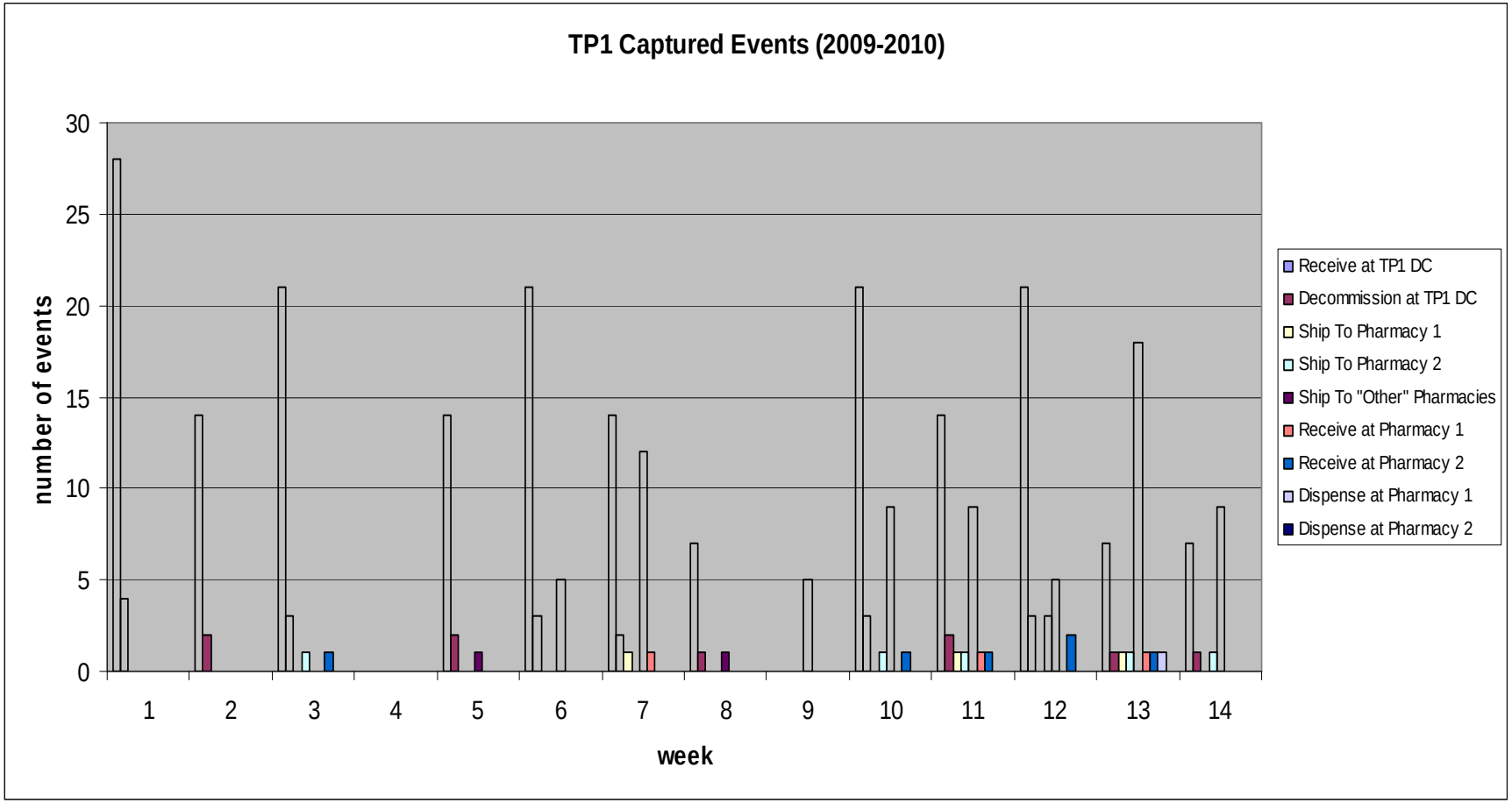
Humira TnT Pilot Metrics – HD Smith



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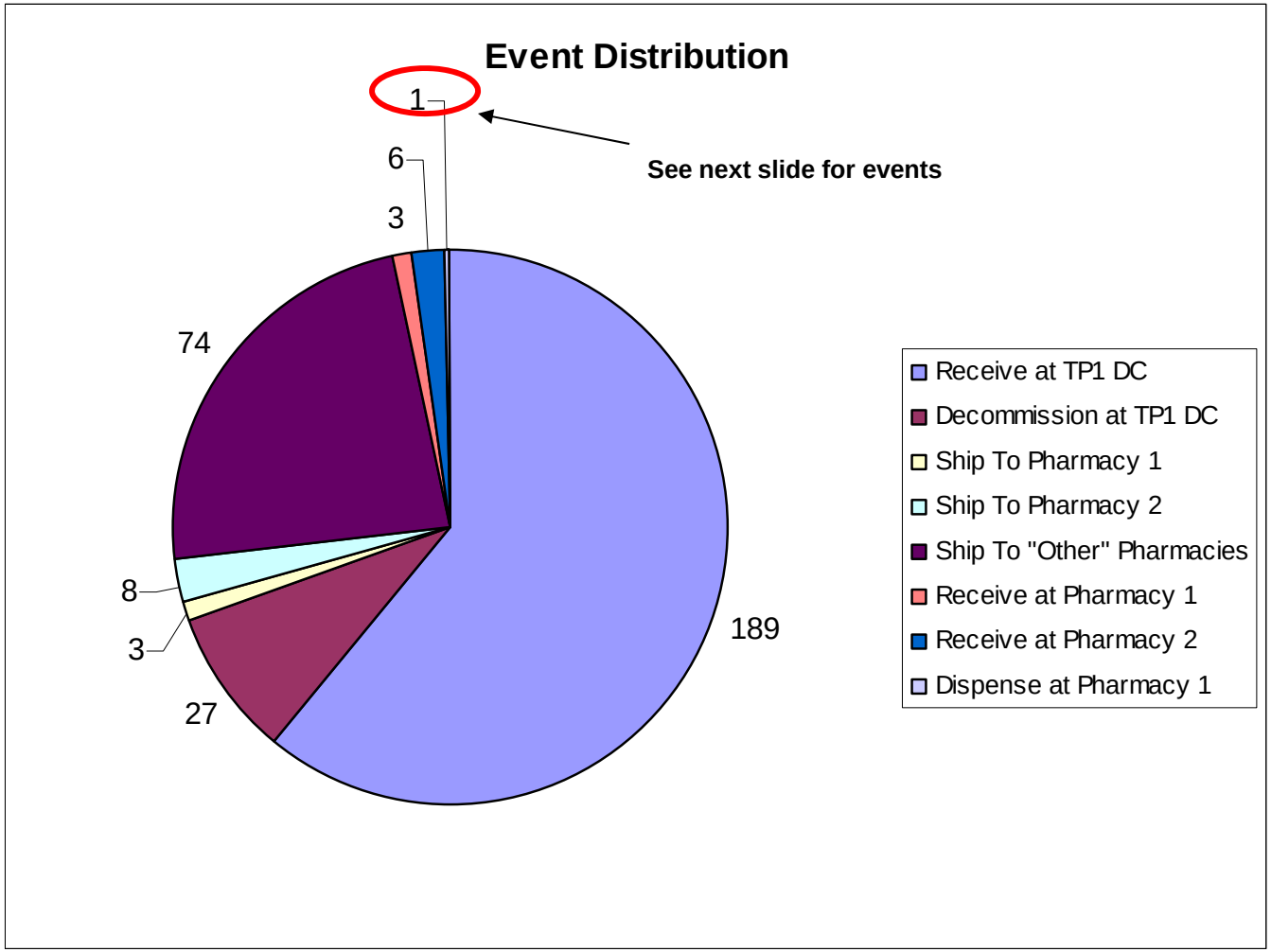
Humira TnT Pilot Metrics – HD Smith



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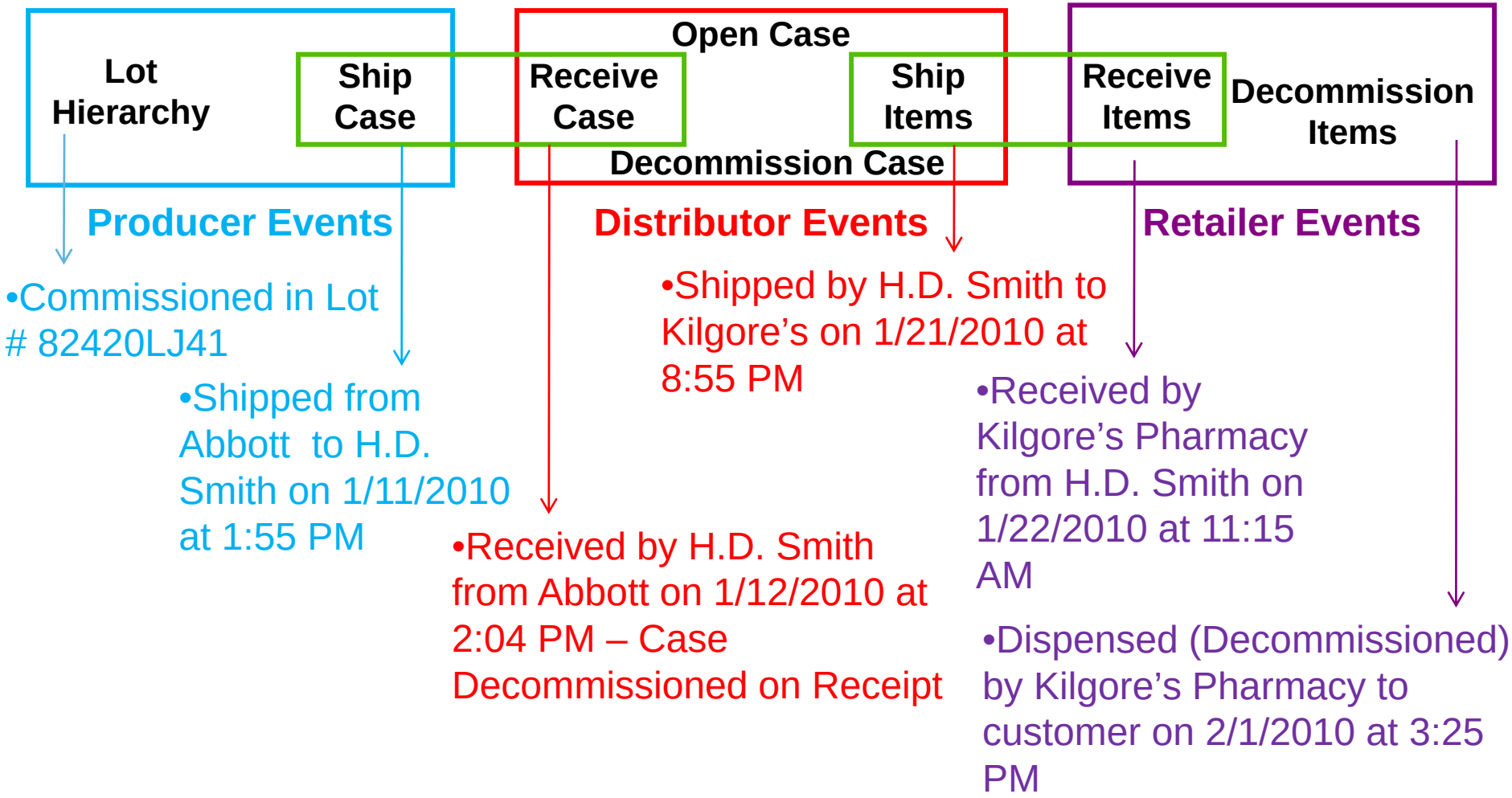
The chain of events for Item 01003007437990262110000012804 7



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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 #: 01003007437990262110000012804 7
Case Serial #: 01303007437990272110000011319 4

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

Object Event: OBSERVE
TIME: 1/12/10 2:01 PM
EPC: SGTINs (cases)
Biz Loc: HD Smith DC
BIZ STEP: receiving
DISP: in progress
EXT: Lot 78376LJ40

Object Event: DELETE
TIME: 1/12/10 2:01 PM
EPC: SGTINs (cases)
Biz Loc: HD Smith DC
BIZ STEP: decommissioning
DISP: inactive

Object Event: OBSERVE
TIME: 1/12/10 2:03 PM
EPC: SGTINs (items)
Biz Loc: HD Smith DC
BIZ STEP: receiving
DISP: in progress
EXT: Lot 78376LJ40

Object Event: OBSERVE
TIME: 1/21/10 8:55 PM
EPC : SGTINs (items)
Biz Loc: HD Smith DC
BIZ STEP: shipping
DISP: in progress

Item Serial #: 01003007437990262110000012804 7
Case Serial #: 01303007437990272110000011319 4

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

Object Event: OBSERVE
TIME: 1/22/10 11:31 AM
EPC: SGTIN (item)
Biz Loc: Kilgores Pharmacy
BIZ STEP: receiving
DISP: sellable accessible
EXT: Lot 78376LJ40

Object Event: OBSERVE
TIME: 2/1/10 3:26 PM
EPC: SGTIN (item)
Biz Loc: Kilgores Pharmacy
BIZ STEP: retail selling
DISP: sold
EXT: Lot 78376LJ40

Item Serial #: 01003007437990262110000012804 7
Case Serial #: 01303007437990272110000011319 4

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Abbott/HD Smith Pilot: Chain of Custody

BUS STEP	BUS LOCATION	Serial Number	TIME STAMP
SHIP	ABBOTT DC	01003007437990262110000002484 4	12/7/10 10:15 AM
RECEIVE	HD SMITH WHLSE DC	01003007437990262110000002484 4	12/8/09 2:06 PM
SHIP	KILGORES MED PHCY	01003007437990262110000002484 4	12/22/09 8:32 PM
RECEIVE	KILGORES MED PHCY	01003007437990262110000002484 4	12/23/09 9:38 AM
SHIP	ABBOTT DC	01003007437990262110000012804 7	1/11/10 10:15 AM
RECEIVE	HD SMITH WHLSE DC	01003007437990262110000012804 7	1/12/10 2:03 PM
SHIP	KILGORES MED PHCY	01003007437990262110000012804 7	1/21/10 8:55 PM
RECEIVE	KILGORES MED PHCY	01003007437990262110000012804 7	1/22/10 11:31 AM
DECOMMISSION	KILGORES MED PHCY	01003007437990262110000012804 7	2/1/10 3:26 PM
SHIP	ABBOTT DC	01003007437990262110000012919 1	1/18/10 10:15 AM
RECEIVE	HD SMITH WHLSE DC	01003007437990262110000012919 1	1/19/10 12:18 PM
SHIP	KILGORES MED PHCY	01003007437990262110000012919 1	2/1/10 9:43 PM
RECEIVE	KILGORES MED PHCY	01003007437990262110000012919 1	2/2/10 9:46 AM

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Abbott/HD Smith Pilot: Chain of Custody

BUS STEP	BUS LOCATION	Serial Number	TIME STAMP
SHIP	ABBOTT DC	01003007437990262110000006440 7	11/9/09 10:15 AM
RECEIVE	HD SMITH WHLSE DC	01003007437990262110000006440 7	11/10/09 11:58 AM
SHIP	COMPLETECARE PHARMACY	01003007437990262110000006440 7	11/25/09 10:29 AM
RECEIVE	COMPLETECARE PHARMACY	01003007437990262110000006440 7	11/25/09 10:54 AM
SHIP	ABBOTT DC	01003007437990262110000012835 6	1/11/10 10:15 AM
RECEIVE	HD SMITH WHLSE DC	01003007437990262110000012835 6	1/12/10 2:03 PM
SHIP	COMPLETECARE PHARMACY	01003007437990262110000012835 6	1/25/10 11:39 PM
RECEIVE	COMPLETECARE PHARMACY	01003007437990262110000012835 6	1/26/10 10:36 AM
SHIP	ABBOTT DC	01003007437990262110000012843 2	1/11/10 10:15 AM
RECEIVE	HD SMITH WHLSE DC	01003007437990262110000012843 2	1/12/10 2:03 PM
SHIP	COMPLETECARE PHARMACY	01003007437990262110000012843 2	1/27/10 10:47 PM
RECEIVE	COMPLETECARE PHARMACY	01003007437990262110000012843 2	1/28/10 10:35 AM
SHIP	ABBOTT DC	01003007437990262110000012920 0	1/25/10 10:15 AM
RECEIVE	HD SMITH WHLSE DC	01003007437990262110000012920 0	1/26/10 12:26 PM
SHIP	COMPLETECARE PHARMACY	01003007437990262110000012920 0	2/3/10 12:14 AM
RECEIVE	COMPLETECARE PHARMACY	01003007437990262110000012920 0	2/4/10 3:07 PM

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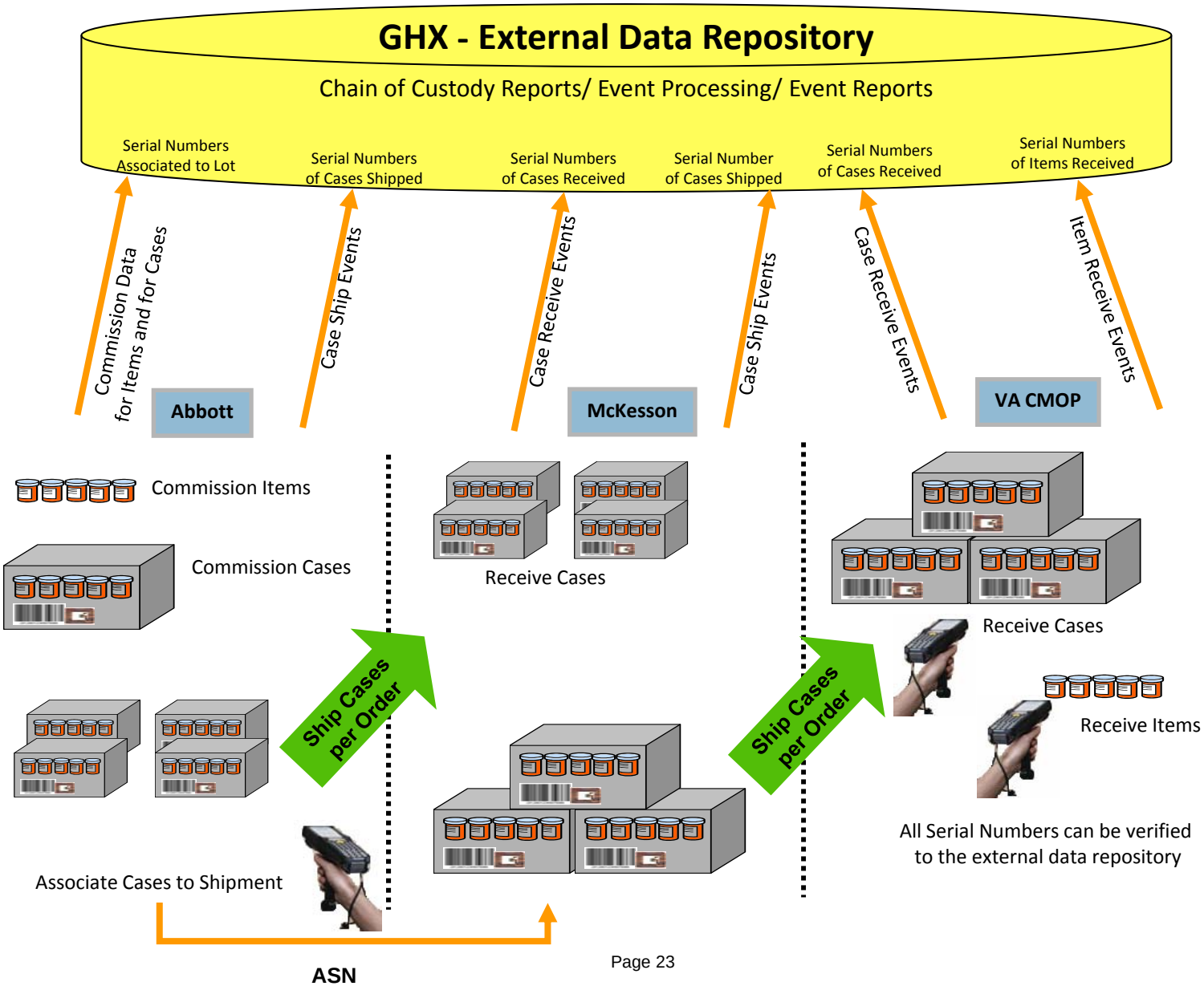
Humira Pen Pilot – May 2012



Abbott Posts Commissioned Serial Numbers by Lot

GHX Track and Trace dleeAsEmployeeOfAbbott

Data Capture - Commission

Read Point: Abbott Pharmaceutical Products

Biz Location: Abbott Pharmaceutical Products

Scan Here:

```
(01)30300744339024(21)100000003932
(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: 2012-05-14 YYYY-MM-DD

Time: 18:55:41 HH:mm:ss (24 hour format)

Time Zone: Central

Batch/Lot Number: 132172E

Expiration Date: 2013-10-31 YYYY-MM-DD

Generate Commissioning Event → Event

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

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Abbott Creates Relationships Between Serial Numbers

GHX Track and Trace dleeAsEmployeeOfAbbott LOGOUT

Data Capture - Aggregation

Read Point: Abbott Pharmaceutical Products

Biz Location: Abbott Pharmaceutical Products

Scan Parent Here:
(01)30300744339024(21)100000003932

Scan Children Here:
(01)00300744339023(21)100000063627
(01)00300744339023(21)100000063628
(01)00300744339023(21)100000063629
(01)00300744339023(21)100000063630
(01)00300744339023(21)100000063631
(01)00300744339023(21)100000063632

Date: 2012-05-14 YYYY-MM-DD

Time: 18:55:41 HH:mm:ss (24 hour format)

Time Zone: Central

Generate Aggregation Event

Commission Aggregation Ship Check Receive Disaggregation

Event

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

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Abbott Posts Certifiable Ship Data

GHX Track and Trace 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

Generate Shipping Event

Event

Commission Aggregation Ship Check Receive Disaggregation

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

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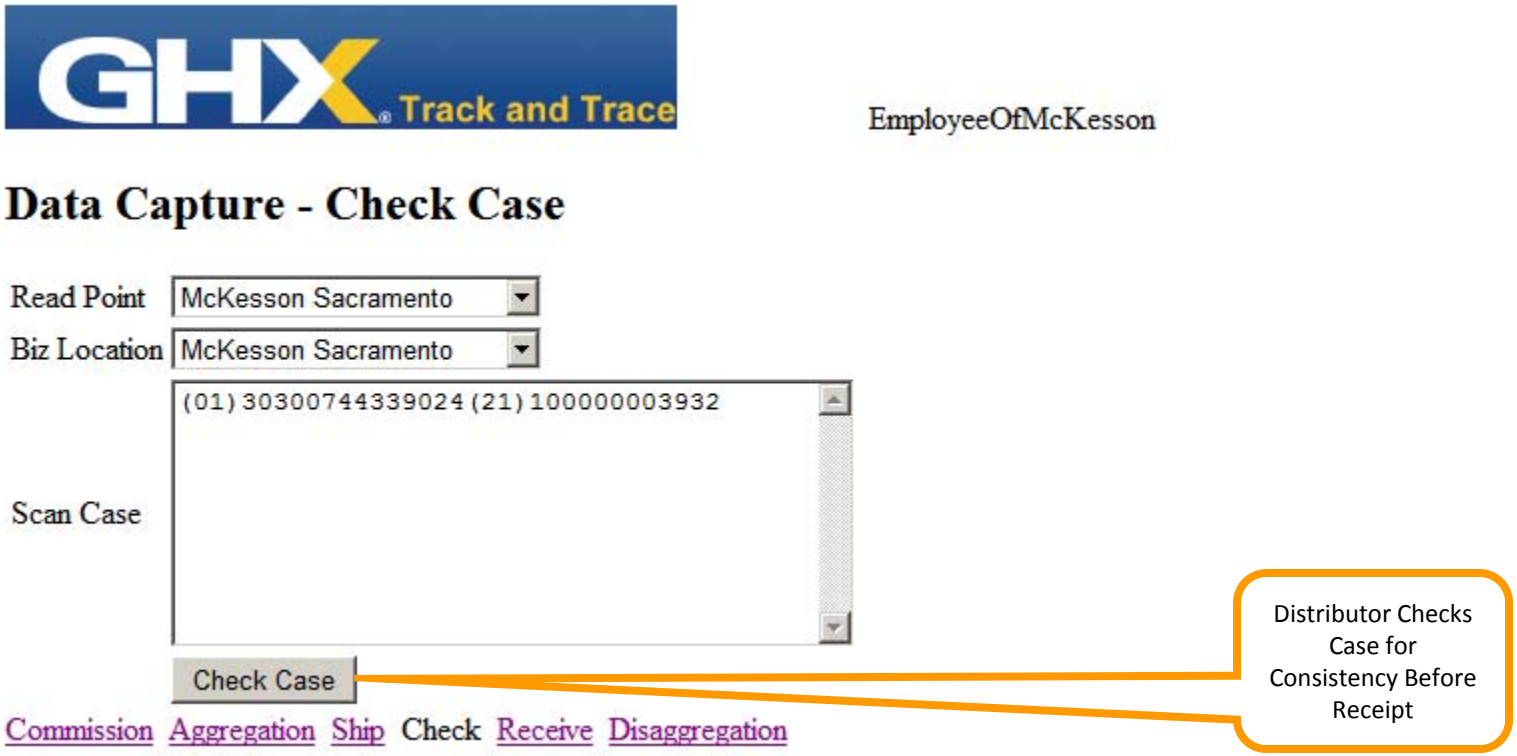
Distributor Receives Shipment Identifier



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Distributor Receives Case – Closes Chain of Custody

GHX Track and Trace

EmployeeOfMcKesson

Data Capture - Receive Case

Read Point	McKesson Sacramento
Biz Location	McKesson Sacramento
Case SGTIN	urn:epc:id:sgtin:030074.3433902.100000003932
Case Status	Consistent ✔
Scan Items	
Date	2012-05-16 YYYY-MM-DD
Time	16:53:05 HH:mm:ss (24 hour format)
Time Zone	Pacific
Related PO Number	po 8182869993 optional
Related Invoice Number	optional
Disaggregation?	☐ Also create Disaggregation event for this Case

Generate Receiving Event

Event

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

GHX Track and Trace

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

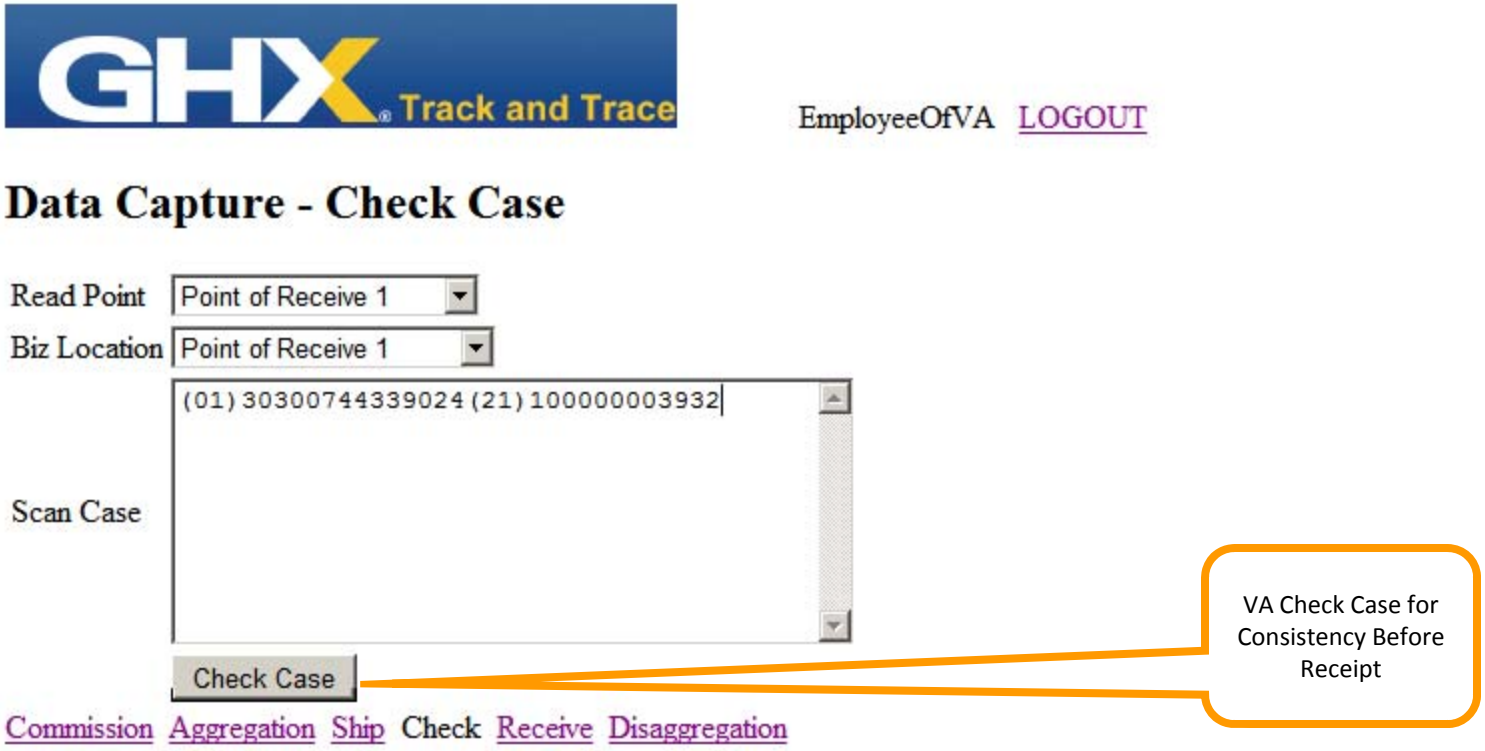
Event

Commission Aggregation Ship Check Receive Disaggregation

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

VA Receives Shipment Identifier



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VA Receives Case – Closes Chain of Custody

GHX Track and Trace

EmployeeOfVA

Data Capture - Receive Case

Read Point	Point of Receive 1
Biz Location	Point of Receive 1
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	2012-05-22 YYYY-MM-DD
Time	12:36:49 HH:mm:ss (24 hour format)
Time Zone	Central
Related PO Number	optional
Related Invoice Number	optional
Disaggregation?	☑ Also create Disaggregation event for this Case

Generate Receiving Event

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.

- [x] **Product History** **Product Number** sgtin:030074.3433902.100000003932
- [ ] **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

Browse...

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 Stength: **0.8 mL**
Package Quantity:
Drug Form: **SYRINGE**
Classification: **TNF Blocker**

Chain of Custody

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

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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 Stength: **0.8 mL**
Package Quantity:
Drug Form: **SYRINGE**
Classification: **TNF Blocker**

Custody Checks

n/a	2012-05-15T23:02:10.909Z	sgln 030074.000000.0
n/a	2012-05-16T14:06:03.587Z	sgln 030074.000000.0
n/a	2012-05-16T16:08:31.506Z	sgln 030074.000000.0

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Business concerns - mapping to models

		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/easily 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
Centralized	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
Distributed	Distributed with Discovery Services	Y		N	Y	Y	N	N	N	N		Y
Distributed	Distributed with Discovery Services and Checking Service	Y	Y	Y	Y	Y	N	Y	N	Y	Y	Y

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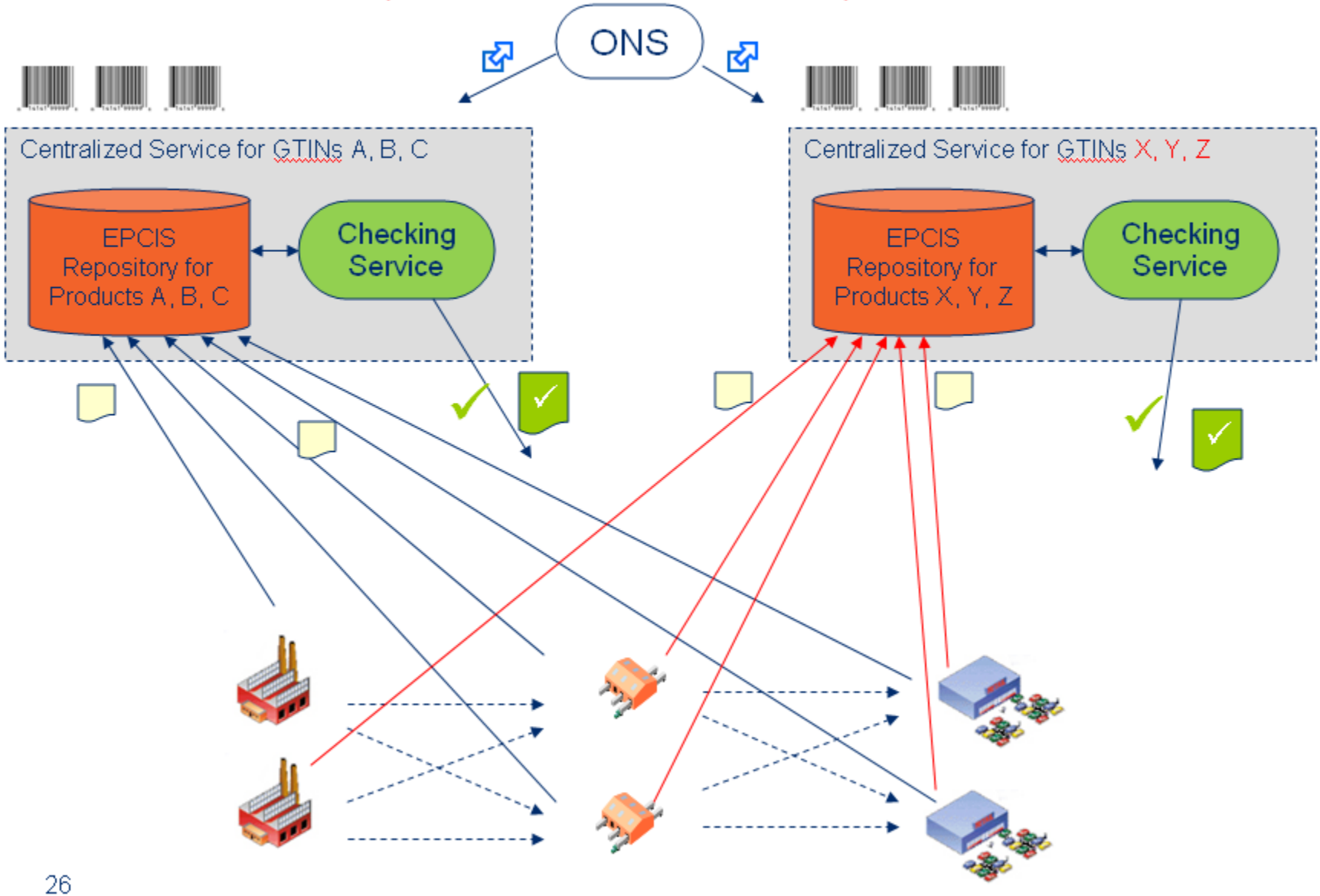
Semi-centralized model [per GTIN]
(architectural model)



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Aggregate and Inference

Inference

- 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

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 <u>and</u> can be verified back to commission data.

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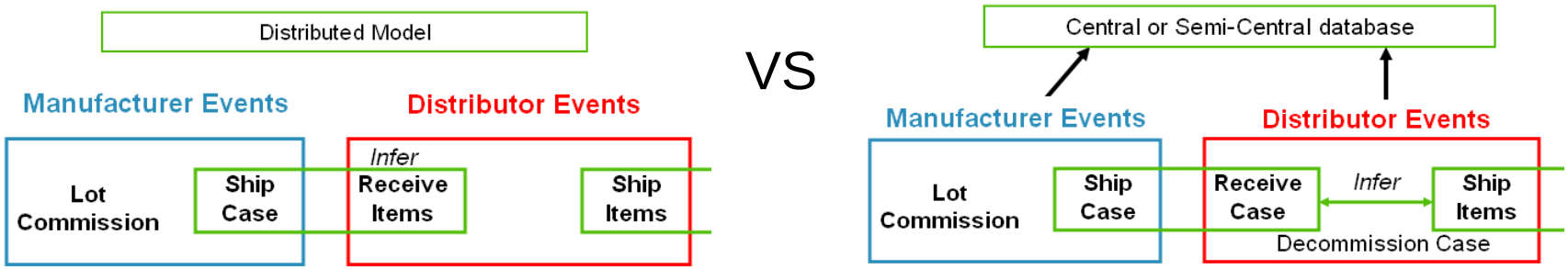
Model Comparisons



- 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?

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Key Concepts & Terminology (2)

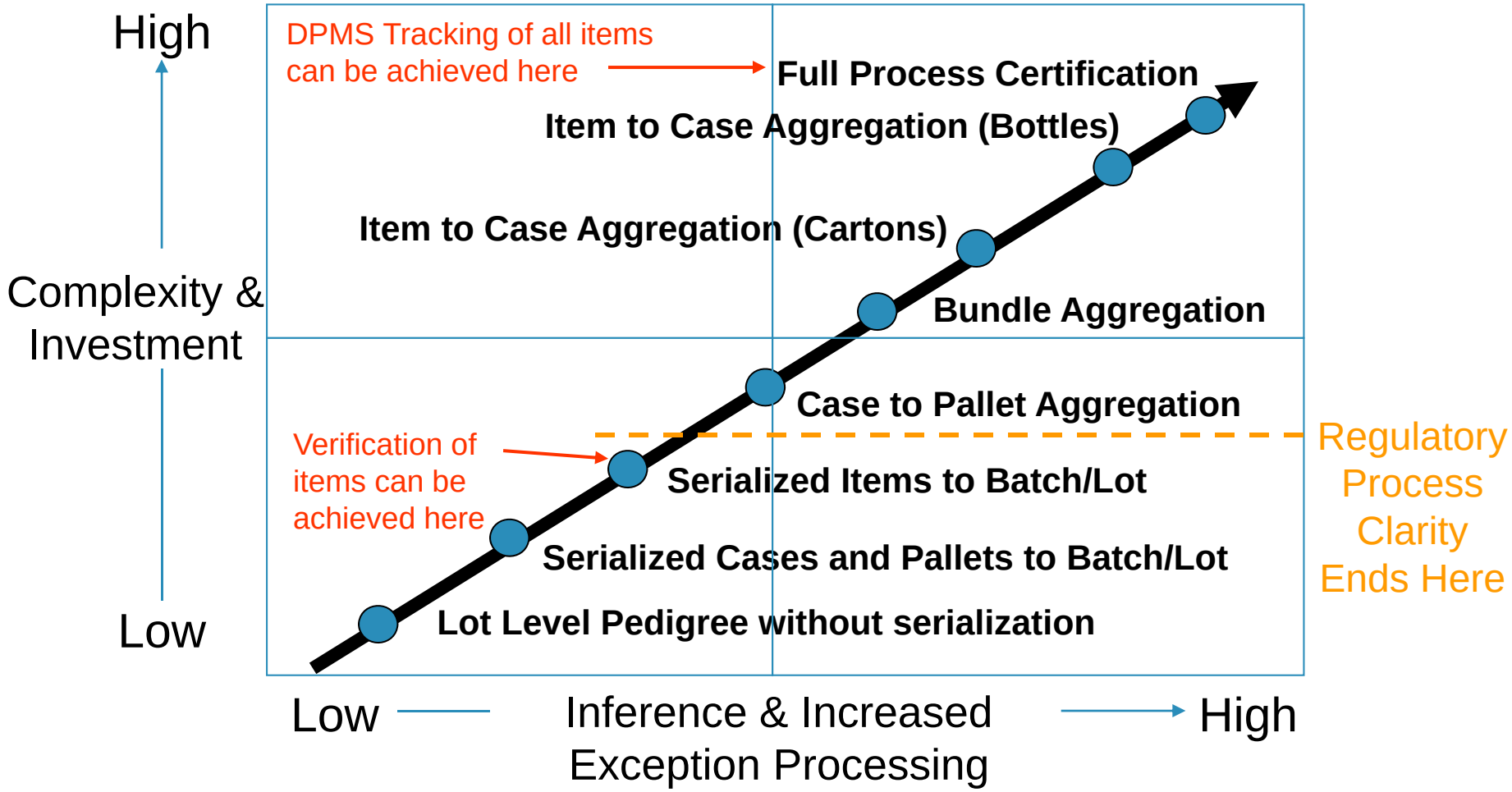
FOR DISCUSSION ONLY

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



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Desired Industry Implementation Approach

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 <u>accurately</u> 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

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Thank you

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