MINUTES
Enforcement Committee and E-Pedigree Public Meeting
June 12, 2012

COMMITTEE MEMBERS 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

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 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.

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

Manufacturer -> Wholesaler

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

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.

Brokers sales to pharmacies.
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 identified.
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
**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?

Apparel

Sea Food

Fresh Foods

Food Service

Consumer Goods

Aerospace

Pharmaceuticals

Healthcare Providers
SERIALIZATION AROUND THE WORLD
IDENTIFICATION OF PHARMACEUTICALS

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

- = country requires serial number
- = country developing requirement for serial number
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

= country requires DataMatrix

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

### EPCIS

#### Who
- Ship-From
- Ship-To
- Buyer
- Seller

#### What
- Products
- Logistics Units
- Assets
- Relationships

#### Where
- Postal Locations
- Warehouses
- Floors, Rooms

#### When
- Time & Date

#### Why
- Commissioning
- Packing
- Shipping
- Receiving
- Dispensing

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<thead>
<tr>
<th>Example</th>
<th>Standard</th>
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<td>Ship-From</td>
<td>GLN</td>
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<td>Ship-To</td>
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<td>Seller</td>
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<td>SSCC</td>
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<td>Assets</td>
<td>GRAI, GIAI</td>
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<td>Relationships</td>
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<td>Postal Locations</td>
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<td>Warehouses</td>
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<td>Floors, Rooms</td>
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**Business Step**
WHAT CAN WE DO WITH TRACK & TRACE STANDARDS?
Pedigree Data (showing Master Data)
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
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

Security Key (2nd Serial Number)

Information

Products

Manufacturer

Wholesaler

Retail Pharmacy

Hospital Pharmacy

Product ID (GTIN)
Serial Number
Lot #
Expiration Date

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

Manufacturer

Wholesaler

Retail Pharmacy

Hospital Pharmacy

Security Key (2nd Serial Number)

Product ID (GTIN)
Serial Number Lot # Expiration Date

Was the Product ID and Serial Number put into commerce?

Is a legitimate company asking?

Have they actually had possession of the item?
ANTI-COUNTERFEIT CONSIDERATIONS
INFORMATION SECURITY

Are they who they say they are?

Yes! That Serial Number was put into commerce.

Product ID (GTIN)
Serial Number
Lot #
Expiration Date

Security Key (2nd Serial Number)

Manufacturer
Retail Pharmacy
Hospital Pharmacy
Wholesaler

Products

Information
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**
STANDARDS ACTIVITIES IN THE U.S.

IMPLEMENTATION SUPPORT
STANDARDS ACTIVITIES WITHIN THE U.S.

INFERENCE
### Statistical Sampling Plan

| A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W |
| 2 | Input required by users: | | | | | | | | | | | | | | | | | | | | | | |
| 3 | | | | | | | | | | | | | | | | | | | | | | |
| 4 | | | | | | | | | | | | | | | | | | | | | | |
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| 35 | | | | | | | | | | | | | | | | | | | | | | |

### 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, the OC curve shows the probability that the shipment will be accepted.

   ![Operating Characteristic (OC) Curve](image)

   - Normal Inspection
   - Reduced Inspection (1)
   - Reduced Inspection (2)

2. **Average Outgoing Quality (AOQ)**

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

   ![Average Outgoing Quality (AOQ)](image)

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

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<th>Topics</th>
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<td>Bar code quality and readability</td>
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<td>Company Governance – Managing Traceability</td>
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<td>RFID Bar Code Interoperability - GS1 Guideline</td>
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<td>Translations between different formats</td>
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<td>9/5/2012</td>
<td>Inference and Aggregation</td>
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</table>
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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Connect with the GS1 US community on

LinkedIn  Twitter  YouTube
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

- 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

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- **Manufacturing Lines Enabled to meet California timeline**
  - Bottle, Carton & Blister packaging lines across three plant sites

- **Pilot Serialized Trades**
  - Primary trade partners

- **Complete Labeling Conversions & Execute Serialized Trades**
  - Approximately 200 SKU’s in scope

- **Enable Third Party Manufacturer Functionality**
  - Transfer of serial numbers and receipt of serialized product
  - 10% Q1, 30% Q2, 30% Q3, 30% Q4

- **DC Process Modification & Technology Implementation**
  - Develop protocols

- **Enable standard trade capability with remaining trade partners**
  - EDI ASN’s and GS1 EPCIS

- **Enable Serialized Ordering & Receiving**
  - Enterprise & WMS
Line Schematic
# Product Packaging Levels

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<th>Packaging Level</th>
<th>Carrier/Encoding</th>
<th>Data Carrier Example</th>
<th>Data encoded</th>
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<td>2D/GS1 Data Matrix</td>
<td><img src="image1.png" alt="Barcode Image" /></td>
<td>GTIN+Serial Number</td>
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<td>1D/e.g. UPC-A</td>
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<td>GTIN</td>
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<td>Case (Full)</td>
<td>RFID/EPC GEN 2 UHF</td>
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<td>GTIN + Serial Number</td>
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<td>1D/GS1-128</td>
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<td>Case (Partial/Mixed)</td>
<td>RFID/EPC GEN 2 UHF</td>
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<td>1D/GS1-128</td>
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<td>1D/GS1-128</td>
<td><img src="image8.png" alt="Barcode Image" /></td>
<td>SSCC</td>
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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
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
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

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

Event Data Log

GSM/3G Cell Network

High speed Web-Access

Product Commissioning

Abbott will publish all the commission data and ship event data to their data repository.

Router / Switch

Firewall

Event Data Repository

Distributor

The case barcode is scanned at receipt. The item barcode is scanned at case open/decommission and ship. All these events will be sent as messages to the event data repository via the 3G handheld.

Motorola MC9090

Retail Pharmacy

The item barcode is scanned at receipt and dispense. These events are sent as a message to the event data repository.

Motorola MC9090

Franwell

This server would act as a repository for H.D. Smith and host the project’s “Data Storage” application.

Firewall

Event Data Repository

Router / Switch

Abbott

A Promise for Life
Humira TnT Pilot Metrics – HD Smith

Abott → HD Smith Shipments (2009-2010)
TP1 Captured Events (2009-2010)

- Receive at TP1 DC
- Decommission at TP1 DC
- Ship To Pharmacy 1
- Ship To Pharmacy 2
- Ship To "Other" Pharmacies
- Receive at Pharmacy 1
- Receive at Pharmacy 2
- Dispense at Pharmacy 1
- Dispense at Pharmacy 2

Week numbers range from 1 to 14.
Event Distribution

- Receive at TP1 DC: 74
- Decommission at TP1 DC: 6
- Ship To Pharmacy 1: 3
- Ship To Pharmacy 2: 8
- Ship To "Other" Pharmacies: 3
- Dispense at Pharmacy 1: 27
- Receive at Pharmacy 1: 189

See next slide for events
The chain of events for Item 010030074379902621100000128047

Lot Hierarchy
- Producer Events
  - Commissioned in Lot # 82420LJ41
  - Shipped from Abbott to H.D. Smith on 1/11/2010 at 1:55 PM

Ship Case

Receive Case
- Distributor Events
  - Shipped by H.D. Smith to Kilgore’s on 1/21/2010 at 8:55 PM
  - Received by Kilgore’s Pharmacy from H.D. Smith on 1/22/2010 at 11:15 AM

Ship Items
- Retailer Events
  - Received by H.D. Smith from Abbott on 1/12/2010 at 2:04 PM – Case Decommissioned on Receipt
  - Dispensed ( Decommissioned) by Kilgore’s Pharmacy to customer on 2/1/2010 at 3:25 PM
Abbott/HD Smith Pilot: End-To-End Visibility

Product Items Commissioned

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

Product Cases Commissioned

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

Product Items Aggregated to Cases

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
EXT: Lot 78376LJ40

Product Cases Associated with Delivery

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

Product Cases Received
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

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

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

Product Item Shipped to a Pharmacy
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 #: 010030074379902621100000128047
Case Serial #: 013030074379902721100000113194
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 #: 0100300743799026211000000128047
Case Serial #: 0130300743799027211000000113194
## Abbott/HD Smith Pilot: Chain of Custody

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<td>1/26/10 12:26 PM</td>
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<tr>
<td>SHIP</td>
<td>COMPLETECARE PHARMACY</td>
<td>01003007437990262110000129200</td>
<td>2/3/10 12:14 AM</td>
</tr>
<tr>
<td>RECEIVE</td>
<td>COMPLETECARE PHARMACY</td>
<td>01003007437990262110000129200</td>
<td>2/4/10 3:07 PM</td>
</tr>
</tbody>
</table>
Humira Pen Pilot – May 2012

GHX - External Data Repository

Chain of Custody Reports/ Event Processing/ Event Reports

- Serial Numbers Associated to Lot
- Serial Numbers of Cases Shipped
- Serial Numbers of Cases Received
- Serial Number of Cases Shipped
- Serial Numbers of Cases Received
- Serial Numbers of Items Received

- Commission Data for Items and for Cases
- Case Ship Events
- Case Receive Events
- VA CMOP

- Abbott
- McKesson

Commission Items
Commission Cases
Receive Cases

All Serial Numbers can be verified to the external data repository

Associate Cases to Shipment
Ship Cases per Order

ASN
Page 23
Data Capture - Commission

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

- Event
- Generate Commissioning Event

Page 24
Abbott Creates Relationships Between Serial Numbers

**Data Capture - Aggregation**

<table>
<thead>
<tr>
<th>Read Point</th>
<th>Abbott Pharmaceutical Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biz Location</td>
<td>Abbott Pharmaceutical Products</td>
</tr>
</tbody>
</table>

**Scan Parent Here**

- (01) 30300744339024 (21) 100000003932
- (01) 00300744339023 (21) 100000003627
- (01) 00300744339023 (21) 100000003628
- (01) 00300744339023 (21) 100000003629
- (01) 00300744339023 (21) 100000003630
- (01) 00300744339023 (21) 100000003631
- (01) 00300744339023 (21) 100000003632

**Scan Children Here**

**Date**

- 2012-05-14

**Time**

- 18:55:41

**Time Zone**

- Central

**Commission**

- Aggregation

**Event**

- Generate Aggregation Event

**Business Step:** Aggregation

**Disposition:** in progress

**Parent Product Number:** sgtn 030074.3433902.100000003932

**Container Qty:** 6

**Child Product Numbers:**

- sgtn 030074.0433902.1000000063627
- sgtn 030074.0433902.1000000063628
- sgtn 030074.0433902.1000000063629
- sgtn 030074.0433902.1000000063630
- sgtn 030074.0433902.1000000063631
- sgtn 030074.0433902.1000000063632

05/15/2012 6:01:32 PM AGGREGATION SGLN 030074.000000.0
### Data Capture - Ship

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sold From Party</td>
<td>Abbott Pharmaceutical Products</td>
</tr>
<tr>
<td>Ship From Location</td>
<td>Abbott Pharmaceutical Products</td>
</tr>
<tr>
<td>Sold To Party</td>
<td>0010939999000 - McKesson Financial Center</td>
</tr>
<tr>
<td>Ship To Location</td>
<td>0010939182000 - McKesson Sacramento</td>
</tr>
<tr>
<td>Read Point</td>
<td>Abbott Pharmaceutical Products</td>
</tr>
<tr>
<td>Biz Location</td>
<td>Abbott Pharmaceutical Products</td>
</tr>
<tr>
<td>Date</td>
<td>2012-05-15</td>
</tr>
<tr>
<td>Time</td>
<td>18:07:29 HH:MM:SS (24 hour format)</td>
</tr>
<tr>
<td>Time Zone</td>
<td>Central</td>
</tr>
<tr>
<td>Related PO Number</td>
<td>8182669993</td>
</tr>
<tr>
<td>Related Invoice Number</td>
<td>Optional</td>
</tr>
</tbody>
</table>

**Generate Shipping Event**

**Event**

- **Business Step:** shipping
- **Disposition:** in transit
- **Container Qty:** 1
- **Child Product Numbers:** sgln 030074 3433902 1000000003932
- **Transactions:** undefined 8182669993
Distributor Receives Shipment Identifier

Data Capture - Check Case

- **Read Point**: McKesson Sacramento
- **Biz Location**: McKesson Sacramento

Scan Case: (01) 30300744339024 (21) 10000003932

- **Commission**  **Aggregation**  **Ship**  **Check**  **Receive**  **Disaggregation**

Distributor Checks Case for Consistency Before Receipt
## Data Capture - Receive Case

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Read Point</td>
<td>McKesson Sacramento</td>
</tr>
<tr>
<td>Biz Location</td>
<td>McKesson Sacramento</td>
</tr>
<tr>
<td>Case SGTIN</td>
<td>urn:epc:id:sgtin:030074.3433902.10000003932</td>
</tr>
<tr>
<td>Case Status</td>
<td>Consistent [✓]</td>
</tr>
<tr>
<td>Scan Items</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>2012-05-16</td>
</tr>
<tr>
<td>Time</td>
<td>16:53:05</td>
</tr>
<tr>
<td>Time Zone</td>
<td>Pacific</td>
</tr>
<tr>
<td>Related PO Number</td>
<td>po 8182869993</td>
</tr>
<tr>
<td>Related Invoice Num</td>
<td>optional</td>
</tr>
<tr>
<td>Disaggregation?</td>
<td>☐ Also create Disaggregation event for this Case</td>
</tr>
</tbody>
</table>

### Event

- **Business Step**: receiving
- **Disposition**: in_progress
- **Container Qty**: 1
- **Child Product Numbers**: sgtn 030074.3433902.10000003932
- **Transactions**: po 8182869993
### Data Capture - Ship

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sold From Party</td>
<td>McKesson Financial Center</td>
</tr>
<tr>
<td>Ship From Location</td>
<td>McKesson Sacramento</td>
</tr>
<tr>
<td>Sold To Party</td>
<td>4703713051710 - Point of Receive 1</td>
</tr>
<tr>
<td>Ship To Location</td>
<td>4703713051710 - Point of Receive 1</td>
</tr>
<tr>
<td>Read Point</td>
<td>McKesson Sacramento</td>
</tr>
<tr>
<td>Biz Location</td>
<td>McKesson Sacramento</td>
</tr>
<tr>
<td>Date</td>
<td>2012-05-18</td>
</tr>
<tr>
<td>Time</td>
<td>14:23:09 (HH:mm:ss)</td>
</tr>
<tr>
<td>Time Zone</td>
<td>Pacific</td>
</tr>
<tr>
<td>Related PO Number</td>
<td>C25018HPEN18</td>
</tr>
<tr>
<td>Related Invoice Number</td>
<td>Optional</td>
</tr>
</tbody>
</table>

**Generate Shipping Event**

**Event**

- **Date:** 05/18/2012 2:23:09 PM
- **Location:** Shipping
- **SGLN:** 0010939.18200.0
- **Business Step:** shipping
- **Disposition:** in transit
- **Container Qty:** 1
- **Child Product Numbers:** sgtin 030074.343902.100000003932
- **Transactions:** undefined C25018HPEN18
VA Receives Shipment Identifier

Data Capture - Check Case

Read Point: Point of Receive 1
Biz Location: Point of Receive 1
Scan Case:

(01) 303007443939024 (21) 1000000003932

[Check Case]

Commission Aggregation Ship Check Receive Disaggregation

VA Check Case for Consistency Before Receipt
VA Receives Case – Closes Chain of Custody

Data Capture - Receive Case

Read Point: Point of Receive 1
Biz Location: Point of Receive 1
Case SGTIN: urn:epc:id:sgtin:030074.34339021.00000003932
Case Status: Consistent

Scan Items:

Date: 2012-05-22
Time: 12:36:49
Time Zone: Central
Related PO Number: optional
Related Invoice Number: optional
Disaggregation?: Yes

Generate Receiving Event

Event

Business Step: receiving
Disposition: in_progress
Container Qty: 1
Child Product Numbers: sgtn 030074.34339021.00000003932

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

Business Step: Disaggregation
Disposition: in_progress
Parent Product Number: sgtn 030074.34339021.00000003932
Container Qty: 6
Child Product Numbers: sgtn 030074.34339021.000000063627
sgtn 030074.34339021.000000063631
sgtn 030074.34339021.000000063628
sgtn 030074.34339021.000000063632
sgtn 030074.34339021.000000063629
sgtn 030074.34339021.000000063630

Page 31
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
- 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

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

<table>
<thead>
<tr>
<th>Product Number</th>
<th>Date</th>
<th>Event Sequence State</th>
<th>Location</th>
<th>Business Step</th>
<th>Disposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>sgtn 030074.3433902.100000003932</td>
<td>05/22/2012</td>
<td>Consistent</td>
<td>sgtn 47037130.5171.0</td>
<td>Disaggregation</td>
<td>in_progress</td>
</tr>
</tbody>
</table>

### 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

- **commissioning** 05/14/2012 6:55:41 PM
- **Aggregation** 05/15/2012 6:01:32 PM
- **shipping** 05/15/2012 6:07:29 PM
- **Custody Check** 2012-05-16T14:06:03.587Z 2012-05-16T14:06:03.587Z
- **shipping** 05/18/2012 2:23:09 PM
- **receiving** 05/22/2012 12:36:49 PM
- **Disaggregation** 05/22/2012 12:36:49 PM
- **Custody Check** 2012-05-22T16:36:49.701Z 2012-05-22T16:36:49.701Z

---

*Abbott*

*A Promise for Life*
Custody Report

<table>
<thead>
<tr>
<th>Product Number</th>
<th>Date</th>
<th>Event Sequence State</th>
<th>Location</th>
<th>Business Step</th>
<th>Disposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>sgtln 030074.3433902.10000003932</td>
<td>05/14/2012</td>
<td>Consistent</td>
<td>sgtln 030074.000000.0</td>
<td>shipping</td>
<td>in_transit</td>
</tr>
</tbody>
</table>

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
- **n/a 2012-05-15T23:02:10.909Z**
- **n/a 2012-05-16T14:06:03.597Z**
- **n/a 2012-05-16T16:08:31.506Z**

## Business concerns - mapping to models

<table>
<thead>
<tr>
<th></th>
<th>Avoid delays to receiving / shipping operations</th>
<th>Data ownership and confidentiality</th>
<th>Data availability</th>
<th>Improvements over DPMS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Centralized</strong></td>
<td><img src="image" alt="Centralized" /></td>
<td><img src="image" alt="Centralized" /></td>
<td><img src="image" alt="Centralized" /></td>
<td><img src="image" alt="Centralized" /></td>
</tr>
<tr>
<td><strong>Semi-centralized</strong> (per GTIN) with checking service</td>
<td><img src="image" alt="Semi-centralized" /></td>
<td><img src="image" alt="Semi-centralized" /></td>
<td><img src="image" alt="Semi-centralized" /></td>
<td><img src="image" alt="Semi-centralized" /></td>
</tr>
<tr>
<td><strong>Distributed with push of links</strong></td>
<td><img src="image" alt="Distributed with push of links" /></td>
<td><img src="image" alt="Distributed with push of links" /></td>
<td><img src="image" alt="Distributed with push of links" /></td>
<td><img src="image" alt="Distributed with push of links" /></td>
</tr>
<tr>
<td><strong>Distributed</strong></td>
<td><img src="image" alt="Distributed" /></td>
<td><img src="image" alt="Distributed" /></td>
<td><img src="image" alt="Distributed" /></td>
<td><img src="image" alt="Distributed" /></td>
</tr>
<tr>
<td><strong>Distributed with Discovery Services</strong></td>
<td><img src="image" alt="Distributed with Discovery Services" /></td>
<td><img src="image" alt="Distributed with Discovery Services" /></td>
<td><img src="image" alt="Distributed with Discovery Services" /></td>
<td><img src="image" alt="Distributed with Discovery Services" /></td>
</tr>
<tr>
<td><strong>Distributed with Discovery Services and Checking Service</strong></td>
<td><img src="image" alt="Distributed with Discovery Services and Checking Service" /></td>
<td><img src="image" alt="Distributed with Discovery Services and Checking Service" /></td>
<td><img src="image" alt="Distributed with Discovery Services and Checking Service" /></td>
<td><img src="image" alt="Distributed with Discovery Services and Checking Service" /></td>
</tr>
</tbody>
</table>
Semi-centralized model [per GTIN] (architectural model)
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 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 company’s 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)

<table>
<thead>
<tr>
<th>Concept</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interoperability</td>
<td>• establishes compatible data and process standards to enable system participants to have the capability of sharing data by integrating into the same system</td>
</tr>
<tr>
<td>Authentication</td>
<td>• 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.</td>
</tr>
<tr>
<td>Data Management</td>
<td>• 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.</td>
</tr>
<tr>
<td>Track-and-trace data</td>
<td>• Any information collected about each package from the point of manufacture to the point of dispense or destruction</td>
</tr>
<tr>
<td>Pedigree</td>
<td>• Distribution history of a drug package</td>
</tr>
<tr>
<td>Accountability</td>
<td>• When a person or entity has to report, explain, justify, or be responsible for effectively takes custody or ownership of a package</td>
</tr>
<tr>
<td>Status</td>
<td>• 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.)</td>
</tr>
</tbody>
</table>
Trade Model Considerations

Segregated databases require 100% accuracy to facilitate Inference

Complexity & Investment

High

Low

DPMS Tracking of all items can be achieved here

Full Process Certification

Item to Case Aggregation (Bottles)

Item to Case Aggregation (Cartons)

Bundle Aggregation

Case to Pallet Aggregation

Serialized Items to Batch/Lot

Serialized Cases and Pallets to Batch/Lot

Lot Level Pedigree without serialization

Verification of items can be achieved here

Inference & Increased Exception Processing

High

Low

Regulatory Process Clarity Ends Here
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 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