



California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Enforcement Committee Report

Stan Goldenberg, RPh, Chair and Board Member
Bill Powers, Board President
Ruth Conroy, PharmD, Board Member
Tim Dazé, Esq., Board Member
Robert Swart, PharmD, Board Member

Including Report of the Meeting of September 20, 2007

A summary of the Enforcement Committee and Workgroup on E-Pedigree Meeting held September 20, 2007 is provided in **Attachment 1**.

ITEM 1: Report of the Workgroup on E-Pedigree:

There are four components to this item.

1. Report of the Workgroup on E-Pedigree Meeting Held September 20, 2007

The September 20, 2007 meeting of the E-Pedigree Workgroup was a very large meeting (approximately 200 people attended) held in a hotel near Los Angeles International Airport. Minutes of the meeting, and the PowerPoint presentations made during the meeting, are provided at the end of this tab section. This portion of the Enforcement Committee meeting lasted approximately four hours.

Presentations were made by drug manufacturers, software companies, associations and pharmacies. Presentations were made by:

- Board of Pharmacy – on a review of California's E-pedigree requirements
- EPCglobal – on the standards implementation progress and an overview of the types of tagging available to convey electronic pedigrees
- rfXcel – a software company, one of three companies certified by EPCglobal for the electronic messaging standard, on its actions to prepare companies for California's requirements
- CVS/Caremark – on its readiness to comply with California's requirements
- GlaxoSmithKline – on its worldwide efforts to prevent counterfeiting of GSK's products, including RFID tags on one of its products
- CPhA – on concerns that pharmacies' issues, and their placement at the end of the supply chain, will leave them absorbing costs for e-pedigree implementation that they cannot afford to absorb

- PhRMA – regarding the need for an extended timeline for adoption of e-pedigree requirements, and a request for risk-based implementation (require e-pedigrees only for those drugs most at risk for counterfeiting) and lot-level serialization
- Bracco Diagnostics – a manufacturer of specialty products used principally in the hospital setting, regarding specific implementation questions it faces
- HDMA – regarding the failure of serialization using lot numbers (which does not comply with California’s requirements for unit level serialization but has been advocated by some in the supply chain as an alternative) to adequately track product distribution throughout the supply chain
- Walgreens – on the readiness of its pharmacies to be ready for California’s e-pedigree requirements, including pilots and its need to have a “giant catcher’s mitt” to be able to read any tag (2-D bar code, HF or UHF chip) that may be provided to them by an upstream trading partner
- Rite Aid – on its readiness to implement pedigree requirements and specific difficult issues it faces and internal pilot studies they have conducted

The members of the Enforcement Committee were unified in stressing that the implementation date for e-pedigree adoption is January 1, 2009. Members emphasized that pilots and cross-company sharing of implementation solutions will be needed to have the e-pedigree requirements in place by 2009, but that the board will assist in any way it can to make this implementation smoother.

The minutes from this meeting are detailed and provide descriptions of the presentations made by each speaker. Again, the PowerPoint presentations are also attached to the minutes for additional detail.

Each speaker made comments supporting the need for added safeguards to the nation’s drug supply, although the route to secure these safeguards differed. Each speaker stated that the first concern is for patient safety and consumer protection.

There were some speakers who identified obstacles to a 1/1/09 implementation date. The following barriers to timely implementation were among those identified by these speakers: an asserted lack of a single tagging standard and confusion about what type of item tagging should be used -- meaning that those entities downstream (i.e., pharmacies and wholesalers) will have to be able to read any tag, increasing their costs and complexity to implement; an asserted lack of maturity in the technology supporting electronic pedigrees, with RFID tags not yet reading at 100 percent and high implementation costs; concerns about the possible damage to some medicines exposed to RFID tags/readers and/or that some medicines themselves (liquids, those wrapped in foils) may inhibit RFID signals; asserted differences between California’s standards and those implemented in Europe or in Florida– with a preference for California to use those standards instead; and a general complaint about the lack of sufficient time to implement this requirement by 2009, 2011 or even 2013. To encourage implementation, certain industry participants have asked for inference to stand in for item-level scanning at every inbound and outbound transaction (e.g., an unopened case of 24 items could be read once, and inferred that all 24 items are intact if the case is

appropriately sealed), for grandfathering of existing products in the supply chain after the implementation date, and a number of other accommodations.

There were other statements made in support of the 1/1/09 date: first, the board members present at the meeting continued to advocate the need for consumer protection from counterfeit drugs dispensed from California's pharmacies, and the need to implement these requirements sooner, not later. Industry needs to work now on pilots that will lead them to wise business decisions when implementing the requirements, and where possible, share the results of these pilots. Technology and software companies indicated that there is knowledge and expertise about how to do this available now, and costs for chips continue to decline. Other comments were made in support of California's requirements for serialization to the saleable package level (but technology may not yet be there to secure this by 2009).

One point made very clear several times during the meeting by Chairperson Goldenberg and Deputy Attorney General Joshua Room was that under California law, the board has the ability to delay implementation of the pedigree requirements until 2011 if the board determines that "manufacturers or wholesalers require additional time to implement electronic technology to track the distribution of drugs within the state." And while none of the board members has expressed interest in extending the deadline, that from a legal standpoint, the board could not extend the deadline without showing data-based evidence to support an extension. The decision must be based on facts, not statements. Moreover, the data must demonstrate that a delay would be in the public interest.

Also in September, the board activated an email address for industry to submit questions regarding implementation issues. At some point in the future and towards the end of this calendar year, the board's staff will produce and release these questions and answers as guidance to the industry. The address is californiapedigree@dca.ca.gov.

During this board meeting, members of the Enforcement Committee will be asked to share their comments about the September meeting.

The board has gained the attention of the industry, and the meetings are becoming information exchanges for those in the supply chain of pharmaceuticals.

2. Presentations to the Board on the Status of Standards for Electronic Pedigrees

Three presentations have been scheduled at this Board Meeting regarding the readiness of electronic pedigree implementation.

- Alien Technology will provide information about the RFID technology available today
- IBM and Amerisource Bergen will present information about EPCIS and the pilot they have underway at Amerisource Bergen Sacramento using this system

- EPCglobal will present information about the status of EPCglobal standards for electronic pedigrees

3. Meeting Summary and Discussion of a Board Subcommittee Review of EPCglobal's Electronic Pedigree Standard

On September 27, 2007, Board President Powers, Board Member Goldenberg, Executive Officer Herold, Supervising Inspectors Nurse and Ratcliff, and Deputy Attorney General Room met with a subcommittee of EPCglobal to refine issues relating to the EPCglobal messaging standards involving California. Minutes of this meeting are provided in **Attachment 2**. This was a nonpublic meeting.

The meeting was framed around a series of PowerPoint slides (also in **Attachment 2**), as a follow up to a meeting held in March 2007 with most of the same individuals.

The issues discussed were:

- Unit dose serialization
- Receipt of partial shipments
- Drop shipments
- Signature and certification (inbound)
- Resale of returned products
- Intra-company transfers
- Voided pedigrees
- Inference

The specific discussion is included on each presentation slide.

As a result of this meeting, five topics will be added as discussion items for future Workgroup on E-pedigree Meetings where comments from the industry are sought:

1. Serialization
2. Drop Shipments
3. Management of Returns
4. Incorrect Pedigree Information (mis-deliveries or other errors in pedigree generation or transmission)
5. Inference

The individuals at this meeting believed that the board would benefit from, and/or industry participants may wish to provide, additional input to the board regarding the prevalence, problems, and possible/preferred industry solutions in these areas.

These discussions could take place either as part of or in conjunction with its quarterly Pedigree Workgroup meetings or separately in topical workgroups on these and/or other topic areas that are identified as implementation discussions continue.

These comments should come in the form of written submissions to the board in advance of meeting(s) at which these topics are discussed, conforming to the template below:

- Submitted by:
- Problem/conflict with California's law:
- Background: Historical overview/framework of current practices in the industry, what are the different scenarios in which this practice or subject area has arisen already, what are the processes employed to date, what members of the supply chain are involved?
- Frequency or prevalence of this practice or subject area:
- A specific discussion of the costs such implementation, on as many variables as possible (per-unit, per-store, per-facility, per-company)
- Can compliance with California's law be met? Why or why not?
- Desired Solution:
- Without the desired solution, what is the potential impact?

It is anticipated that these presentations will come, at least initially, from industry associations or other representatives, so as to capture larger quantities of data or experience and focus the discussions on systemic rather than individual solutions. It is also anticipated that competing concerns of different industry players may need to be suspended to advance the presentation.

While the board is not precluding submissions by individual companies, it would be most helpful for any written submission to be representative of more than an individual experience or preference.

4. Discussion and Action regarding Implementation of Electronic Pedigree Requirements for Prescription Medicine in California

In September 2007, President Bush signed a 400 plus page bill to recodify the operations of Federal Food and Drug Administration with respect to prescription drugs. Included in this bill are three pages that deal with electronic pedigrees. These pages have been excerpted and are provided in **Attachment 3**. Additionally, Deputy Attorney General Joshua Room has written comments analyzing these provisions and their impact on California's requirements (also **Attachment 3**).

Mr. Room's comments are that this federal legislation does not conflict with but supports California requirements and general timeline. There is no preemption of any state's ability to regulate this area.

During this portion of the meeting, the board will have an opportunity to discuss issues arising from implementation of the electronic pedigree requirements, where the board wishes future Workgroup on E-Pedigree Meetings to focus, and future reports to the board. Other items involving e-pedigree issues may also be taken up at this point.

For the December 2007 meeting, staff will prepare as discussion items information on inference and on what has been called "grandfathering" of prescription medicine already in the supply chain on January 1, 2009, when the pedigree requirements start.

Regarding grandfathering, the board often has used a phased implementation to encourage compliance of major new regulatory or statutory requirements (e.g., patient consultation, quality assurance programs, security prescription forms). Sometimes referred to as "enforcement discretion," such practices usually involve education by board inspectors for a period of time before more aggressive enforcement sanctions are used.

Industry has indicated that in order for an implementation date of January 1, 2009 to be realized, the products themselves must be tagged and enter wholesale distribution by July 1, 2008.

Comments made during the December meeting will be returned to the board for discussion and action at the January 2008 meeting.

ENFORCEMENT COMMITTEE ITEMS: Discussion and Action Report of the Enforcement Committee Meeting of September 20, 2007

ITEM 1: FOR ACTION: Develop an Ethics Course for Pharmacists, Modeled After That Developed by the Medical Board of California

At the January 2007 Board Meeting, the board voted to form an exploratory subcommittee to examine the development of an ethics course for pharmacists as an enforcement option when establishing discipline parameters for licensees. President Powers appointed Dr. Ravnar and Dr. Swart to this subcommittee.

In June 2007, the subcommittee (along with Ms. Herold and Ms. Sodergren) met with an ethicist who works with the Dental Board. This ethicist provides assessment and individual (one-on-one) therapy to respondents referred by the Dental Board. Upon approval by the Dental Board, the respondent must comply with the individual therapy directed.

The subcommittee considered the benefits of such counseling and how this could benefit some disciplined pharmacists.

In August 2007, Dr. Ravnan, Ms. Herold and Ms. Sodergren met with the representatives from the Institute for Medical Quality, the course provider for the Medical Board's 22-hour specialized ethics course, which is authorized in Medical Board regulations. (Lori Rice of the UCSF School of Pharmacy provided an overview of the Medical Board's program at the January 2007 Board Meeting.)

The Medical Board's course requirements include:

- Pre-program Requirements
Background Assessment Application
Baseline Assessment of Knowledge Test
Reading Assignment
Participant Expectation of Program Statement
- Two-Day Ethics Course
Case presentations
Break-out groups
Experimental exercises
Role-playing
- Longitudinal Follow up at
6 month
12 month

This model relies upon small group interaction (only 12 individuals are enrolled at any time) led by a therapist, with personal written assessments before and for up to 12 months after completion of the two-day group session meeting with the therapist.

Dr. Ravnan, Ms. Herold and Ms. Sodergren believe that this would be a good model for developing an ethics program as an enforcement option for a disciplinary term for some pharmacists. However, a separate course from the Medical Board's program will be needed for pharmacists for the scenarios other components of the program to be meaningful.

At this board meeting, Jill Silverman, MSPH, of the Institute for Medical Quality, will provide an overview of the Medical Board's ethics program and how this board could develop a program for pharmacists. Initial discussions with Ms. Silverman indicate that the development of the course would not require significant resources from board staff; a principal duty would be to identify case scenarios that would be discussed during the course based on investigations of unethical pharmacy practices.

If developed, the board could also offer enrollment in this course to other state boards of pharmacy that have difficulty in identifying meaningful ethics courses for disciplined pharmacists.

Sample language that could be incorporated into the board's *Disciplinary Guidelines* is as follows:

Within 60 calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.

A copy of the Medical Board's regulation is included in **Attachment 4**, as is a description of the Institute of Medical Quality's course. However, Department Counsel Spencer Walker indicates that the board would need to promulgate regulations to specify the content of the course.

ITEM 2: FOR ACTION: Adopt the Veterinary Food Animal Drug Retailer Self-Assessment Form and Move Forward with the Formal Rulemaking Process (Addition of 16 CCR section 1785)

Supervising Inspector Judi Nurse recently completed work on a self-assessment form for use by veterinary food animal drug retailers. This form was developed following a motion at the January 2007 Board Meeting that a self-assessment process be established for veterinary food animal drug retailers. The self-assessment form is in **Attachment 5**.

Veterinary food animal drug retailers are specialty wholesalers who label and provide medicine (both OTC and prescription), prescribed by a veterinarian, directly to the owners of animals that are raised for food or are food producing (e.g, milk). However, instead of the veterinarian dispensing and labeling the medicine, the veterinary food animal drug retailer labels and distributes the medicine, in part because of the sheer quantity of medicine that is often provided to large food-producing herds. The Department of Agriculture requires that any medicine provided to a food-producing animal or an animal raised for food be labeled for use on the animal species with withholding times specified to prevent higher than allowed drug residues in our food.

For these animals, the goal is to assure that drug residues in our food do not exceed legislated levels for safety. "Vet retailers" hold two licenses – they must be licensed as both wholesalers and as vet retailers. The designated representative who may work in a vet retailer also has to meet special requirements to be able to receive veterinarian prescriptions and label the medicine to what could be thousands of animals on a ranch or dairy.

The proposed language to require the self-assessment for veterinary food animal drug retailers is to add section 1785 :

§1785. Self-Assessment of a Veterinary Food Animal Drug Retailer by the Designated Representative-in-Charge.

- (a) The designated representative-in-charge of each veterinary food animal drug retailer as defined under sections 4041 and 4196 of the Business and Professions Code shall complete a self-assessment of the veterinary food animal drug retailer's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
- (b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:
 - (1) A new veterinary food animal drug retailer permit is issued, or
 - (2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a veterinary food animal drug retailer is responsible for compliance with this subdivision
 - (3) There is a change in the licensed location of a wholesaler to a new address.
- (c) The components of this assessment shall be on Form XXXXX (rev. 10/24/2007) entitled "Veterinary Food Animal Drug Retailer Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.
- (d) Each self-assessment shall be kept on file in the licensed veterinary food animal drug retailer premises for three years after it is completed.
- (e) The veterinary food animal drug retailer is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4041, 4042 and 4196-4199 Business and Professions Code

ITEM 3: FOR ACTION: Approve the *Disciplinary Guidelines* as Proposed to Be Amended and Move Forward with the Formal Rulemaking Process (Amend 16 CCR section 1760).

For the last two years, staff has been working on modifications to the *Disciplinary Guidelines*. The final draft of these guidelines is provided in **Attachment 6**. This version has not been changed from the copy mailed to board members in August 2007 with the few exceptions noted below.

The guidelines are used by board staff in settling cases, by board members when considering proposed decisions and stipulations, and by administrative law judges in establishing proposed decisions.

The proposed changes are truly a team effort. Board members have provided comments over the last two years, and staff have spent considerable effort; specifically, Susan Cappello, Bob Ratcliff and Joshua Room, along with Judi Nurse, Karen Cates and Anne

Sodergren to update the guidelines to make them more responsive to our enforcement program needs.

The Enforcement Committee has seen a draft of the guidelines at the last two committee meetings. A descriptive memorandum is provided in **Attachment 6** that lists all changes from the *Disciplinary Guidelines* currently in use.

Also written comments were twice submitted by attorney Ron Marks. These comments, and the staff responses are also included in **Attachment 6**.

At the September meeting, the Enforcement Committee discussed the guidelines in some detail. The following changes were incorporated:

- Tolling of Probation (pg 38) - an option was added that would require a pharmacist to practice in a licensed pharmacy dispensing medication for a minimum of one year prior to the completion of probation.
- Pharmacist Self-Assessment Mechanism Exam (PSAM) (pg 52) -- options were added to allow the board to have access to the examination results for recommendation of remedial education if needed.
- Model Language of Premises (pg 111) regarding Suspension – language was added to clarify that failure to comply with the suspension term is a violation of probation.
- Revocation (pg 111), Surrender (pg 112) and license surrender while on probation/suspension (pg 116) - requires the pharmacy to notify its patients where records were transferred if the pharmacy will be closed as a result of discipline.

ITEM 4: FOR INFORMATION: Requirements of the Center for Medicare and Medicaid Services to Use Security Prescription Pads for Written Medicaid Prescriptions

In June, President Bush signed legislation that required effective October 1, 2007, that Medicaid-funded prescriptions be written on security prescription forms if not issued orally or electronically. Guidelines for the security forms were released in mid August. The guidelines directed that the forms contain at least one of three security elements.

At beginning of October, subsequent federal legislation delayed the implementation date of these requirements for six months. This means that by April 1, 2008, Medical prescription forms the security forms must have at least one of the three features, and by October 1, they must possess all three.

Whereas California's security prescription forms for controlled substances contain features that exceed the federal requirements, the California Department of Health Care Services will allow prescribers to develop their own security forms that possess one (or by October 2008) or the three requirements. This will mean that pharmacies may see a diversity of security prescription forms in the future.

However, prescriptions for controlled substances, whether paid by MediCal or not, must be written on the California security form pursuant to the requirements in California's Health and Safety Code.

Information about these requirements are on the board's Web site and are in **Attachment 7.**

ITEM 5: FOR ACTION: The board has received a request from University Specialty Pharmacy seeking to waive provisions of 16 CCR section 1717(e) to improve patient care. A copy of the request is provided in Attachment 8.

A representative of University Specialty Pharmacy will attend this meeting to make the request for a waiver directly from the board.

The request is to deliver dispensed Synagis prescriptions to a licensed home health agency (HHA) for administration by the HHA to the patient at his/her residence.

Section 1717(e) provides that:

No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The board may in its sole discretion waive this application of the regulation for good cause shown.

To take action on this proposal, a motion and second are needed.

ITEM 6: Meeting Summary

A summary of the September 20, 2007 Enforcement Committee and Workgroup on E-Pedigree is provided as **Attachment 9.**

ITEM 7: Report on Enforcement Actions

The First Quarterly Status Report on Enforcement Committee Goals is provided as **Attachment 10.**

List of Attachments

Attachment 1

Minutes of the Enforcement Committee Meeting Including the Workgroup on Implementation of E-Pedigree

Attachment 2

Minutes of the Meeting with EPCglobal of September 27, 2007

Attachment 3

Federal Requirements for the FDA on Drug Pedigrees

Attachment 4

Development of an Ethics Course for Pharmacists

Attachment 5

Proposed Self Assessment Form for Veterinary Food Animal Drug Retailers

Attachment 6

Proposed Disciplinary Guidelines

Attachment 7

CMS Security Forms for Written Medicaid Prescriptions

Attachment 8

Request for Waiver of 16 CCR 1717(e) by University Specialty Pharmacy

Attachment 9

Enforcement Statistics
First Quarter 2007-08

Attachment 10

First Quarterly Update on the Enforcement Committee Goals for 2007/08

Attachment 1

*Minutes of the Enforcement Committee
Meeting Including the Workgroup on
Implementation of E-Pedigree*



California State Board of Pharmacy

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

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
Enforcement Committee and Workgroup on E-Pedigree
Minutes**

Date: September 20, 2007

Location: Hilton Los Angeles Airport
5711 West Century Boulevard
Los Angeles, CA 90045

Board Members

Present: Bill Powers, Public Member, Board President
Stanley Goldenberg, RPh, Chairperson
Ruth Conroy, PharmD
Rob Swart, PharmD
D. Timothy Dazé, Esq., Public Member

Staff Present: Virginia Herold, Executive Officer
Karen Cates, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Joshua Room, Deputy Attorney General
Anne Sodergren, Legislation and Regulation Manager
Susan Cappello, Enforcement Coordinator
Karen Abbe, Public and Licensee Education Analyst

Call to Order

Chairperson Goldenberg called the meeting to order at 9:04 a.m. He said that several presentations would be given, and asked everyone to hold their questions until the end of each presentation due to the large attendance at this meeting. There would also be time provided for additional comments at the end of all the presentations.

Ms. Herold advised that anyone who wanted to receive Board of Pharmacy (board) agendas and be notified via e-mail of upcoming committee meetings could sign up on

the document provided at the sign-in table. There was also a sign-up sheet for those interested in receiving continuing education credit for attending this committee meeting.

Ms. Herold added that an e-mail address had been established to receive questions directed to the board related to drug pedigree requirements in California. Questions can be sent to californiapedigree@dca.ca.gov. The board will acknowledge that your question has been received, and an answer may be provided later. She also advised that the next meeting of the Enforcement Committee would be held on December 5, 2007 in Sacramento.

1. Workgroup on E-Pedigree

a. Progress of the EPCglobal Workgroup and Standards for Electronic Pedigrees

Chairperson Goldenberg noted that many of the PowerPoint presentations that would be given were available on the board's Web site as part the meeting materials for this committee. Other PowerPoint materials presented at this meeting would be added to the meeting minutes. Ms. Herold stated that joining this meeting via telephone was Ilisa Bernstein of the FDA. Mr. Goldenberg said the first presentation would be made by Judi Nurse, Supervising Inspector.

Dr. Nurse provided of summary of her full presentation, which covered the general principles of California Prescription Drug Pedigree. She noted that January 1, 2009 is the implementation date.

Dr. Nurse emphasized that pedigree tracks each prescription drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler and received by the pharmacy. This means "saleable units."

There are four components to electronic pedigree requirements – prescription drug information, transaction and source information, ownership information, and certification.

Dr. Nurse noted that during repackaging the original pedigree must be maintained. Pedigree includes every change of ownership from initial manufacturer through the final transaction to a pharmacy or other person for furnishing, administering or dispensing the prescription drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number.

Prescription drugs returned to the manufacturer or wholesaler are documented on the same pedigree document as the transaction that resulted in receipt of the drug by the party returning it.

Dr. Nurse also stated that reporting requirement for e-pedigree is that a manufacturer, wholesaler or pharmacy with reasonable cause to believe a

prescription drug in, or having been in, its possession is counterfeit or subject of a fraudulent transaction, the manufacturer, wholesaler or pharmacy must notify the California Board of Pharmacy in writing within 72 hours of obtaining that knowledge.

Dr. Nurse stated that the following reasons led the board to seek this legislation:

- Counterfeit drugs entering legitimate pharmaceutical supply chain
- Inability to track source of counterfeits
- Obvious danger to health and safety of public
- Federal legislation implementation delayed

Ms. Nurse's presentation also noted other changes in law:

- All wholesalers selling into or located in California must be licensed in California (effective 1/1/05)
- Surety bond required for all licensed wholesalers (1/1/06)
- Restrictions on pharmacy furnishing, manufacturers and wholesalers (effective 1/1/05)
- Wholesaler or pharmacy may not purchase, sell, trade or transfer a prescription drug without receiving or issuing a pedigree (effective 1/1/09)

A member of the audience asked whether the public would be able to view the questions sent to the board, as well as the board's responses to the questions about California pedigree.

Ms. Herold responded that the intent to provide guidance is long range and aimed at public information. Answering a single question to one individual is not beneficial to others who may have the same question but did not ask it. Soon, a portion of the board's Web site will be devoted to information related to California pedigree. The Governor's Office has directed all state agencies to have a state-standardized Web site by November 1, 2007. The board will make its conversion to the new state Web site design shortly. The board's Web site will thereafter contain information about California's pedigree law, as well as questions and answers (Q&A). The board has not released Q&As in over a year.

Ms. Herold added that the law changed after the existing Qs and As were developed and in some cases may be inaccurate. She encouraged people to send in their questions because they will help the board know what general concerns are.

Chairperson Goldenberg introduced Bob Celeste who was representing EPCglobal North America.

Mr. Celeste provided the following information as an update on the standards:

- Pedigree Messaging Standard – define a standard format for Pedigree Messaging to meet all current Federal and State Pedigree requirements. Status:
 - Ratified standard – 01/2007
 - Certification Program - 3 companies certified
 - Axway
 - rfXcel
 - SupplyScope
 - Education and awareness web seminars underway

- Item Level Tagging – Define requirements for tagging pharmaceuticals at the item level. Include requirements for manufacturing lines, distribution environments, transportation and Retail environment. Status:
 - HF & UHF initiatives underway to provide uniform air interface protocol at item level
 - HF Standard expected 2007
 - Completed vote for item level tagging requirements document
 - Ratification of standard anticipated 10/07
 - Anticipate silicon available for prototyping 2nd quarter of 2008

- Serialization – Define requirements for the EPC identifier to be encoded on an RFID tag. Status:
 - Pharma Requirements complete. Identified 2 GS1 identifiers [Global Trade Item Number (GTIN) and Serialized Shipping Container Number (SSCC)] to be used.
 - Collaborating with GS1/HUG via the “Global Healthcare Initiative” -- starting with Serialization.
 - Joint HUG/HLS Work Team
 - Medical Devices, Biologics & other Business Requirements started

- Supply Chain Integrity – Define requirements for and/or guidelines for authenticating and decommissioning tags consistent with optimizing tag utility and consumer/patient privacy. Status:
 - Predominately HLS, however, cross industry work group expected
 - Authentication and decommission alternative scenarios identified
 - Anticipate completion by end of October

- Track & Trace – Define supply chain use cases, processes and information needs for sharing EPC related data for forward and reverse logistics. Status:

- Forward & Reverse Logistics (Returns) processes and data exchanges completed
 - Integrate with GS1 Traceability efforts
 - Track & Trace to be interoperable with Pedigree Model
 - Additional use cases addressed:
 - Repackers
 - To be done: 3rd Party Logistics Providers & Product Recall
 - Sub-team within Supply Chain Integrity focused on security and pedigree integration
 - Data Sharing Strategy & Guidelines will addressed in Data Exchange JRG
 - Common vocabularies and location identifiers incorporated into just ratified EPCIS Standard
- Tag Data Standards – Define requirements for Tag Data JRG focused on defining additional user memory requirements for tags (i.e., Lot Number, Expiration Date). Status:
- Work underway. Defining common data structure that can be used by all industries.
 - Captured business requirements
 - Comment phase approved
 - Specification phase started

Mr. Celeste advised that there are overlapping uses for RFID and barcode technology, and there are different development trajectories. There are also distinct reasons to choose one over the other. For example, RFID can track temperature and light. Mr. Celeste also outlined the different barcode types and RFID types.

➤ Differences in Barcode types

- Linear Barcodes:

Commonly seen in retail and in logistics
 Usually read by laser scanners – can be read by optical scanners
 Size increments, as additional data is stored
 Large installed base

- 2D Barcodes:

Used in pharmaceuticals, documents, retail
 Read by optical scanners
 Small size
 Redundant data for fault tolerance

- Mixed types:

Used in retail for loose items (fruit)
Portions can be read by laser scanner – serialized portion can be read by optical scanner
Relatively small size

➤ Differences in RFID types (passive)

- Ultra High Frequency (UHF):

Can be read from 0 – 5 meters
Fastest read speed
Reading around liquids and metals is a challenge (but not impossible)
Used in pharmaceuticals, surgical sponges, etc.

- High Frequency (HF):

Used in pharmaceuticals, books, access control
Moderate read speed
Usually larger than UHF

- Low Frequency (LF):

Used in manufacturing processes, access control
Slowest read speed
Very simple antenna design

Mr. Celeste spoke about a “mixed” type of barcode that would be used on a particular product. For example, there are environments like fruit sales, which use mixed barcodes. The bottom part of the barcode identifies the type of apple, and the top part of the barcode identifies the grower of the apple.

Mr. Celeste also spoke about RFID types, and some of the challenges associated with that technology. For example, liquids tend to absorb the frequency. The human body contains a high percentage of liquids. High frequency is similar to two magnets that get close together. Low frequency is the slowest read, but it is still usable when you can get separation between items.

Mr. Celeste also spoke about barcodes that do not support serialization.

Ms. Herold asked how long it would take to see a transition to one standard.

Mr. Celeste responded that it would take about five years. He emphasized that they want to prevent year-2000-type problems. For example, barcodes getting larger and longer; even going from 13 digits to 14 digits is a big deal. He also referred to passive tags and active tags; active tags would be used in shipping and in hospitals.

Mr. Room clarified that active tags send a signal.

Mr. Celeste added that battery-assist tags are semi-active. True active tags have transmitters in them. Homeland Security uses active tagging, and particularly for containers shipped overseas. Active tags ensure that containers remain packed and shipped as originally packed.

A question came from the audience related to GS1 Serialization Standards, and that the serial number must be unique in relation to the Global Trade Item Number (GTIN).

Mr. Celeste responded that it would be like a box of Viagra vs. a can of Coke. A serial number will identify each individual item, except companies that "mask" an item. The serial number goes across all items. He stressed that if we embed intelligence into identifiers, we will find ourselves in year-2000-type problems.

Mr. Celeste concluded by speaking about GS1 Barcode and EPC/RFID Convergence. He said it's important for pharmaceutical companies because they may use both technologies, one as a backup.

A question was asked about the relationship between RFID tags and barcodes and how they track pedigree information.

Mr. Celeste responded that in the pedigree itself, the GS-1 system identifies objects. When you open a pedigree, you see an identifier. A number on a bar code would be reflected in e-pedigree as each item.

There was a question from the audience about bundled products.

Mr. Celeste said the question related to a manufacturer's pallet with individual items in it. The pedigree would reflect the identifier of the pallet, the case, and identifiers of all the items.

Ms. Herold added that there is an inference issue included in Mr. Celeste's answer inferring items inside an unopened box or pallet.

Mr. Room stated that there is a parent-child relationship between the identifier of a pallet and each individual item in the pallet.

Dr. Swart asked about the consolidation of pharmacies. When a company buys the inventory of another pharmacy, does the pedigree transfer over? He added that others are asking similar questions as well.

Mr. Celeste responded that there is a standard number system. You can identify all your products with one company prefix.

Mr. Room also noted that Dr. Swart's question related to the consolidation of stocks from pharmacies.

Mr. Room clarified that in a change of ownership, there must be another "wrapper" around that pedigree. He suggested a software vendor be asked this question later in the meeting.

A question was asked about a transition between EPCglobal and GS1. Given that California has stringent requirements and many manufacturers are global, how will they merge the two, and what are the plans to meet everyone's needs?

Mr. Celeste responded that transition from EPCglobal to GS1 is an international issue. EPCglobal and GS1 are one company. The HUG (Healthcare User Group) will be one group, and go forward from there. Once requirements are defined by the new unified group, development will take place.

A follow-up question asked if California's stringent requirements could affect worldwide supply chains internationally, complying with the requirements of one country, without complying in another.

Mr. Celeste responded that the current standards could be applied to anyone. Companies will have to comply with regulators and regulations that are essentially regional.

Mr. Celeste was asked about his sense of progress of the convergence of 2-D barcodes and RFID.

Mr. Celeste responded that if you're using GS1, there is no convergence problem; it's the same number.

b. Presentations and Updates by Manufacturers, Wholesalers and Pharmacies on Implementation of Electronic Pedigrees

Jim Ensell, President and COO of rfXcel, gave a presentation entitled, "A Practical Solution to Improve Drug Security."

Mr. Ensell stated that rfXcel is an e-pedigree management supplier, fully certified by EPCglobal, and compliant with all state and federal regulations. He spoke about the problems they are trying to solve:

- Drug Counterfeiting is an increasing threat to public safety – lack of traceability is a huge problem

- Pedigrees introduced to protect the nation's drug supply – pedigrees are currently perceived by industry as a cost burden without a corresponding value added
- A system for tracking at the "smallest package or immediate container level" requires serialization – industry may be ill-equipped to move forward with full serialization for all drugs at the current time

Mr. Ensell emphasized that California's law provides the highest degree of public safety. There are no exemptions for manufacturers or authorized distributors of record, and they involve the entire supply chain. It requires 100% electronic tracking, and serialization at the product container level. No organization is completely ready at this time for serialization on all product lines.

Mr. Ensell's presentation referred to lot-level pedigree generation that is relatively mature. It is generated primarily at the wholesaler level, and there is minimal implementation by manufacturers and retailers thus far. Serialized pedigree generation is being piloted by multiple companies. Passing pedigrees to wholesalers, matching them with the drugs they receive, then shipping back out to another wholesaler or distributor in the chain, or to a retailer – these capabilities do exist and are being used today.

Mr. Ensell displayed a sample pedigree – a "repacked" pedigree – automated by an e-pedigree management system. He stressed that getting a customer up and running does not have to take long. It can be done in an 8-week period.

Pedigrees are being done at the lot level right now, not item level. Serialization is not as far along as lot level pedigree, but progress is being made. Until recently, the standards were lacking, but now they're in shape. Companies are divided into two different technology "camps" – RFID (HF and UHF) verses 2D barcode. Some industries would like California to dictate which standard to use. The solution could be a hybrid. Mr. Ensell suggested three potential approaches to consider:

- 1) delay implementation until 2011 – though this would not assure progress, even in the delayed timeline
- 2) implement by January 2009 – this would present challenges to industry, but it is possible
- 3) deploy a phased approach – begin with product container level tracking for high risk drugs and Lot-Level Tracking for all others, then phase in product container level serialization for a broader set of drugs, and then full product container level enforcement at a later date.

Mr. Ensell's presentation outlined the pros and cons of each approach, but he stated his preference for the third (phased) approach. He concluded his presentation by restating that drug counterfeiting is a big problem that must be addressed and California's pedigree law was designed to provide the highest degree of public

safety, challenges with implementation and serialization are resolvable, and a phased enforcement approach may be the most practical path to take.

Mr. Dazé stated that he has served on this board for a year. He recalled that President Kennedy said we would put a man on the moon before the end of a decade. Mr. Dazé emphasized that industry can make efforts to put e-pedigree on-line by 2009. He spoke passionately about public safety, and that not implementing e-pedigree by the deadline would put public safety on the line.

Chairperson Goldenberg added that he echoed Mr. Dazé's statement, and that 2009 is the implementation date. He stated that, as a board, we take public protection extremely seriously. We also must base our decisions on evidence. He said that these presentations are part of that evidence. Continually delaying implementation is not on the board's agenda, and 2009 is the date currently before the board. To go with any date beyond that, the board must make recommendations based on evidence. Mr. Goldenberg emphasized that everyone present must make efforts to reach this goal. In the balance is public safety from counterfeit drugs.

Mr. Room noted that he delayed Dr. Swart's earlier software question concerning adding to a pedigree where a pharmacy is sold.

Mr. Ensell responded that when inventory is brought in, their software will allow adding to the pedigree, either product by product, or all en masse. He said it could be done either way.

A question came from the audience regarding the cost of pharmaceutical products.

Mr. Ensell responded that he was not sure about the cost of pharmaceutical products, and suggested that he was not the best person to talk about cost. He added that pilot projects are being conducted, and there are costs to implement those pilots that may be fairly large.

President Powers commented that there are other costs as well that should be considered. For example, the costs of drug recalls or the cost of people dying and getting sick from counterfeit drugs.

Mr. Ensell responded that trying to trace and recall counterfeit drugs would be high.

Chairperson Goldenberg introduced Brian Whalen and Richard Mazzoni from CVS Caremark.

Mr. Whalen conducted a presentation that included CVS Caremark's action to date, and touched on the challenges facing care pharmacies. He stated that the concerns of manufacturers have been expressed, but not pharmacy's concerns.

Mr. Whalen stressed that he shares the concerns of the board to have a secure pharmaceutical supply chain. He said that CVS Caremark has taken a leadership position to implement measures having an immediate impact upon the security and integrity of the supply chain.

In May 2005, CVS/pharmacy announced they would only purchase directly from the manufacturer or from wholesalers that would certify that they only purchase products directly from the manufacturer. Cardinal, McKesson, and AmerisourceBergen have since implemented similar policies. CVS Caremark has been an advocate for stricter licensing requirements for wholesale distributors, and they support pedigree requirements for transactions outside the normal path of pharmaceutical products. Mr. Whalen said they have essentially opened up their practices for others to review, and they have been actively engaged in researching emerging technologies and standards development. CVS Caremark has participated in a number of industry groups working on standards and pilots.

Regarding technology and serialization, Mr. Whalen stated that there is no single technology that exists that will satisfy California pedigree requirements, and serialization standards are still in process. He commented on 2-D Barcode technology, RFID, and a combination of both.

➤ 2-D Barcode

- Capable of supporting serialization at the item level
- Requires line-of-sight and will add significant costs to the supply chain
- Relatively low costs to the manufacturing community, but adds significant complexity and labor to the downstream partners

➤ RFID

- Strongly suited to the goal of serialization at the item level
- Non-line-of-sight technology, which allows for supply chain efficiencies
- Highest start up costs (and potential on-going costs)
- Not suitable for "special situation" products (i.e. biologics)
- Potential reliability issues resulting in operational inefficiencies and product disposition concerns

➤ Combination

- Creates the biggest challenge as wholesalers and pharmacies will have to invest in multiple technologies and processes to receive and track pedigrees

Mr. Whalen stressed that there are potential liability issues when RFID tags don't read, and a patient is ready for the medication.

Mr. Whalen stated that members of the pharmaceutical supply chain have embarked on pilot projects regarding serialization and pedigree. He said that each pilot has employed different technologies. For example, manufacturers have tagged products with UHF and HF RFID tags, as well as 2-D Barcodes. Some products have been tagged at the pallet, case, or item level.

Mr. Whalen emphasized the challenges facing the scope of trading partners. There are hundreds of manufacturers, and a pharmacy communicates with wholesalers and manufacturers. There are challenges identifying where a product has been, downstream from a manufacturer to a pharmacy, plus there are different types of transactions. He said that these issues need to be fleshed out because pharmacies cannot support multiple approaches.

Mr. Whalen stated that one solution is required in order for their 400 individual stores to be ready on time. He added that individual solutions will complicate things to the point where implementation will not be successful and there will be additional hurdles, problems, and expenses. Brand and generic manufacturers are concerned that they won't be ready by 2009, and are waiting to see if an extension will be granted. One manufacturer has stated that they may choose not to bring products into California. The single largest thing is that the generic manufacturers are saying they can't comply by 2009. It's unclear where and how to invest and deploy resources. The standards are only a framework. CVS believes manufacturers can comply, but there are problems. For example, there is a lack of consistency in lot numbers; each manufacturer identifies lot numbers differently, causing other hurdles.

Mr. Whalen concluded his presentation by stating that CVS continues to research technology options, but they are dependent on manufacturers to determine their approach. He suggested a modified risk-based approach instead, stating that not all drugs and transactions pose a risk. He also suggested phased-implementation by business segment because it will be a challenge for retail pharmacies to meet the same date as manufacturers and wholesales. Mr. Whalen stressed that CVS wants to be sure that they can test the systems to ensure that everything is working properly and that supply is not interrupted.

Chairperson Goldenberg asked whether there was information they could share with the board about their pilot findings. Definitive pilot studies that show outcomes that will help the board understand their issues.

Mr. Whalen responded that he would speak at a high level regarding the pilots, but it was his understanding that they were conducted in a controlled environment.

Chairperson Goldenberg added that CVS has 400 pharmacies plus a distribution system, which could potentially help the board understand problems and resolve them before they become law. He emphasized that sharing studies with the board will help.

Mr. Room stated that as staff receive inquiries and communicate with members of the supply chain, a clear tension is developing about 2-D barcode and RFID. He asked whether retailers would prefer RFID tagging.

Mr. Whalen said that RFID is an emerging technology, so we must look down the road to see whether it holds an option. He said they struggle with serialization. He added that they're not saying it has to be either of those two choices.

Mr. Room stated that people have asked the board to legislate or regulate a data carrier standard. He said that that is also implied in one of the slides in the CVS presentation. He asked whether CVS is asking the board to make a decision.

Mr. Whalen responded, no. He understands that generic manufacturers may not have the capital for RFID, so they may want 2-D. Most of the challenges are related to manufacturers and wholesalers, but that's a challenge they need to overcome.

Mr. Room amplified what Mr. Goldenberg stated earlier regarding extending the deadline. He said that none of the board members have expressed any interest in extending the deadline. Mr. Room emphasized that from a legal standpoint, the board could not extend the deadline without showing data-based evidence to support an extension. As a public protection body, the board would need such evidence.

Chairperson Goldenberg added that it goes back to the pilot studies conducted, and other evidence presented.

Mr. Room said that the board can only extend the deadline if the industry is not ready, but that decision must be based on facts presented to the board. If the board exceeds its authority, a writ of mandate will be filed.

Chairperson Goldenberg stressed that industry must start providing this data so that the board will understand the challenges faced. It's critical to have that data so that information can move up the system, especially when meeting with stakeholders.

Mr. Whalen responded that, in that regard, one of their points is that they are reliant upon the manufacturers and wholesalers to know what to do. For example, he doesn't know how Pfizer will comply yet, and so on. Without information from manufacturers and wholesalers, CVS can't know.

Mr. Room clarified that he was not soliciting requests for an extension of the deadline, nor have any board members requested an extension of the deadline.

Ms. Herold followed up on one of the comments from Mr. Goldenberg. She said that there are a couple of manufacturers and wholesalers that are running pilots or tagging products. It's very important that retailers get involved in those pilots as

soon as possible. She added that CVS' presentation laid out the issues well, but it was short on describing what CVS was doing at the retail level.

Ms. Herold added that the board wants to know how pharmacies deal with RFID chip technology or 2-D barcodes. She offered the board's help if pharmacies would like to join such studies. The board cannot make it mandatory, but will try to connect retailers with manufacturers conducting pilot projects.

Chairperson Goldenberg added that the board understands proprietary advantages and practices, but it takes second place to what is best for the consumer. Mr. Goldenberg asked CVS and pharmacies in general to be more aggressive in planning these studies and getting that information in to the board early, as opposed to later.

Dr. Swart said that the last thing the board wants to see happen is CVS having to purchase 400 UHF scanners, and 400 HF scanners, and so on, to take out to their pharmacies. He understands that they'll need to know what technology will be used in the retail store, and that a company cannot make a purchase without knowing what will be needed at the store level.

Mr. Dazé commented that the argument that the board will choose which technology should be used was like Beta and VHS 15 years ago. There is a similar battle now underway between HD and Blu-ray, and soon you won't see one of those technologies. For the board to say that one is better than the other, that's not necessarily true because industry will have to choose.

Chairperson Goldenberg introduced Tim Kvanvig from GSK.

Tim Kvanvig, Vice President of GSK US Pharmaceuticals, provided an overview of GSK, and emphasized that they want their products to make it safely to patients. They are actively working with regulators and they support this board's efforts to protect the patient. He gave a high-level view of the impact that serialization will have on GSK. It will affect more than 30 sites in 12 countries, 2 distribution centers, and more than 130 packaging lines, which will require unique implementations due to variations in speed, space, and packaging. It will impact more than 300 SKUs, and he clarified that when they refer to SKUs, they mean "package types."

Mr. Kvanvig summarized their experience with serialization. They agreed to do a pilot, tagging pallets, cases, and units. They are actively continuing that program, but it's still a variable experience in reading those tags. Their view is that they're not ready for vigorous validation at this point, and less than 5% of the units tagged have actually been read across the industry. They are working with standards bodies and regulators to find the best solutions and technology. Along with many industry partners, GSK has been working with EPCglobal, PhRMA, HDMA, NACDS, and GS1 to address the role of serialization in supply chain security issues.

Mr. Kvanvig outlined the actions needed at this time:

- Active standards and solution development needs to continue
- Manufacturer/wholesaler/pharmacy pilots are needed to test standards and develop ways of working across the end-to-end process
- Consistent set of requirements across US, e.g., pedigree standards, 2D sizes
- Guidance from the FDA regarding:
 - Expand Compliance Policy Guide to include all forms of serialization and extend date to encourage pilots
 - Use and protocols of RFID on liquids, biologicals

Mr. Kvanvig emphasized that they need to conduct pilots and they intend to move forward on that. They also need a consistent set of requirements across the US, and they believe guidance from the FDA needs to be extended in this area. Using RFID with liquids and biologicals is an issue as well.

Mr. Kvanvig outlined the next steps they recommend at this time:

- A prioritized approach to start with the higher risk products
- A focus on industry adoption
 - Unit Serialization: maintain Trizivir serialization using RFID and adding 2-D barcode. Implement other products using our prioritization methodology utilizing 2-D barcodes.
 - ePedigree & authentication: Build an infrastructure to facilitate early implementation and flexibility in deployment, including item-level, case-level, and lot-level ePedigree and product authentication. Agree on standard processes among Manufacturers/Wholesalers/Pharmacies.
- Ongoing work with the Manufacturers/Wholesalers/Pharmacies and regulators to enhance the security of our products in the supply chain

Mr. Kvanvig emphasized that their recommendation is to start with high-risk products. They will use current serialization and add 2-D Barcodes as the next step, then build a robust approach of e-pedigree and authentication. He commented on statements made earlier by Chairperson Goldenberg regarding pilots. Mr. Kvanvig stressed that GSK intends to make progress on their pilots, and make outputs visible to the industry and to the board.

Chairperson Goldenberg asked Mr. Kvanvig to comment on the severe situation in Florida where counterfeit GSK products were discovered. He asked what happened and what their responses were.

Mr. Kvanvig responded that they have their security staff actively working with government investigations on that, but he's not prepared to talk about it today.

Chairperson Goldenberg stated that he believed there were hundreds of drugs that were counterfeit, which was of the utmost concern to the board.

Mr. Room asked whether the unit serialization GSK is doing on Trizivir was backed up with 2-D Barcodes.

Mr. Kvanvig responded that only RFID was used on that product in the industry, with no backup. They plan to do a pilot with unit level serialization and 2-D Barcodes.

Ms. Herold asked who has been reading the tags if they have been tagging Trizivir for three years.

Mr. Kvanvig responded that GSK has been reading the tags, and GSK's intention is to define points and to see where the product is. They have been reading the tags in several places and distribution points.

Ms. Herold asked what their hopes were when they first started tagging the product. She asked whether they first started tagging for their benefit or for the supply chain benefit, and what their expected outcome was.

Mr. Kvanvig responded that they wanted to see if tagging would work, and how they could apply it. Their next steps are to learn "downstream" in the business process. He added that they haven't gotten to the end-to-end process for the product.

Chairperson Goldenberg asked whether GSK identified any counterfeit drugs that made their way to patients.

Mr. Kvanvig responded that he thinks not, but he will get back to the board on that. He believed there may have been one incident in one pharmacy where the product was found.

Mr. Room stated in response to another question that manufacturers will have to deal with getting their packaging and labeling requirements ready by the deadline, and that is the FDA's region of control.

Chairperson Goldenberg asked Ms. Bernstein, FDA Director of Pharmacy Affairs, about the ability of manufacturers to do validation on the manufacturer level.

Ms. Bernstein responded that they are considering it.

Lynn Rolston, representing CPhA, said that CPhA doesn't have the levels of data or resources for a presentation, but she wanted to emphasize that pharmacies in California are very concerned about this issue. She said that "everyone is horrified when something bad happens" and they are concerned about patient safety. Ms. Rolston added that pharmacists have been battered by declining reimbursements, Part D, tamper-resistant prescriptions, and AMP is coming soon. These are all cost issues that don't contribute to patient care.

Ms. Rolston said they met with the board on these issues, and they just want to take the whole view of it into consideration. She wants the most upfront safety for patients, in care and in services. She added that they speak for independent pharmacies that can't set up ahead of time and do pilots. CPhA will help with pilots, if they are contacted to do so. They prefer a phased-in approach or a delay, and want to be sure they put their two cents in regarding the patient safety aspect.

Ms. Rolston stressed that CPhA doesn't want additional delays to providing services to patients, and 25% of pharmacies are already operating on only a 2% margin. With AMP coming up, many pharmacies could go out of business. This unknown cost may be a tipping point. She doesn't have data on costs or time involved. Their members are conflicted because they don't want counterfeit drugs, but they also want to be able to provide high level of patient care.

Chairperson Goldenberg suggested that there is a need for someone to start coordinating some of these pilot studies, whether at the pharmacy level and connecting upstream to a manufacturer, or "downstream" instead. He added that the board's concerns are to protect the public. He asked Ms. Rolston to consider getting people to work together create some studies.

Ms. Rolston responded that she'll speak with Mr. Goldenberg offline and will undertake that, but that they would be short on resources.

President Powers commented that the board has been sensitive to pharmacies regarding Part D and AMP, and alleviating those conditions, but we are a consumer protection agency and must face these issues and be consistent.

Mr. Dazé wanted to emphasize that the board members are consumer advocates. Everyone out there wants to protect consumers, but so did Mattel, whose inspectors fell down on the job and brought lead-based paint to our children. He said he understood that it's expensive.

Chairperson Goldenberg introduced the next speaker, David Albrecht.

Mr. Albrecht clarified that this presentation was from PhRMA.

Marjorie Powell from PhRMA joined Mr. Albrecht, and stated that Mr. Albrecht was responsible for putting the timeline together. She said she agreed with the board and is concerned about patient safety. She added that individual companies and PhRMA are not fully there yet to meet California's requirements. She said they think it's vitally important that products are secure throughout the supply chain. The idea of pilots working down from the manufacturer all the way to the retailer, or the opposite, is an excellent idea. Ms. Powell said that Mr. Albrecht would talk about what's involved in the chart so you'll see what manufactures have been working on.

Mr. Albrecht thanked the board for the opportunity to present. He said he had just one slide, and their message is straightforward. He suggested that we start now with e-pedigree, with the potential readiness of 2009, and then add risk-based serialization. He said he believed companies could begin implementing pedigree now, using the standards that were developed and ratified in 2007. The standards are in place today. Some manufacturers have already implemented pedigree, and others are in the process.

Mr. Room asked if Mr. Albrecht was talking about "lot level pedigree" when he used the word "pedigree."

Mr. Albrecht responded that it's lot level or case level pedigree. Serialization is much different than e-pedigree, and they tried to separate the two from the board's definition. He added that more collaboration needs to occur, but they are already collaborating. Interoperability is a big issue.

Mr. Albrecht stressed that the January 1, 2009 implementation date does not provide enough time to prepare. He said industry-wide implementation with operable systems and the ability to exchange data would be an enormous task and very complex. Mr. Albrecht stated that to implement successfully, companies must work through transactional-level security and that item level serialization can come only after industry-wide success. He said that industry also needs additional guidance from the FDA, including product labeling and other issues we haven't thought through like biologics. Data sharing openly is an enormous challenge. Industry must also work through the concept of "inference" as product moves through the supply chain.

Mr. Albrecht stated there is no one silver bullet in PhRMA's view. He suggested that we start with e-pedigree, which is an important step forward, and then add in high-risk serialization. He said they must have interoperability industry-wide first.

Mr. Dazé asked whether they had a problem with biologics and liquids having 2-D Barcodes and others having RFID.

Mr. Albrecht said that companies must look at that specifically.

Mr. Dazé said that RFID may interfere with certain drugs, but he hasn't heard that 2-D barcodes can't work on it.

Mr. Albrecht responded that item level serialization requires reworking of each label, and he can't say, "unequivocally yes."

Ms. Powell stated that there are potential problems with trading when some companies have 2-D barcodes and others have RFID. Companies are looking at (both) 2-D or RFID barcode – no company has a sense that one over the other will be better.

President Powers asked what percentage of PhRMA's members are engaged in e-pedigree right now.

Ms. Powell responded that they haven't polled their members during the last year, but 18 months ago, most of them were involved in some kind of pilot activities with some of their trading partners. Companies with more high-risk products are moving forward more aggressively because they have a need and urgency. She said she would be happy to go back and poll their members.

Ms. Powell said that companies are looking at what their trading partners want before they make investments.

Chairperson Goldenberg said that the timeline didn't sit right with him. Their proposal showed that in the year 2012 and 2013 there will still be no product serialization which is six years from now. Mr. Goldenberg suggested that PhRMA poll not only PhRMA members, but also find out what pilots are being done, and what coordination is occurring. He encouraged them to avoid duplication of pilot studies, and also to present their evidence to the board instead of just asking the board to move the date out six year or longer. Mr. Goldenberg reiterated Mr. Room's earlier comments that the board needs written evidence and needs that evidence as soon as possible.

Ms. Powell responded that her technical people have a grasp on the pilots, and she will commit to finding out what pilots are going on, and will offer to meet with chain pharmacies to set up coordination.

Chairperson Goldenberg said he was encouraged by Ms. Powell's commitment, and asked that they move faster than a response by the next work group meeting. He asked Ms. Powell to work with Executive Officer Herold and the board members on the time frame.

Mr. Room said he wanted to address semantics and the top half of Mr. Albrecht's slide. He asked whether "pedigree" of documents referred to lot level information, and whether it's 2-D barcoding or RFID.

Mr. Albrecht responded that they are referring to "lot level" serialization.

Mr. Room clarified that that means it is dependant on manufacturers passing information along, not validating it. Sales and invoicing does not constitute validating a product. They are merely taking the information given by the manufacturer, with no validation downstream.

Chairperson Goldenberg next introduced Robert Zachow, who was representing Bracco Diagnostics.

Mr. Zachow provided a frame of reference for his presentation by stating that Bracco is in the hospital sector. Bracco manufactures and sells injectable and oral diagnostic imaging contrast agents and nuclear medicine imaging agents. Their products are distributed through authorized distributors and directly to hospitals and imaging centers. Healthcare professionals administer all of Bracco's products.

Bracco's products are distributed in sealed boxes of 5-10 vials or bottles. As a reference, Mr. Zachow displayed an image of the label on one of their containers of 10 Power Injector Syringes. The detail on the container's label showed that 2 boxes were enclosed, and each box contained 5 – 125 mL Power Injector Syringes. The label's lower right corner displayed their lot number and product expiration date.

Mr. Zachow noted that all direct manufacturer shipments are exempt from e-pedigree requirements until January 1, 2010 for injectibles that are administered directly by a prescriber. Bracco asked for guidance as follows:

- Can the injectable dangerous drug exception be extended to include Bracco's authorized distributors?
- Can the injectable dangerous drug exemption be applied to both oral as well as injectable contrast media since they are all administered by only healthcare professionals?
- What are your plans for the administration of nuclear medicine imaging agents?
- How does Bracco obtain an exception certificate?

Mr. Zachow stated that serialization will enable Bracco and its customers to track and trace their products through the supply channel, and Bracco will provide serialization at the market unit level, which is the "box." With regard to serialization, Bracco asked for guidance as follows:

- Given that the cost for serialization will greatly increase our cost of goods, would an ePedigree provided from the point of manufacture be acceptable?
- Knowing that Bracco will meet your regulations, how does the Board ensure compliance is enforced?

Mr. Zachow said that he did not expect answers to all of their questions at this meeting. He concluded his presentation by stating that Bracco plans to support and meet all regulations for e-pedigree in California. They also request clarification of their obligations for compliance regarding distribution of products administered by healthcare professionals, as well as serialization.

Mr. Room asked for clarification regarding their questions about injectibles. He wanted to know if Bracco was asking those questions for their own needs, or only to see how the law will be applied.

Chairperson Goldenberg asked if wholesalers break the boxes.

Mr. Zachow responded that, as early as three years ago, breakage and openings occurred, and they have since corrected that. Authorized distributors are not allowed to sell what's inside that box separately.

Chairperson Goldenberg asked for clarification about whether the serialization will be on the product or the box.

Mr. Room stated that those questions may be better answered in a Q&A format. The idea is that serialization is required as to the smallest package to be sold, not a transfer of ownership of individual vials because they will be administered bedside.

Chairperson Goldenberg called on Elizabeth Gallenagh for a presentation from HDMA.

Elizabeth Gallenagh introduced herself as the Senior Director of State Government Affairs for HDMA. She also introduced John Howells, Director of Industry Relations for HDMA. She added that Mr. Howells works on a lot of the pilot programs and is involved in EPCglobal as well.

Ms. Gallenagh said she would speak about lot number tracking, and follow up on some of the points brought up during the June meeting. She said that HDMA was committed to patient safety, and emphasized their support for item-level serialization and California law.

Ms. Gallenagh demonstrated the limitations of lot number tracking vs. item-level serialization. Some of evidence she presented during her presentation included the following points:

- Lot numbers identify batches, not individual units
- Lot number can't identify additional (counterfeit) items
- Lot number can't link electronic transactions to specific products with certainty
- In previous cases, counterfeit products have had counterfeit paper pedigrees with valid lot numbers
- Lot numbers cannot be used to identify stolen product unless the entire lot is stolen
- Some products are only manufactured in a single batch per year, so a lot equals a year's supply of product
- There are no standards for lot number
- There are inconsistencies in lot number length

- The same lot number frequencies can be found in multiple locations, at different points in the supply chain, at different times

Ms. Gallenagh summarized her points by emphasizing that serializing using lot number is unreliable and results in errors when used as the primary identifier for ensuring supply chain integrity. She stated that lot number entry errors will be caused by inconsistent lot number data length, variability in size and font of printed lot numbers, and inconsistencies between case and item lot numbers. For example, a lot number manually entered with characters alpha "l" vs. numeric 1" has a better than 50% chance of error.

Ms. Gallenagh demonstrated some of the benefits of item-level serialization by speaking about these features:

- Unique Item Identification
- Link Physical Item to Data
- Detect Counterfeit
- Track & Trace Products in Supply Chain
- Efficient Recalls
- Detect Stolen Products

Ms. Gallenagh summarized her presentation by emphasizing that unique identification at the item level is required in order to further enhance patient safety and effectively track and trace pharmaceuticals through the supply chain. She stressed that because of the operational challenges that lot number tracking presents, it is not a viable option for pedigree. Lot number tracking as a method of pedigree adds no safety value and erodes supply chain efficiencies.

Mr. Room commented on a lot number representing a particular production date. He asked about the "human-readable" factor, and whether they were validating the products received against the advance shipment notice.

Mr. Howells responded that very few advance shipment notices were sent, and of those received, they were sometimes incorrect.

Ms. Gallenagh reiterated her earlier points that lot numbers are unreliable to ensure supply chain integrity. She added that the collection process is overly burdensome, and she wanted to commend PhRMA for their efforts. She urged PhRMA to work with distributors because no one can work in a bubble. Distributors are working in a unique position, and she wants everyone to work together to get to implementation throughout the supply chain.

Chairperson Goldenberg stated that their pilot study said it loud and clear that tracking by lot numbers would not ensure supply chain integrity. He asked for further comments from the board or from the audience.

Ms. Powell, PhRMA, said that she wanted to echo HDMA's statement about the importance of having standards for serialization because there are differences in lot numbers. She added that it is essential that standards be adopted and the systems for verifying them.

Chairperson Goldenberg introduced Emily Stamos from Walgreens.

Ms. Stamos said she serves as Associate Category Manager for Pharmaceutical Strategy at Walgreens. She said she was appreciative that the board was letting them tell what's happening in their individual stores. Just four months ago, she was a pharmacy manager, and remembers well what it was like to be a pharmacist at the practicing level.

Ms. Stamos emphasized that Walgreens is an industry leader that strives for standards to ensure patient safety, regardless of the requirements of the law. Walgreens has in excess of 450 pharmacies in California, growing to 500 pharmacies soon. Different states have different pedigree laws, but Walgreens' commitment to patient safety goes across the board, with the best safeguards in place.

Ms. Stamos said they received a variety of responses from their trading partners regarding pedigree, and each company is trying to do what's in their best interest. So Walgreens designed what they call a "giant catcher's mitt." They assume that anything can be thrown at them, and when tossed, they will catch it.

For example, Walgreens is testing to see how accurate what the wholesaler says is happening is actually happening. So far, they have never achieved 100% on this because of poor data flow from their systems to Walgreens' system. Sometimes the errors are a result of hardware issues, and sometimes it is human error. For the past two years they have undergone revisions to improve program accuracy. Any errors are unacceptable though, and Walgreens wants to know where the products in their pharmacies have been and how they got there.

Ms. Stamos provided information about a pilot conducted with scanners reading 2-D barcodes designed to see how quickly they could receive data. During the pilot, a person pulling the trigger on a scanner sometimes got a read right away, and sometimes several seconds would pass by with no response. When the ink on a barcode was smudged, they did not get good results. Walgreens wants to improve their accuracy with the scanners because this pilot study showed that they were not getting consistent results.

Ms. Stamos gave an estimated timeline for implementation. She said that once Walgreens knows what their trading partners want, they will design to those specifications. They want to know the "concrete" plans of their upstream partners and then based on that information, they estimate it will take 9 months to code new programs, and 6-9 months to train staff and troubleshoot the system. They estimate

total implementation time as 15-18 months, which would be right on target to meet California's deadline. It will take longer if their upstream partners do not communicate their needs very soon.

Ms. Stamos emphasized that when one manufacturer uses one type of scanner and another manufacturer used another type of scanner, this affects the training of their pharmacy staff on the varying hardware and software. She estimated the cost impact of preparing each of their pharmacies would be \$25,000-30,000, but that standardizing the processes across the supply chain would reduce those costs. Ms. Stamos stressed that if they knew that everyone would only be using one technology, they could cut costs in hardware and software, and more efficiently train their staff.

Ms. Stamos spoke about the impact of these changes on time spent for patient care. Walgreens doesn't want anything to take time away from focusing on their patients. They do not want staff checking paperwork instead of providing service to their customers, and patients perceiving that pharmacists are too busy to talk to them. Their number one priority is that patients are taking their medications properly, and know the side effects of those medications. She also mentioned that when working in Milwaukee, she saw an impact on cash payors when third party payors did not reimburse costs. Those patients who pay cash may choose to take their medications only every other day, or go to unregulated internet pharmacies.

Ms. Stamos stressed that there must be an accurate flow of data. This is the key because other problems will occur downstream otherwise. She asked for clarification about the risk-stratification concept that was mentioned in the previous meeting. She asked whether that would be allowed because it would complicate the process for their staff to determine which medications fall into which risk categories. Ms. Stamos stated that operationally, the fewer exceptions there are, the better. She also noted other considerations as follows:

- Patient privacy issues
- Pharmacy buyouts
- Potential delay in patient care (trying to get proper documentation – balancing the need for patient care)
- Technology still emerging

Ms. Stamos' suggested the following solutions during her presentation:

- Universal interoperability
- Inference use
- Pooling
- Grandfathering existing inventory
- Phased implementation

Mr. Room asked for clarification about the term "pooling."

Ms. Stamos responded that it meant lot level, which HDMA spoke about earlier. She also commented on having deadlines for manufacturers and wholesalers, and then retailers, so that retailers can make changes and bleed out their inventory. She reiterated Walgreens' commitment to meeting the January 1, 2009 deadline and doing everything in their power to make that happen. She also stated that they don't have control about what comes to them "upstream" and they can set up all these systems, but if they're not receiving item level serialization, they won't know how to handle those situations.

Mr. Room asked whether they were conducting RFID pilots.

Ms. Stamos responded that they are not conducting those pilots at the store level because of the training investment involved. They are also still trying to figure out what equipment to buy.

Mr. Room noted that his memory of a presentation by their distribution center showed that they preferred item level serialization from manufacturers, with 2-D barcodes as a backup.

Chairperson Goldenberg next introduced David Vucurevich from Rite Aid.

Mr. Vucurevich thanked the board for the opportunity to speak, and said that he would provide an update on where Rite Aid is regarding compliance with the California statute.

Mr. Vucurevich is Group Vice President in Pharmaceutical Purchasing and Clinical Services for Rite Aid. He said that Rite Aid operates 5,200 drug stores, and has one distribution center in California. Rite Aid acquired the Brooks and Eckerd chain of pharmacies, including their distribution centers, and are responsible for pharmaceutical procurement. They only buy directly from manufacturers, or from wholesalers who only buy from manufacturers.

Mr. Vucurevich stated that Rite Aid is "in lock step" with California's board and statute, and they are working diligently to meet the deadlines. Rite Aid wants to be good corporate representatives in health care. They performed a cost analysis to meet California's pedigree statutes, and they have been active in trying to find solutions for supply chain authentication. They participated in a track and trace project conducted by Accenture in 2003-04, as well as other projects including McKesson.

Mr. Vucurevich expressed concerns about some of the overarching issues affecting the pharmaceutical industry. Like the "big catcher's mitt" idea mentioned earlier, Rite Aid will try to accommodate all the various data carriers at the distribution level and pharmacy level. Mr. Vucurevich spoke about some of the issues that need to be resolved:

- Limited interoperability testing
- Serialization
 - Standards are not yet established
 - Multiple data carriers will multiply the cost and complexities for community pharmacies
 - In the absence of serialized inference, barcode data carrier used at lower packaging levels will significantly decrease the productivity of retail distribution centers
 - Trading partners may choose serialized hierarchy and/or pedigree in different formats (i.e. pedigree built at item or per-lot level)
- Existing inventories

Mr. Vucurevich said that trading partners are needed for pilots. For example, a pilot was conducted with Viagra and Trizivir, and though it was an important learning center for them, it was a very small sample. They need partners actively engaged. In one study, their read rate was 98.5%, but Mr. Vucurevich stressed that it was not without handholding. Some of the cases needed to be moved around and manipulated to get them to be read. He concluded his presentation by suggesting that the compliance date be moved to January 1, 2011, at a minimum. He also suggested legislative action to adopt model wholesale language reflective of “normal channel of distribution” pedigree exemption until complete technical and economic evaluation of a long-term solution can be determined.

Chairperson Goldenberg asked what an individual pharmacy would incur as far as cost, if they are looking at the “giant catcher’s mitt.”

Mr. Vucurevich responded that a template developed by Accenture allows some of the hardware and software development to be obtained at a lower cost. For example, some of their scanners currently read 2-D barcodes already.

Mr. Vucurevich added that they expect to experience significant decreased productivity resulting in increased labor costs. He said there is a challenge with staffing today with further demands on a pharmacist’s time. There are great concerns about generic pharmaceutical companies as well, and some manufacturers may opt to not provide drugs in California. Generics are important to consumers. Serialization is the key – once trading partners are established, he believes they will be able to comply with that part of the statute. He sees considerable evidence to move the compliance date out to 2011 and consider legislative action.

Chairperson Goldenberg stated that this comment was to Ms. Powell from PhRMA. It appeared that two or three times there were active pilot studies going on, but they were pretty well kept secrets. He urged everyone to get on the same page. He asked if there were any other comments or questions at this time. There were none.

Mr. Goldenberg stated that this ended the Workgroup on E-pedigree meeting. The committee would take a lunch break and resume to discuss the Enforcement Committee's agenda.

2. Enforcement Committee

a. Proposal to Develop an Ethics Course for Pharmacists, Modeled After the Experiences of the Medical Board of California In Establishing an Ethics Course for Physicians

Chairperson Goldenberg stated that the committee may want to make a recommendation to the full committee on this issue, and he'll open it up for discussion. He added that the issue of the Disciplinary Guidelines might overlap into this issue. The background was provided in the meeting materials.

At the January 2007 Board Meeting, the board voted to form an exploratory subcommittee to examine the development of an ethics course for pharmacists as an enforcement option as part of discipline. President Powers appointed Dr. Ravnan and Dr. Swart to this subcommittee.

In June 2007 the subcommittee met with an ethicist that works with the Dental Board. The ethicist provides assessment and individual therapy to respondents referred to him by the Dental Board. Upon approval by the Dental Board, the respondent must comply with the individual therapy recommended. The therapy is one on one.

In August 2007, Dr. Ravnan, Ms. Herold and Ms. Sodergren met with the representatives from the Institute for Medical Quality, the course provider for the Medical Board's 22-hour course, which is authorized by Medical Board regulations. The course requirements include:

Pre-program Requirements

Background Assessment Application Baseline Assessment of
Knowledge Test Reading Assignment Participant Expectation of
Program Statement

Two-Day Ethics Course

Case presentations
Break out groups
Experiential exercises
Role-playing

Longitudinal Follow-Up

6 month
12 month

Initial discussions with a potential course provider indicate that the development of the course would not require significant resources from board staff, a principal duty would be to identify case scenarios that would be discussed during the course. This course focused on small group interactions and personal written assessments.

Sample Language that could be incorporated in the board's Disciplinary Guidelines is as follows:

Within 60 calendar days of the effective date of this Decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the Board, or its designee. Failure to successfully complete the course during the first year of probation is a violation of probation.

Respondent shall submit a certificate of completion to the Board or its designee within 5 calendar days after completing the course.

Dr. Ravnan recommended that the board pursue adoption of a course similar to the one used by the Medical Board.

Dr. Swart said he was unable to attend the last meeting of the subcommittee.

Ms. Herold stated that Dr. Ravnan, Ms. Sodergren and herself all liked the structure and components of the structured course used by the Medical Board. She added that she has added completion of an ethics course designated by the board into two stipulations in prior months. She had envisioned one-on-one counseling with an ethicist to fulfill this requirement.

Ms. Herold stated that the independent foundation uses funding from the California Medical Association's Foundation, but stands independent from CMA. Their ethics course sounded inspiring. The Institute for Medical Quality works with individuals as to why they got into a problem in the first place, they give them a lengthy questionnaire, and also have them in groups of 11-12 people for two days, along with follow up. There is a lot of intensive interaction.

Ms. Herold said that, for example, a pharmacist who had no qualms about prescribing medicine (using forged prescriptions) and dispensing to a family member could work through how he or she came to that decision in a program like this. There are case-specific instances, and the goal is to set up scenarios for participants to work through, including writing essays, and one-on-one counseling and group therapy. The cost to participate is approximately \$2,000.

Chairperson Goldenberg asked whether Ms. Herold was suggesting that the Board of Pharmacy use the Medical Board's program as a model, and then create our own.

Ms. Herold responded, yes, and we would provide our own cases for the case scenarios.

Chairperson Goldenberg said if we build it, will they come?

Ms. Herold responded that she believed that not every violation is an ethical violation and that completion of an ethics course would not be a full resolution to a violation in a disciplinary decision. She also indicated that other state boards of pharmacy may be interested in referring pharmacists to this course.

President Powers suggested that the committee bring it to the full board, recommending that we use it.

Ms. Herold noted that it would probably take two years to have this program set up. This program recognizes 5-10% of people will just play the game to get through the course, and will have no change in their behavior, but having the threat of losing their license is an important incentive.

Mr. Room asked whether participants can be terminated for not completing the program.

Ms. Sodergren responded that a doctor conducts a pre-assessment and a post-assessment. It is a "closed decision" and not a board decision as to whether they pass the course or not.

Ms. Herold offered to ask the Institute for Medical Quality to come to the October Board Meeting to offer more information about their program.

MOTION: Recommend adoption of an ethics course from the Institute for Medical Quality tailored for pharmacists.

M/S: POWERS/SWART

SUPPORT: 5 OPPOSE: 0

b. 2007 Self Assessment Forms for Veterinary Food Animal Drug Retailer

Chairperson Goldenberg referred to the Veterinary Food-Animal Drug Self-Assessment Form in the meeting materials.

At the January 2007 board meeting, the board voted to approve the addition of 16 CCR 1785 - Self Assessment of a Veterinary Food-Animal Drug Retailer. The adoption of this section would establish a self-assessment form for veterinary food-animal drug retailers and require that the designated representative-in-charge complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with the legal requirements of their operations and therefore increase public safety as a result of this compliance.

Ms. Herold stated that we have a self-assessment form for most of our regulatory programs. It's a good way to advise licensees as to what to expect during inspections, and how to come into compliance. This is another self-assessment to bring this small group of licensees into compliance. Judi Nurse supervises the team of inspectors over wholesalers and veterinary food animal drug retailers.

Chairperson Goldenberg asked whether these licensees have to pass a test for this designated license.

Ms. Herold responded that in the past the board did, but the specially developed exam was eliminated about four years ago. These individuals need knowledge of prescriptions, knowledge of pharmacy, and knowledge of withdrawal times for drugs provided to food animals before the animals can be used for food, to have the qualifications for this.

The vet retailer designated representatives are required to have specialized training. In the past, this training was provided by the UC Davis veterinary school. However, apparently this course is no longer given so it is difficult for these individuals to obtain the training needed to become exemptees.

Chairperson Goldenberg asked whether any pharmacist could be a consultant.

Dr. Nurse responded, yes. She added that the board's staff has just started a series of meetings with the Veterinary Medical Association who has a subgroup on dairy. She noted that this group had given input for the self-assessment form to make it more meaningful, and that the board may want to revisit the regulations on this issue.

Dr. Nurse noted that the chairman of the dairy group would train the six pharmacists on her team. The designated representatives who work in these locations are not aware of the significance of what they're doing. They label the drugs that go to dairies, and they are complex labels. For example, withdrawal timing is an issue. Drugs should not be administered shortly before milking or slaughtering. There are other considerations as well, such as lactating or non-lactating, feedlots vs. dairy, and medicines bought over-the-counter vs. off label use that need a prescription. Most people who administer these drugs to the animals do not speak English. Administering a drug when it shouldn't be given is

a safety issue. Dr. Nurse emphasized that there needs to be a better training program.

Chairperson Goldenberg asked if we could we ask for consultant pharmacists for each of these facilities.

Dr. Nurse responded that our inspectors are going in and doing compliance, and hopefully the self-assessment will help them too.

Ms. Herold noted that the program was enacted around 1998 as a result of animal owners who wanted to purchase massive amounts of drugs needed to care for their herds without having a vet specifically label each container. The USDA was citing and enforcing laws regarding drug residues on animals that become food or produce food. The real issue was that veterinarians could label, sell, and distribute the products, but the ranchers did not want to pay that cost. This way, wholesalers could label the product for 5,000 cows in one dairy. The problem was getting vet retailers qualified. Drug wholesalers who do not license veterinary food animal drug retailers cannot otherwise label drugs for patient use for humans or food animals.

Dr. Nurse noted that there are only 53 licensed designated representatives.

Ms. Herold suggested that if we can't adequately safeguard the quality of the designated representatives, then we should seek a legislative solution to return this important function to the veterinarians. The full board should make this decision. The issue for this committee at this time is the self-assessment form.

Chairperson Goldenberg asked if there was any downside to having this form out there.

Dr. Swart asked what other states do.

Ms. Herold responded that California is one of the few states that allow this, reflecting California's strong ranching industry. We need the ongoing assistance of veterinarians to participate though, and until recently they have not been involved.

Steve Gray, Kaiser Permanente, commented on Western University's pharmacy school that has a close alliance with Cal Poly Pomona.

Dr. Nurse stated that veterinary prescriptions are very strange. They are either written on January 1 or July 1, and are good for six months (under the board's regulations).

Ms. Herold stated that she would contact Dean Robinson of Western University and ask him about the relationship they have with veterinary training and drugs.

MOTION: Recommend adoption of the Veterinary Food-Animal Drug Retailer Self-Assessment Form and move forward with the formal rulemaking process after the October Board Meeting.

M/S: POWERS/DAZÉ

SUPPORT: 5 OPPOSE: 0

c. Enforcement Statistics

Chairperson Goldenberg advised that the Enforcement Committee statistics for July-September of the 2007/08 fiscal year were provided in the meeting materials.

Ms. Herold noted that the board has been down staff, specifically investigators. We have been encouraging our inspectors to get their cases in timely. They are getting their cases in, and spending more time doing investigations.

Chairperson Goldenberg asked about the statistics of office conferences.

Mr. Room said that 14 citations were affirmed.

Chairperson Goldenberg noted that it appeared to be beneficial for licensees to come to the office to give additional information.

Dr. Nurse stated that sometimes we have misworded a citation, and that we try to be fair and listen to what people say, and not wrongly cite and fine a pharmacist, pharmacist-in-charge or a pharmacy.

Ms. Herold emphasized that merely showing up to an office conference does not in and of itself reduce the penalty, as most citations, fines and letters of admonition are upheld. The licensee must produce additional information that was not available at the time of the cite and fine. However, office conferences do provide a sometimes-needed opportunity for a licensee to share information that was not otherwise known prior to the conference.

Chairperson Goldenberg asked if the message that there is an opportunity to present additional information is getting out to our store licensees.

Orriette Quandt, Longs Drugs, stated that the message is clear that there is an opportunity to bring additional information.

Dr. Nurse added that the larger chains evaluate which cites and fines warrant an appearance before the committee for discussion.

Mr. Ratcliff stated that the board dismissed \$2,500 on one case because they were inappropriately cited and fine and had been misinformed by staff for this action that led to the violation. Most pharmacists are willing to pay a fine, as long as it's not put on their record. Sometimes they ask for a reduction in a fine, and it may be warranted based on the circumstances.

Dr. Gray commented that the cite and fine does serve a purpose.

Ms. Herold said that generally people are nervous about what caused them to be there, and in approaching the board for this conference.

Dr. Gray stated that some people are so upset they don't even want to appear.

Dr. Swart noted that it's not like showing up in traffic court, and getting credit for making the appearance where your fine will be reduced.

Ms. Herold added that during an office conference, there is the chance to talk with people one on one, which is often important.

Dr. Quandt asked about those licensees that appeal the office conference decisions to the Attorney General's Office.

Ms. Herold noted that very few cases go to the Attorney General's Office.

10 cases were referred to the Attorney General's Office in the last quarter.

d. Proposed Modified Disciplinary Guidelines for the Board of Pharmacy

Chairperson Goldenberg noted that at the last board meeting, he asked that the proposed guidelines be sent to all members of the board because of the significance of the issue. He thanked Susan Cappello for the summary contained in the meeting materials.

The meeting materials contained the proposed modified Disciplinary Guidelines and a memo outlining the revisions. Written comments on the revisions received by Ronald Marks, and a summary of the board's response to those comments were also provided.

The Disciplinary Guidelines are being revised to clarify language, ensure that terms and conditions are consistent for all license types (where appropriate), to define consequences for non-compliances, and to include new terms of

probation. Specific items identified by Chairperson Goldenberg for this meeting's discussion were:

- Posting a notice when licensee is on probation
- Requirements for the notice employers must sign
- Whether revocation based on nonpayment of cost recovery fees should be pursued

Chairperson Goldenberg said that one thought he had was to create a single piece of paper that can be used by board members in closed session as to reconsideration of an individual. When reviewing the guidelines, he was reminded that public service is a possible option, and writing letters to journals or to graduating students. He believes those options are better than providing free services to a clinic, which is like picking up trash on the highway.

Chairperson Goldenberg said he had another thought about the payment of fines before they make a presentation to us. He is concerned about this because, for example, three years can go by with no payment of the fine.

Dr. Swart commented that licensees want reinstatement before making any payment of a fine. We ask them if they have paid while on probation, and if any effort had been made to pay, it's usually very little.

Dr. Conroy commented that licensees do not seem to have a vested interest in paying a fine, unless the board says they will be reinstated.

Chairperson Goldenberg said he was concerned that they don't take the matter seriously.

Mr. Dazé noted that criminals have to pay restitution or a fine, and you don't get off without paying it in full. Even people in prison making \$1 a day must pay toward their restitution or fine. When he hears that a licensee hasn't paid anything on the fine, it looks bad.

Mr. Room said that, from a legal perspective, the board could set its own guidelines as to when it would consider granting penalties for reinstatement. The statutes set forth conditions for someone to present information to the board. He said he was pretty sure there would have to be a change in law if they were not allowed to make a presentation to the board before paying their fine. He can look into it, but hesitates making prepayment of a fine a precondition to make a presentation to the board.

Mr. Room clarified that the board can change the language that the board will take into account whether a person has made an effort to pay the fine.

President Powers asked whether we could require prepayment of the fine before a presentation can be made to the board.

Mr. Room clarified that we can't refuse to hear their petition until they have made an effort to prepay because that would constitute a conditional obligation. We could inform potential petitioners that cost recovery is taken seriously and a good faith effort is encouraged before making a presentation.

Chairperson Goldenberg restated his interest in having a single sheet of paper with a check off list, if these guidelines are approved. He also asked about an item on Page 52 of the guidelines. Item #28 relates to a respondent completing the Pharmacist Self-Assessment Mechanism (PSAM) provided by NABP. He asked what the board does with that, if we're not tying the outcome of the PSAM to educational needs. A person taking an on-line course on cough syrup is not understanding the intent of the education requirement.

Ms. Herold responded that that could be a discussion item with the quarterly probation monitoring done by board inspectors. There is no requirement that if a person takes the PSAM that the board will be able to review the results or direct specific coursework based on the results.

Chairperson Goldenberg said he interpreted it to read that it is confidential. The course is encouraged to be taken for self-improvement.

Mr. Dazé asked if a waiver could be signed for an inspector to see the results.

Mr. Room responded, yes, as there is for drug testing. They could execute a waiver to share the information with the inspector, so the inspector can monitor the person on probation.

Dr. Coyne added that she has found that an individual going along on the right track will voluntarily share information with their inspector.

Mr. Room suggested one option could be the results of the PSAM being reported to the probation monitor. Another option could be the results of the PSAM are reported to the probation monitor, and also as a guide to CE.

Dr. Swart noted that we require passing the CPJE as a condition for reinstatement, and that might be a better option.

Ms. Herold added that typically passing the CPJE or even the NAPLEX would be required of a pharmacist who had been out of practice for a period of time. This is a probation term, not a reinstatement term.

Mr. Dazé noted that in the last couple of cases argued before the board, people had been out of practice for years were not always conversant with pharmaceutical issues.

Mr. Room asked to loop back to another issue. A checklist might be of more use for purposes of a reinstatement, when applying standard conditions for consideration of cases. You may be able to ask for PSAM exam information during the open hearing, and we are allowed to ask for technical assistance from staff.

Ms. Herold offered to provide a checklist.

Mr. Dazé noted that on Page 2 of the disciplinary guidelines, the second to last paragraph, the wording is "manager, and/or pharmacist-in-charge responsible for the acts of employees who operate the pharmacy." Mr. Dazé questioned whether the wording "employees that operate the pharmacy" should instead be "employees that work in the pharmacy." He also asked about the operative term, "operate."

After discussion, Mr. Room stated that the term will be changed to "pharmacy personnel."

Dr. Conroy said that she had questions about two items. On Page 38, Section 13, Tolling of Probation. The wording is, "Respondent is required to practice as a pharmacist in a licensed pharmacy setting that dispenses medication. After the first year of probation, the board or its designee may consider a modification of this requirement. If the respondent fails to comply with this requirements or a subsequent modification thereto, such failure shall be considered a violation of probation." Dr. Conroy noted that it's under the mandatory terms of probation. She questioned whether, if a pharmacist diverted a controlled substance, shouldn't they spend time away from dispensing? Why require that condition right up front?

Mr. Room clarified that that discussion occurred some time back, and a correction was going to be made to the guidelines. Document degradation caused that correction to not appear. He said that a respondent is required to practice as a pharmacist in a licensed pharmacy for a minimum of one year before the end of the probationary period.

Dr. Gray asked whether "dispense" also means to furnish, like a pharmacist in charge of a warehouse.

Ms. Herold responded, yes.

Dr. Quandt asked about acting on a consultant basis outside a pharmacy (e.g., reviewing insurance claims), would pharmacists on probation return to that position or start work in at a pharmacy?

Dr. Conroy asked why working in a pharmacy isn't optional, instead of mandatory.

Ms. Sodergren clarified that part of the issue is to be able to monitor them in some type of licensed facility before they complete probation.

Ms. Herold added that whether it should be mandatory or discretionary should be up to the board.

Dr. Conroy noted that, for the PRP program, it would make sense for someone with a problem with diversion of drugs to be barred from working in a pharmacy while the pharmacist was early in recovery.

Mr. Room stated that the best way to do this is to continue to house this under term number 13, and make it an option under a standard term.

Dr. Conroy said that the other item she wanted to discuss was on Page 53, No Supervision of Ancillary Personnel. She questioned under what situation would you not want them to be able to supervise. Pharmacists cannot get a job if they can't supervise a technician.

Mr. Room clarified that this is for folks abusing their supervisory authority.

Chairperson Goldenberg added that this is an optional term.

Dr. Swart added that there are times when it has been appropriate.

Mr. Room said that the board can strike or reduce terms.

Chairperson Goldenberg asked the committee to look at Ronald Marks' letter dated June 15, 2007. His letter included comments about the proposed Disciplinary Guidelines. Mr. Marks also sent a fax dated September 14, 2007. Dr. Goldenberg noted that Mr. Marks' last comments (in the fax) were more of a comment on policy, as he doesn't want everyone to be mandated into an ethics course.

Mr. Room stated that if the respondent changes employment, it is the respondent's responsibility to ensure that his or her employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. The respondent shall have his or her new supervisor, within 15 days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in the case,

and be familiar with the level of supervision needed. The wording in the guidelines states that:

“Respondent shall not practice pharmacy and his or her license shall be automatically suspended until the board or its designee approves a new supervisor. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.”

Mr. Room emphasized that there should be no lapse between supervisors when changing employment. If there is, the pharmacist is barred from entering a pharmacy during that period of time. A subsequent paragraph in that section provides:

“During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.”

Mr. Room stated that the written responses to Mr. Marks' comments were responsive.

Dr. Gray said that Mr. Marks' letter referenced a posted notice to warn the public about a pharmacy on probation. He asked whether, if quality of care is not at issue, why should the notice be posted? He gave an example of a pharmacy in an institution. If the notice is posted in a basement or near a loading dock where the pharmacy may be located, how does the public notice serve a bona fide purpose?

Ms. Herold responded that the public should be advised if a pharmacy is on probation.

Chairperson Goldenberg noted that not many pharmacies are put on probation, maybe only 5-10 a year, so it's not often. Usually a pharmacy closes before we put them on probation.

Mr. Herold noted that they inadvertently left out wording regarding warning consumers about the sale or closure of the pharmacy. The pharmacy needs to tell their patients of the impending closure of the pharmacy, if this is the sanction of a board decision or stipulation.

Mr. Room commented on notifying the patients about what a pharmacy should do with their drug stocks. Probationers need to know what is expected.

MOTION: Recommend approval of the proposed changes to the Disciplinary Guidelines by the full board in October 2007 for the purposes of amending Section 1760.

M/S: CONROY/DAZÉ

SUPPORT: 5 OPPOSE: 0

Adjournment

There being no additional business, Chairperson Powers adjourned the meeting at 3:55 p.m.



California Prescription Drug Pedigree

Enforcement Committee Meeting
9/20/07



Addition to Pedigree Definition 2006 Legislation

- Pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution

California Pedigree Legislation

- 1/1/2009 pedigree implementation date
- CA Board of Pharmacy may delay implementation of pedigree until 1/1/11

Interoperable electronic system defined

- For prescription drugs
- Uses unique identification number
- Established at point of manufacture
- Contained within standardized non-proprietary data format and architecture
- Uniformly used by manufacturers, wholesalers and pharmacies

Pedigree Definition

- "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition(s) and sale(s) by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering or dispensing the dangerous drug.

Pedigree tracking

- Pedigree tracks each prescription drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler and received by the pharmacy (i.e. saleable unit)

Electronic Pedigree Requirements

- Prescription Drug Information
- Transaction and Source Information
- Ownership Information
- Certification

Ownership Information

- For each prior owner of the drug the pedigree must contain:
 - Prescription drug information
 - Source information
 - Transaction information
 - Name & address of each person certifying delivery or receipt of prescription drug

Prescription Drug Information

- Drug name – trade or generic
- Quantity
- Dosage form
- Strength
- Container size
- Number of containers
- Expiration dates
- Lot numbers

Pedigree Certification

- A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate

Transaction and Source Information

- Business name
- FDA manufacturing registration number or state license number as determined by the Board
- Principal address of the source
- Date of transaction
- Sales invoice number

Repackaging-a part of original pedigree

Single pedigree includes every change of ownership from initial manufacturer through the final transaction to a pharmacy or other person for furnishing, administering or dispensing the prescription drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number

Drug Returns

- Prescription drugs returned to the manufacturer or wholesaler are documented on the same pedigree document as the transaction that resulted in receipt of the drug by the party returning it.

Reporting requirement

- Manufacturer, wholesaler or pharmacy with reasonable cause to believe a prescription drug in, or having been in, its possession is counterfeit or subject of a fraudulent transaction, the manufacturer, wholesaler or pharmacy shall notify CA Board in writing within 72 hours of obtaining knowledge.
 - Applicable only if drugs sold or distributed in or through the state of California.

Transactions not requiring a pedigree

- Samples –provision of prescription drug samples by a manufacture's employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge

What is the problem , why state legislation?

- Counterfeit drugs entering legitimate pharmaceutical supply chain
- Inability to track source of counterfeits
- Obvious danger to health & safety of public
- Federal legislation implementation delayed

Transactions not requiring a pedigree (cont)

- Injectable prescription drugs delivered directly by manufacturer to an authorized prescriber directly responsible for the administration of the injectable
 - may not be dispensed to a patient or patient's agent for self administration
 - Must be administered to patient by prescriber or other authorized entity receiving drug directly from manufacturer.
 - Exemption expires 1/1/10 unless industry requests extension and Board grants to 1/1/11

California regulation of prescription drugs

- Prescription drugs from manufacture through all stages of distribution until dispensed or administered to a patient by a pharmacy or prescriber are regulated in CA through required licensing of both the business and the individuals working in those businesses

Related Existing Law

- All wholesalers selling into or located in CA must be licensed in CA (effective 1/1/05)
- Surety bond required for all licensed wholesalers
- Restrictions on pharmacy furnishing, manufacturers and wholesalers (effective 1/1/05)
- Wholesaler or pharmacy may not purchase, sell, trade or transfer a prescription drug without receiving or issuing a pedigree (effective 1/1/09)

Other restrictions

- Manufacturer/wholesaler may only furnish to an authorized person
- Manufacturer/wholesaler/pharmacy may only furnish prescription drugs to a licensed business or prescriber
- Acquire prescription drugs only from a manufacturer or licensed wholesaler
- Effective 1/1/09, a wholesaler or pharmacy may not receive, sell, trade or transfer a dangerous drug without a pedigree

Pharmacy Furnishing Restrictions

- Pharmacy may only furnish prescription drugs to:
 - Wholesaler/manufacturer from whom the drug acquired
 - Pharmacy/wholesaler of common control – drugs may only be transferred to wholesaler by pharmacy if drugs originally purchased from commonly controlled wholesaler
 - Licensed wholesale reverse distributor
 - Pharmacy or wholesaler in sufficient quantity to alleviate a specific shortage

What do we do to prepare for 1/1/09

- Develop interoperability standards
- Develop unique identifier standards
- Participate in public CA Board of Pharmacy quarterly pedigree workgroup meeting
- Participate at pharmacy, wholesaler and manufacturer levels to assure compliance by 1/1/09

Pharmacy furnishing restrictions (cont)

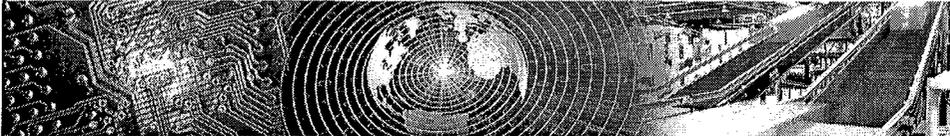
- Patient or pharmacy pursuant to a prescription
- Health care provider authorized to purchase prescription drugs
- Pharmacy under common control



Questions?

Visit our Web site at
www.pharmacy.ca.gov
Or call us at (916) 574-7900





EPCglobal Update
State of Pedigree and EPC/RFID Standards

California Board of Pharmacy

September 20, 2007
Mike Rose, Tri-Chair, EPCglobal HLS IAG
Ron Bone, Tri-Chair, EPCglobal HLS IAG

Bob Celeste, EPCglobal North America

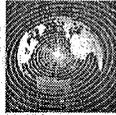


Overview

- State of the Standards
- Follow Up Items from March 8, 2007 Workshop
- Next Steps

2

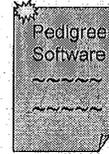
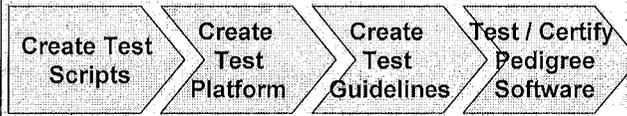




Post Ratification Activities Pedigree Messaging Standard

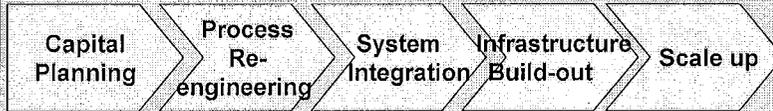
Pedigree Standard Ratified January, 2007

EPCglobal



Completed 6/01/2007

Individual Companies



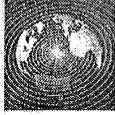
Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define a standard format for a Pedigree Messaging standard that will meet all current Federal and State Pedigree requirements.

Status:

- Ratified standard – 01/2007
- Certification Program - 3 companies certified
 - ✓ Axway
 - ✓ rfxcel
 - ✓ SupplyScope
- Education and awareness web seminars



Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define requirements for tagging pharmaceuticals at the item level. Include requirements for manufacturing lines, distribution environments, transportation and Retail environment.

Status:

- HF & UHF initiatives underway to provide uniform air interface protocol at item level.
- HF Standard expected '07.
- Completed vote for item level tagging requirements document
- Ratification of standard anticipated 10/07
- Anticipate silicon available for prototyping 2Q08

7



Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

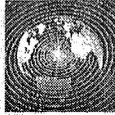
Define requirements for the EPC identifier to be encoded on an RFID tag.

Status:

- Pharma Requirements complete. Identified 2 GS1 identifiers [Global Trade Item Number (GTIN) and Serialized Shipping Container Number (SSCC)] to be used.
- Collaborating with GS1/HUG via the "Global Healthcare Initiative" -- starting with Serialization.
 - Joint HUG/HLS Work Team
- Medical Devices, Biologics & other Business Requirements started

8





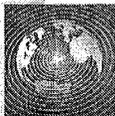
Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define requirements and/or guidelines for authenticating and decommissioning tags consistent with optimizing tag utility and consumer/patient privacy.

Status:

- Predominately HLS, however, cross industry work group expected
- Authentication and decommission alternative scenarios identified
- Anticipate completion by end of October



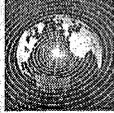
Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define supply chain use cases, processes and information needs for sharing EPC related data for forward and reverse logistics.

Status:

- Forward & Reverse Logistics (Returns) processes and data exchanges completed
- Integrate with GS1 Traceability efforts
- Track & Trace to be interoperable with Pedigree Model
- Additional use cases addressed:
 - Repackers
 - To be done: 3rd Party Logistics Providers & Product Recall
- Sub-team within Supply Chain Integrity focused on security and pedigree integration
- Data Sharing Strategy & Guidelines will be addressed in Data Exchange JRG
- Common vocabularies and location identifiers incorporated into just ratified EPCIS Standard



Standards Update

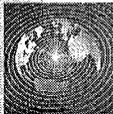
6	Tag Data Standards
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Tag Data JRG focused on defining additional user memory requirements for tags (ie. Lot Number, Expiration Date).

Status:

- Work underway. Defining common data structure that can be used by all industries.
- Captured business requirements
- Comment phase approved
- Specification phase started

11



Industry Adoption Task Force Executive Summary

- **Mission:**
 - Define a 'starting set' of guidance for industry trade associations
 - Work closely with EPCglobal and GS1.
 - Educate and hand-off the Roadmap to industry trade associations.
- **Objectives:**
 - Guidance on: Unique Identification based on Serialization.
 - Guidance on: Carrier and Auto-Identification Alternatives
 - Guidance on: Two Options to provide a Pedigree:
 - Option 1 – Drug Pedigree Standard (Available Now)
 - Option 2 – Track and Trace (Under Development)
 - Guidance on: Trading Partner Action Steps for Adoption
- **Timeline:**
 - Document presented to numerous groups
 - In process of resolving comments

12





EPCglobal HLS Update Follow up Items

Follow Up Items
From
March 8, 2007 Pedigree Workshop
with
Subset of California Board of Pharmacy



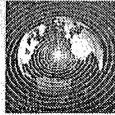
Follow Up Items Summary Update

Current Status

Weekly conference calls to work on follow up items

		Assign Responsibility	Document & Identify Item	Status
1	Unit Dose Serialization	Individual company	Business Practice	On going
2	Receipt of Partial Shipments	Pedigree WG	Supported by Current Standard	Completed
3	Drop Shipments	Pedigree WG	Supported by Current Standard	Completed
4	Sign & Cert. Inbound	Industry Assoc	Supported by Current Standard	Completed
5	Resale of Returned Product	Pedigree WG	Supported by Current Standard	Completed
6	Intra-Company Transfers	Individual company	Business Practice	
7	Voided Pedigrees	Industry Pedigree WG	Standard enhancement	In Progress
8	Inference	Industry Adoption WG	Guidance on use of standard	In Progress





1. Unit Dose Serialization Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Mfgs sellable unit may be "broken down" and sold as eaches.

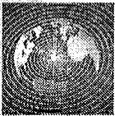
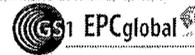
Issues:

1. How are the eaches serialized
2. What is the impact to Repackers
3. How will Repackers continue the pedigree

Assignment: Individual Company

Status:

- Business process issue for Supply Chain stakeholders to address level of serialization



2. Receipt of Partial Shipments Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Orders are not always received complete, having likely pedigree implications.

Issues:

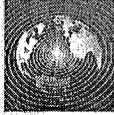
1. How often does this occur
2. What pedigree or business process changes may be required

Assignment: Pedigree Workgroup

Status:

- Current Pedigree standard addresses partials receipts





3. Drop Shipments Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Mfgs ship certain products to end-customers, while billing goes through wholesalers.

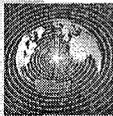
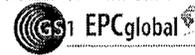
Issues:

1. Where should the pedigree be sent
2. What transaction information should it reflect

Assignment: Pedigree Workgroup

Status:

- Current Pedigree std addresses drop shipments



4. Sign & Certify Inbound Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Signature and certification of in-bound shipments, as well as out-bound.

Issues:

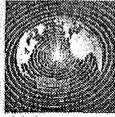
1. Evaluate the implications of not using inference

Assignment: Industry Associations

Status:

- Standard supports signing requirements for in-bound and out-bound





5. Resale of Returned Product Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: There are times when saleable product is returned by the Whlsr to the Mfgr and may be resold by the Mfgr.

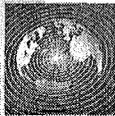
Issues:

1. Customers may not want returned product if the pedigree must reflect the previous distribution of the product.
2. How should a pedigree treat this transaction – reflect all previous movement of the product, or start anew when sold by the Mfgr
3. What documents, processes, controls and enforcement would be required

Assignment: Pedigree WG

Status:

- Pedigree standard addresses Resale of Returns



6. Intra-Company Transfers Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Pedigree Status for intra-company transfers into CA.

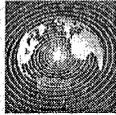
Issues:

1. Product sold to a Whlsr to an out-of-state location that does not require a Mfgr originated pedigree may be Intra-company transferred to CA.
2. What are the CA pedigree implications

Assignment: Individual Company

Status:

- Standard supports manufacturer and/or wholesaler originated pedigrees



7. Voided Pedigrees Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Pedigree needs to be updated or changed to correct simple administrative errors such as shipping wrong product or incorrect serial number.

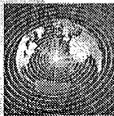
Issues:

1. What is the process of voiding pedigrees where an error has occurred, or a product has been returned
2. How are pedigrees for products marked for destruction managed

Assignment: Industry & Pedigree WG

Status:

- Identified as a pedigree management issue
- Initiating Work Group to address issue, in the interim, Standard provides guidelines & best practices



8. Inference Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Whether inference will be allowed at any step requiring "certification of the receipt", meaning that the receipt is positively affirming that they received all of the products specified in the pedigree without physically verifying all serial numbers.

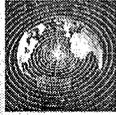
Issues:

1. Does the pedigree std allow two separate signature events for one receipt step (one to receive, one to certify at a later date).
2. What is the Industry's view on inference and it's application
3. Is there a time limit from inbound receipt Inference until all unique ID numbers have been certified

Assignment: Industry Adoption Workgroup

Status:

- Establishing a set of inference recommendations



Next Step

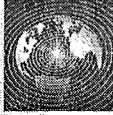
- In process of scheduling another pedigree workshop with the following recommended objectives:
 1. Review status of the work on the follow up items in detail,
 2. Discuss impact to standards, and
 3. Review work of the Industry Adoption workgroup

23



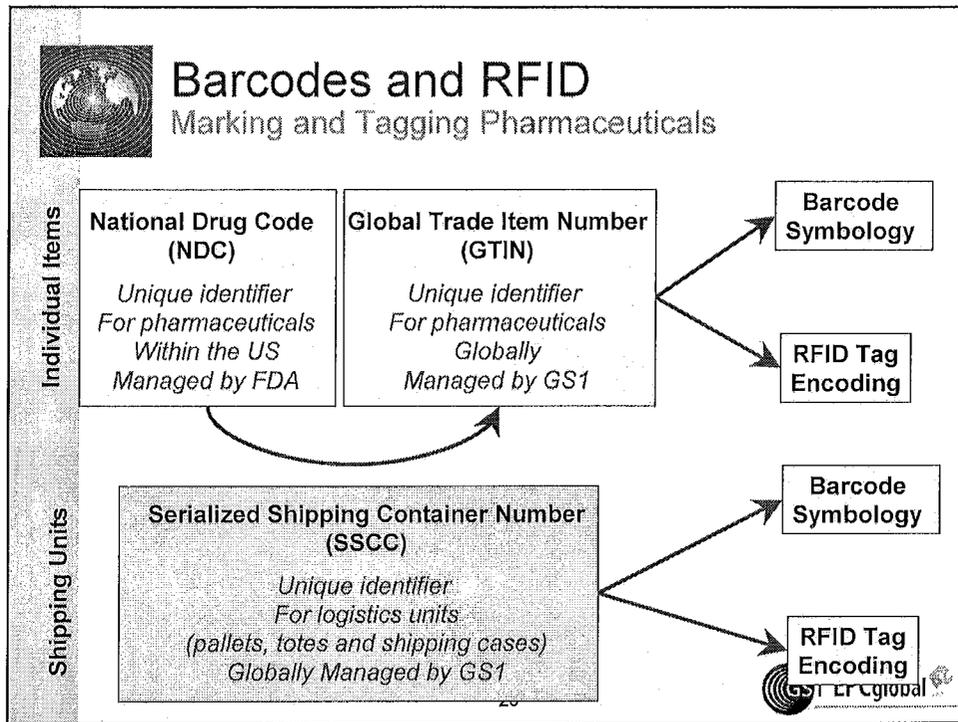
Electronic Tagging and Marking Options





Barcodes and RFID

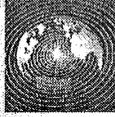
Marking and Tagging Pharmaceuticals



Barcodes and RFID

Differences and similarities

- Overlapping uses
- Different development trajectories
- Distinct reasons for choice
 - Thompson Memorial Hospital example



Barcodes and RFID

Differences in Barcode types

- Linear Barcodes:
 - Commonly seen in retail and in logistics
 - Usually read by laser scanners – can be read by optical scanners
 - Size increments as additional data is stored
 - Large installed base
- 2D Barcodes:
 - Used in Pharmaceuticals, documents, retail
 - Read by optical scanners
 - Small size
 - Redundant data for fault tolerance
- Mixed types:
 - Used in retail for loose items (fruit)
 - Portions can be read by laser scanner. Serialized portion can be read by optical scanner
 - Relatively small size



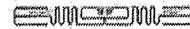
27



Barcodes and RFID

Differences in RFID types (passive)

- Ultra High Frequency:
 - Can be read from 0 – 5 meters
 - Fastest read speed
 - Reading around liquids and metals is a challenge (but not impossible)
 - Used in Pharmaceuticals, surgical sponges, etc.
- High Frequency (HF):
 - Used in Pharmaceuticals, books, access control
 - Moderate read speed
 - Usually larger than UHF
- Low Frequency (LF):
 - Used in manufacturing processes, access control
 - Slowest read speed
 - Very simple antenna design



28





"The nice thing about standards is that there are so many to choose from."

... Thomas Rittenhouse, former CEO of the Uniform Code Council (GS1)

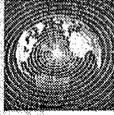



Bar codes that do not support serialization

Carrier	Example	Data	Use Case	Other
UPC-A		GTIN-12	•Retail Point-of-sale	•Linear scanner
UPC-E		GTIN-12	•Retail Point-of-sale	•Linear scanner
EAN-13		GTIN-13	•Retail Point-of-sale	•Linear scanner
EAN-8		GTIN-8	•Retail Point-of-sale	•Linear scanner

30





Bar codes that do not support serialization

Carrier	Example	Data	Use Case	Other
ITF-14 Type of Interleaved 2 of 5	 1 06 14141 00041 5	GTIN-14	•Non-retail POS items (primarily preprinted corrugate boxes)	•Linear scanner



Bar codes that do support serialization

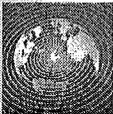
Carrier	Example	Data	Use Case	Other
GS1-128	 0010 0031 2343 67890 6 1213 1752650207	•All GS1 identification numbers including application identifiers, as required •Max: 48 a/n characters •Serial Number 20 characters max	•Non-retail POS items •Logistics units (SSCC)	•Linear scanner
GS1 DataBar™ [Reduced Space Symbology (RSS)]		•All GS1 identification numbers including application identifiers, as required •Max: 74 a/n characters •Serial Number 20 characters max	•Loose produce •Variable measure items (meat/deli) •Coupons •Very small healthcare items	•Linear scanner
GS1 Data Matrix		•All GS1 identification numbers including application identifiers, as required •Max: 2335 a/n characters 3116 num characters •Serial Number 20 characters max	•Direct part marking •Very small healthcare items	•Image scanner required



RFID tags that do support serialization

Carrier	Example	Data	Use Case	Other
EPC Gen 2 UHF passive Frequency 860-960 MHz		<ul style="list-style-type: none"> •All GS1 identification numbers including application identifiers, as required •No limit on user memory size determined by cost •Current serial number capacity 200B on 96 bit tag 	<ul style="list-style-type: none"> •Item level •Logistics 	<ul style="list-style-type: none"> •Range < 5m •Rewritable (under password protection) •Non-line of sight •Authentication •Kill capability
EPCglobal HF passive (under development) Frequency 13.56 MHz		<ul style="list-style-type: none"> •All GS1 identification numbers including application identifiers, as required •No limit on user memory size determined by cost •Current serial number capacity 200B on 96 bit tag 	<ul style="list-style-type: none"> •Item Level 	<ul style="list-style-type: none"> •Range < 2m •Rewritable (under password protection) •Non-line of sight •Authentication •Kill capability
EPC Active Tag (under development) Frequency 433 MHz		<ul style="list-style-type: none"> •All GS1 identification numbers including application identifiers, as required 	<ul style="list-style-type: none"> •Logistics 	

33

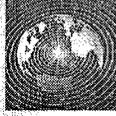


GS1 Serialization Standards

- A serial number, identified with AI 21, is an alphanumeric field of up to 20 characters.
- The capacity of a 20 character serial number is huge.
 - The capacity of an all numeric serial number is 100 quintillion (100×10^{18}).
 - The capacity for an alphanumeric serial number is 13.36749 nonillion (13.36749×10^{30}) when just using 0 to 9 and A to Z.
 - If all 82 alphanumeric characters are used, the serial number has a capacity of 188.9196 undecillion (188.9196×10^{38}).
- The serial number must be unique in relation to the Global Trade Item Number® (GTIN®).
 - Example, serial number 1098765432AC may be associated with both GTIN 00614141123452 and GTIN 00614141999996.

34

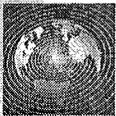




GS1 Serialization Standards (2)

- The serial number is NOT to be parsed by trading partners.
 - There is no provision in the standard to support or enable this.
 - It is also contrary to basic GS1 principles that data elements are not to be parsed.
- Manufacturers may construct the serial number in anyway they see fit, including the use of internal logic or intelligence.
 - There exist no limitations or rules on serial number construction in GS1 standards.
- The SGTIN can always be represented as GTIN (AI 01) plus Serial Number (AI 21).
- The SGTIN-96 structure limits the serial number (AI 21) to a defined subset.
 - This subset is all numeric 38 bit field or 274,877,906,943 unique numbers.
 - This subset requirement exists due to chip size and cost considerations.

35

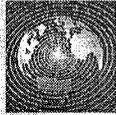


GS1 Serialization Standards (3)

- The SGTIN-198 structure completely supports the serial number (AI 21) - an alphanumeric field of up to 20 characters.

36

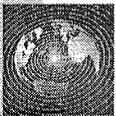
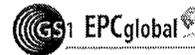




Serialization Implementation Thoughts

- The GS1 community should build applications that support a serial number field of 20 characters.
- If a manufacturer has applied an Electronic Product Code™ (EPC) tag to a product and it is bar coded, then the information must match. Specifically, the GTIN must match and the serial number must match.
- Manufacturers that are unable to accept the serial number subset of the SGTIN-96 in an EPC tag will need to specify EPC tags that support SGTIN-198.
- The lot / batch number must be a distinct data element, defined as AI 10, both when bar coded and in an EPC tag, if it intended for trading partners to use. In a bar code it is AI 10 and in an EPC tag it would need to be in user memory. Should a manufacturer wish to include the lot / batch number in the construction of the serial number, this is their choice but the manufacturer can not expect any trading partners to parse out the lot / batch number from the serial number.

37



Data Convergence

Bar Code and EPC - Different Data Formats

Different data formats for the same GS1 ID number

Data Output

00312345678906

0312345.067890.0

urn:epc.id:sgtin:0312345.067890.0

Data Capture

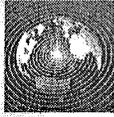


GS1 ID Number Encoded in Data Carriers



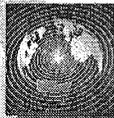
38



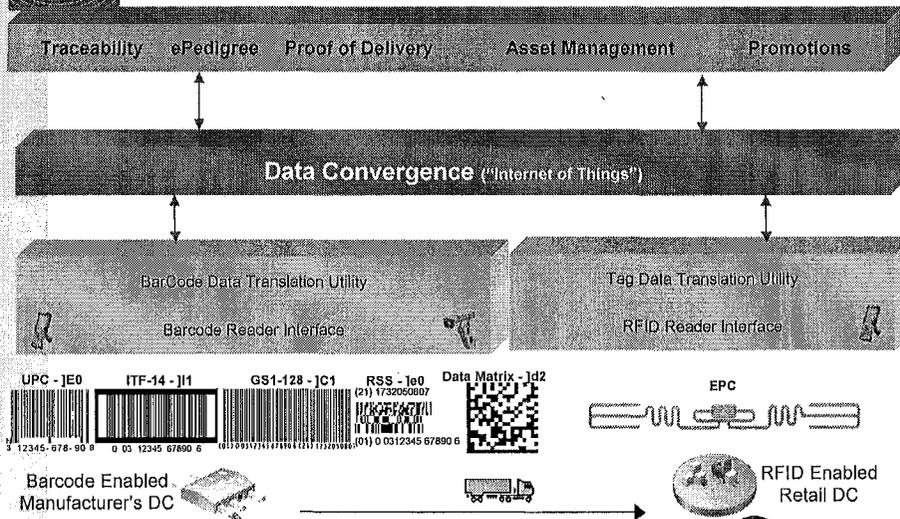


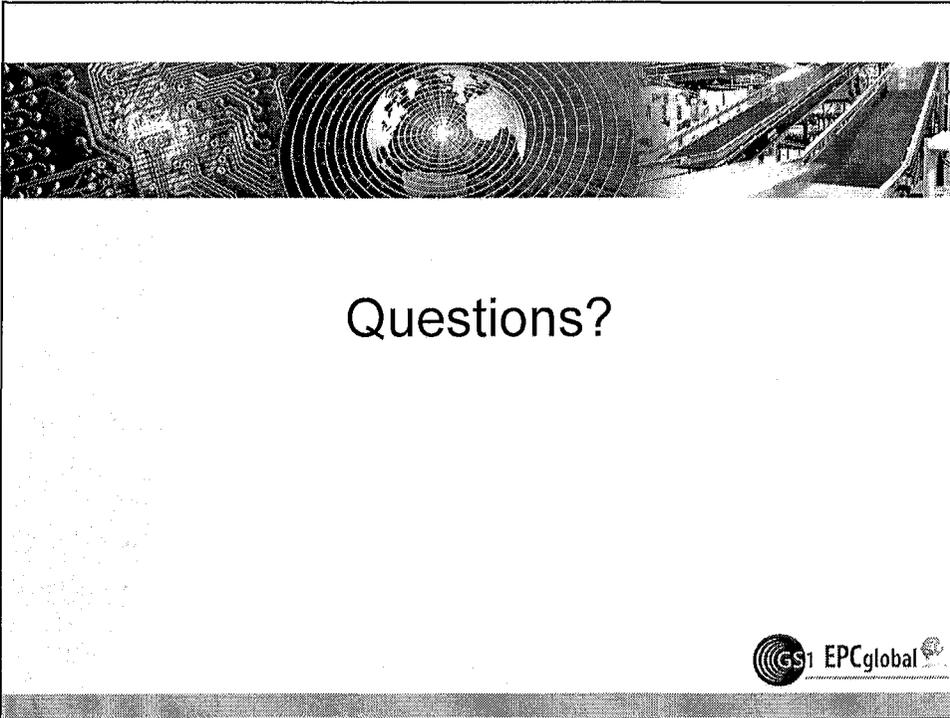
URI Identification System

- URI are the addressing technology standards (IETF) for identifying resources on the Internet or private intranet. Fundamental component of World Wide Web.
 - Uniform Resource Locators (URLs) are addresses for network locations
 - Defines "where"
 - Example: www.gs1.org
 - Uniform Resource Names (URNs). A URN is a name that identifies an information resource on the Internet
 - Defines "what"
 - Example: urn:epc:id:sgtin:0029000.107313.2147488897
 - Foundation for "Internet of Things"



GS1 Barcode and EPC / RFID Convergence





Questions?



rfXcel Active ePedigree Management™

A Practical Solution to Improve Drug Security

Jim Ensell
 President and COO
 9-20-2007

www.rfXcel.com

rfXcel Active ePedigree Management™

Agenda

- Introduction to rfXcel
- The Problem
- Current State of the Practice
- Possible Paths Forward
- Conclusion

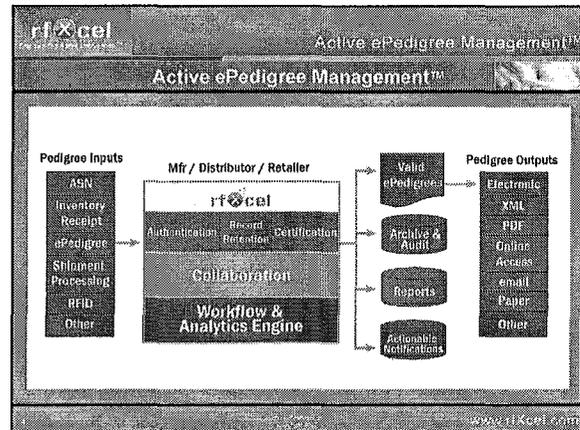
www.rfXcel.com

rfXcel Active ePedigree Management™

Company Overview

- Founded in 2003
- Based in San Ramon, CA (Silicon Valley)
- Leading Provider of Pedigree Management Solutions
 - Fully Certified by EPCglobal
 - Compliant with All State & Federal Regulations
- Focused on Health/Life Sciences and CPG Industries
- Strong Management Team with Industry Expertise
- Many Customers in Production
 - Manufacturers, Wholesalers/Distributors, and Retailers

www.rfXcel.com



rfXcel Active ePedigree Management™

The ePedigree Application Partner of Choice

The rfXcel Advantage

- ✓ Legislative Compliance with All State & Federal Laws
- ✓ Fully Certified by EPCglobal
- ✓ Simple File Transfer Integration with Existing Systems
- ✓ Ease of Use: Intuitive Web Browser Interface
- ✓ Secure and Scalable
- ✓ World Class 24/7 Customer Support
- ✓ Rapid Implementation in Just a Few Weeks
- ✓ Most Cost-Effective Solution on the Market

www.rfXcel.com

rfXcel Active ePedigree Management™

The Problem

- Drug Counterfeiting is an Increasing Threat to Public Safety
 - Lack of Traceability is Huge Problem
- Pedigrees Introduced to Protect Nation's Drug Supply
 - However, Pedigrees are currently perceived by industry as a cost burden without a corresponding value add
- A System for Tracking at the "Smallest Package or Immediate Container Level" Requires Serialization
 - Industry May be Ill-equipped to Move Forward with Full Serialization for all Drugs at the Current Time

www.rfXcel.com

rfXcel Active ePedigree Management™

CA's Approach and Requirements

- The CA Law was Designed to Provide the Highest Degree of Public Safety
 - No exemptions for MFR or ADRs; involves the entire supply chain
 - Requires 100% electronic tracking
 - Requires serialization at product container level
- Where the Industry Is Today
 - Some Manufacturers & Some ADRs are doing something; some are doing nothing
 - CA has proposed extensive serialization, but no organization is completely ready

www.rfXcel.com

rfXcel Active ePedigree Management™

Current State of the Practice

www.rfXcel.com

rfXcel Active ePedigree Management™

Pedigree State of the Practice

- Lot Level Pedigree Generation is Relatively Mature
 - Generated Today Primarily at the Wholesaler Level
 - Minimal Implementation by Manufacturers and Retailers thus Far
 - Industry Proof Exists – Many Established Companies are passing Pedigrees
- Serialized Pedigree Generation is Being Piloted by Multiple Companies

www.rfXcel.com

rfXcel Active ePedigree Management™

Pedigree Standard in Place - EPCglobal

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define a standard format for a Pedigree Messaging standard that will meet all current Federal and State Pedigree requirements.

Status:

- All Standards work complete
- Ratified standard – 01/2007
- Certification Program underway
- rfXcel was One of the First to be Certified

www.rfXcel.com

rfXcel Active ePedigree Management™

Pedigree Applications Can Be Simple

www.rfXcel.com

rfXcel Active ePedigree Management™

Sample Pedigree – PDF Format

Source Drug Information	Ownership & Distribution History	Digital Signature
Name: NDC: Lot: Exp: Mfg: Pkg: Qty: Unit: Pkg Desc: Lot Desc: Pkg Desc: Lot Desc: Pkg Desc: Lot Desc:	Name: NDC: Lot: Exp: Mfg: Pkg: Qty: Unit: Pkg Desc: Lot Desc: Pkg Desc: Lot Desc: Pkg Desc: Lot Desc:	Name: NDC: Lot: Exp: Mfg: Pkg: Qty: Unit: Pkg Desc: Lot Desc: Pkg Desc: Lot Desc: Pkg Desc: Lot Desc:

www.rfXcel.com

rfXcel Active ePedigree Management™

And It Doesn't Have to Take Long!

Complex Project: Major Manufacturer Integrates Data from 3 Back-end Applications

Task Name	Duration
1 Project Kickoff	1 day
2 Integration Workflow / Design	2 weeks
3 Integration & Development	3 weeks
4 Testing	1 week
5 Full-Scale Rollout & Training	1 week
6 Production (Compliance Deadline)	1 day

Project Start-to-Finish: 8 Weeks
Creating & Shipping Pedigrees Since November, 2006

www.rfXcel.com

rfXcel Active ePedigree Management™

Serialization Not Mature Yet

- Up-front Costs
- Consumer Privacy
- Lack of Skilled Personnel
- Multiplicity of Vendors
- Until Recently, Lack of Standards Causing:
 - Equipment Incompatibility
 - Lack of Interoperability
 - Low Tag Yield
 - High Tag Costs

www.rfXcel.com

rfXcel Active ePedigree Management™

Serialization Progress

- Pilots Ongoing by Many Established Pharmaceutical Companies
- Companies are Divided up into Two Technology Camps
 - RFID (HF versus UHF)
 - 2D Barcode
- Some Industry Participants Would like CA to Dictate a Standard
- The Level of Serialization is Also In Question
- Perhaps the Solution Might be a Hybrid
- Progress is Being Made Every Day

www.rfXcel.com

rfXcel Active ePedigree Management™

Possible Paths Forward

www.rfXcel.com

rfXcel Active ePedigree Management™

Three Potential Approaches

- Approach 1: Delay Implementation Until 2011
- Approach 2: Implement Complete Serialization by January 2009
- Approach 3: Deploy a Phased Approach

www.rfXcel.com

rfXcel Active ePedigree Management™

Approach 1. Delay Implementation Until 2011

- Pros
 - Relieves Industry of Burden of Compliance Today
 - Industry has more Time to Prepare
 - Some Potential for RFID Technology to Improve
- Cons
 - Violates the Spirit of the Original Law
 - Original Law required 2007 Compliance Date
 - Does not Address Public Safety
 - Sends the Wrong Message to Counterfeiters

No Assurance of Progress even at the Delayed Timeline!

www.rfXcel.com

rfXcel
Active ePedigree Management™

Approach 2: Implement Complete Serialization in 2009

- Pros
 - Provides Best Protection at the Earliest Date
 - Full Pedigrees With Product Container Level Tracking from Manufacturer for all Drugs
 - Most Minimal Counterfeiting Risk
- Cons
 - Industry Concerned about Technology Readiness
 - Industry Concerned about Cost Impact

*Industry has Some Challenges,
but Compliance is Possible by 2009!*

www.rfXcel.com

rfXcel
Active ePedigree Management™

Approach 3: Phased Approach

- Implement Audits with Enforcement Milestones
 1. Begin with Product Container Level Tracking for High Risk Drugs and Lot-Level Tracking (at a minimum) for All Others with Electronic Pedigree Enforcement by January 2009
 2. Phase in Product Container Level Serialization Enforcement for a Broader Set of Drugs
 3. Full Product Container Level Enforcement at Some Later Date (To Be Defined)

www.rfXcel.com

rfXcel
Active ePedigree Management™

Approach 3: Phased Approach (Cont.)

- Pros
 - Balances the Critical Issue of Public Safety with Industry Challenges
 - Introduces Discipline of Pedigrees into the Pharmaceutical Industry's Processes & Procedures
 - Industry Will Move at a Much Faster Pace
 - Paves the Way for Serialization
 - Gets Systems in Place throughout the Supply Chain... which takes time
 - Incentive to Make Serialization work
- Cons
 - Delays Implementation of Product Container Level Serialization
 - Industry Will Still be Challenged, but there Would be More Time to Implement Solutions

*Effective Balanced Approach that Addresses the Key
Public Safety Issues and the Spirit of the Law!*

www.rfXcel.com

rfXcel
Active ePedigree Management™

Conclusions

- Drug Counterfeiting is a Growing Problem that MUST be Addressed in the Interests of Public Safety
- The CA Pedigree Law was Designed to Provide the Highest Degree of Public Safety
- Challenges with Pedigree Implementation and Serialization Exist, but they ARE Resolvable
- A Phased Enforcement Approach May be the Most Practical Path

www.rfXcel.com



**California Board of Pharmacy
Enforcement Committee
September 20, 2007**

Discussion Points

- Background
- Actions to Date
- Technology and Serialization
- Pilots
- Challenges
- Summary and Additional Opportunities

CVS Caremark

- CVS Caremark is the nation's premier integrated pharmacy services provider, combining:
 - CVS/pharmacy
 - Caremark Pharmacy Services
 - MinuteClinic

- CVS Caremark has an extensive presence in California:
 - Approximately 400 CVS/pharmacy stores
 - Over 1.3 million square foot distribution center in La Habra, California
 - 8 specialty pharmacy locations

- CVS Caremark recognizes the paramount importance of a secure pharmaceutical supply chain.

- CVS Caremark has taken a leadership position in implementing practical measures that have an immediate impact upon the security and integrity of the supply chain.

2



CVS Caremark Actions to Date

- Wholesaler Certification
 - May 2005 - announced CVS/pharmacy would only purchase directly from the manufacturer or from wholesalers that would certify that they only purchase products directly from the manufacturer.
 - Each of the 3 largest wholesalers – Cardinal, McKesson and AmersourceBergen - have since made public announcements stating this exact policy.

- Regulatory
 - Actively engaged in state level initiatives to address this issue.
 - Advocate for stricter licensing requirements for wholesale distributors.
 - i.e. criminal and financial background checks, inspections, surety bonds and penalties.
 - Support pedigree requirements for transactions outside a defined "normal or primary distribution" channel.
 - Support national accreditation – i.e. NABP's VAWD program
 - 8 of 9 CVS/pharmacy DC's have received VAWD accreditation with the final DC pending as it was recently inspected.

In addition to the CVS Caremark actions, other industry participants have also taken actions to address the potential for issues in the legitimate supply chain.

3



CVS Caremark Actions to Date

- Technology
 - CVS Caremark has participated in a number of industry groups working on standards and pilots:
 - EPCGlobal
 - CVS Caremark is a one of the Tri-Chairs with McKesson and Johnson & Johnson.
 - Participate in industry standards development.
 - Industry Adoption Roadmap
 - Jump Start Program
 - One of the first industry efforts regarding RFID and emerging technology.
 - On Track II program
 - Industry pilots for RFID and 2D barcode serialization
 - NACDS Supply Chain Workgroup
 - RxSafeTrack
 - Cross-industry group working on adoption

CVS Caremark has been actively engaged in researching emerging technologies and standards development.



4

Technology and Serialization

No single technology exists that will satisfy California pedigree requirements.

- 2-D Barcode
 - Capable of supporting serialization at the item level
 - Requires line-of-sight and will add significant costs to the supply chain.
 - Relatively low costs to the manufacturing community, but adds complexity and labor to the downstream partners
- RFID
 - Strongly suited to the goal of serialization at the item level
 - Non-line-of-sight technology which allows for supply chain efficiencies.
 - Highest start up costs (and potential on-going costs).
 - Not suitable for "special situation" products, i.e. biologics.
 - Potential reliability issues resulting in operational inefficiencies and product disposition concerns
- Combination
 - Creates the biggest challenge as wholesalers and pharmacies will have to invest in multiple technologies and processes to receive and track pedigrees



5

Technology and Serialization

- Serialization
 - Standards are still "in process"
 - Data management is not the largest issue – data standards, data carrier and the data transfer process remain the biggest hurdles.
 - "Special situation" supply chain products present new challenges, i.e. biologics, cold chain, contract manufacturing, etc.
 - Potential different approaches by trading partners.

6

CVS
CAREMARK

Pilots

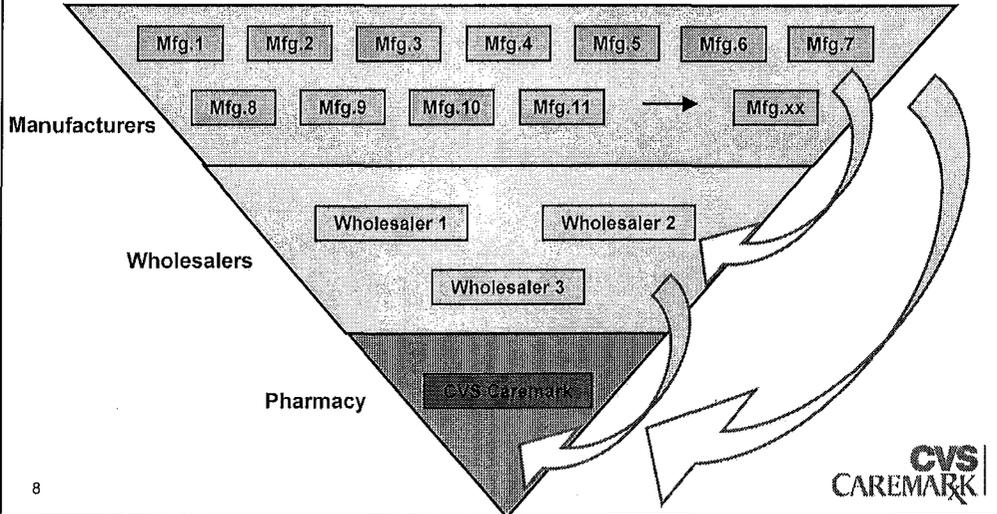
- A number of members of the supply chain have embarked on pilots to address serialization and pedigree.
- Each of these pilots have employed different technologies and approaches which makes it difficult for pharmacy providers to select a standard approach.
 - Manufacturers have tagged product with UHF & HF RFID tags as well as 2-D Barcodes
 - There have also been different types of data carriers depending on whether the product is "tagged" at the pallet, case, or item level
 - Two key wholesalers have piloted and focused on UHF RFID based pilots and solutions
 - A third key wholesaler has been testing UHF at the case level and HF at the item level (in the same shipment) and has also incorporated 2-D barcodes
 - While this "mixed" mode approach may work at the "pilot" level with a single location and only a small number of products, there is significant concern about the scalability of such and approach

7

CVS
CAREMARK

Challenges – Scope of Trading Partners

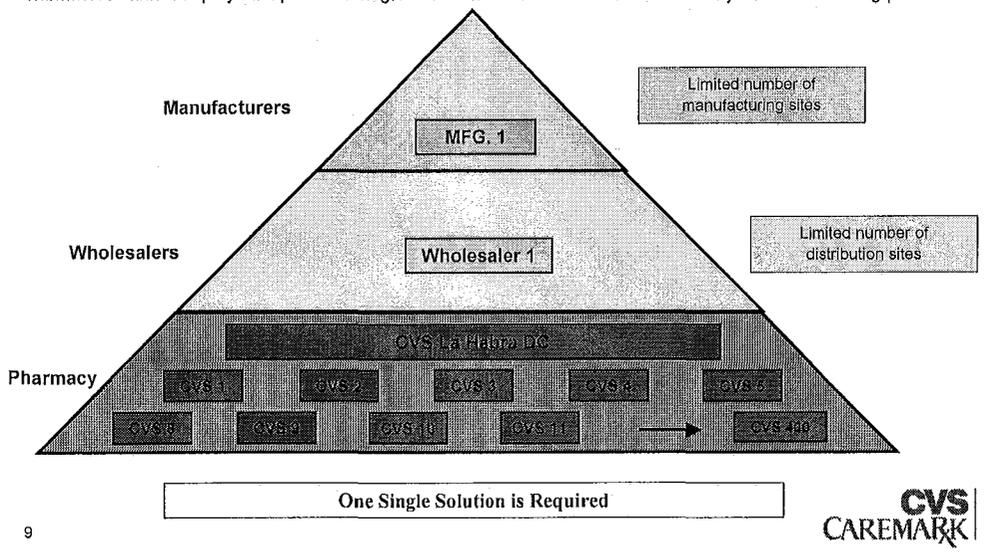
Pharmacies cannot support multiple approaches considering the scope of trading partners involved.



8

Challenges – Scope of Implementation

Pharmacies cannot deploy multiple technologies at each location to ensure connectivity with each trading partner.



9

Challenges – How will Manufacturers Comply?

- Approached brand and generic manufacturers for information regarding their compliance plans as well as how they will approach product serialization.

"...waiting to see if an extension will be granted..." – Brand Manufacturer

"...we are going to send out surveys to our customers seeking information on how they would like us to send the pedigree information..." – Brand Manufacturer

"...uncertain whether we will be able to comply and we may need to cease distributing products into California..." – Generic Manufacturer

"...California requirements are unclear ... manufacturers only need to serialize to the smallest package distributed by the manufacturer, i.e. case not unit..." – Brand and Generic Manufacturers

"...we can't comply by January 1, 2009..." – Brand and Generic Manufacturers

10

CVS
CAREMARK

Challenges

- Standards Development
 - Implementation is not guaranteed once standards are developed.
 - Ex. EDI transactions – trading partners that are not EDI capable today.
- Phased Implementation / Risk Based Approach
 - Significant benefit to Manufacturer community since it spreads investment over a longer period of time.
 - Wholesalers and pharmacies will need to be "technologically" ready whether it is 10 products, 100 products or all products.
 - Places an undue burden to meet an implementation deadline that the manufacturer community can't meet.
- Serialization by lot number
 - Lack of consistency in lot number schema.
 - Unknown benefit since serialized product will not be mutually exclusive.
 - Less – if any – operational benefits at wholesale and pharmacy level.
- Limitations
 - At best, working perfectly, track and trace technology only tracks the package, not the product.

11

CVS
CAREMARK

Summary and Additional Opportunities

- Continue to research technology options, however we are dependent on manufacturers to determine their approach.

- Modify Risk Based Approach – High Risk Products v. High Risk Transactions
 - Not all purchasing transactions pose risk.
 - Consider legislative changes that would recognize "normal" or "primary distribution channel" and require pedigrees for transactions outside that defined channel.

- Phased Implementation by Business Segment
 - Challenge for pharmacy segment to meet the same date as manufacturers and wholesalers since pharmacies need to wait for those trading partners to determine approach to compliance.

- Extend implementation date to ensure industry readiness.



**California Board of Pharmacy
Enforcement Committee
September 20, 2007**

Discussion Points

- Background
- Actions to Date
- Technology and Serialization
- Pilots
- Challenges
- Summary and Additional Opportunities

GSK Serialization Experience Update to the California Board of Pharmacy – September 2007



Tim Kvanvig
VP, US Pharmaceuticals



GSK Around the World

- We make almost four billion packs of medicines and healthcare products every year
- We supply one quarter of the world's vaccines and by the end of February 2007 we had 23 vaccines in clinical development
- In 2006 we shipped 206 million tablets of preferentially-priced Combivir and Epivir (our HIV treatments) to developing countries - including 120 million tablets supplied by generics manufacturers licensed by GSK
- In 2006 our global community investment was \$600 million, 3.9% of profit before tax



Do more, feel better, live longer.

Our Commitment to Patient Safety

Ensuring patient safety is extremely important and GSK takes the safety of all our medicines and medical devices very seriously, hence...

GSK supports CA BoP in their efforts to protect the patient!

In addition to ensuring the effectiveness and reducing side effects of our medicines, GSK is using various approaches to ensure GSK product makes it to the patient through...

- Use of authorized wholesalers / distributors
- Investigating criminal activity and tampering reports and proactively working with governments and regulators to address the threat of counterfeiting
- Adding overt and covert security devices on packaging
- Utilizing serialized packaging (RFID or 2D) at the pallet, case and unit level (early adopters)



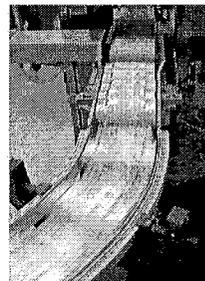
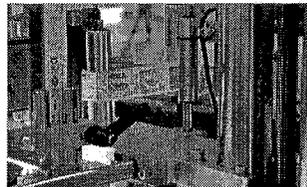
Do more, feel better, live longer.

3

Impact of Serialization on GSK in the US...

Areas of impact...

- 30+ sites in 12 countries (GSK and contract manufacturing)
- 130+ packaging lines which will require unique implementations due to variations in speed, space, packaging, etc.
- 300+ SKU's sold
- All US distribution: 159 million units
- 2 GSK Distribution Centers



Do more, feel better, live longer.

4

Our Experience with Serialization



- In Nov 2005, GSK agreed with the FDA to pilot RFID – Trizivir
- Pilot began tagging pallets, cases and units in March 2006
 - Less than 5% of the units tagged have been read across the industry
- Challenges
 - Read rates with wholesalers and pharmacy partners have varied ranging from 50% to 95%
 - Software, readers, supply chain environmental requirements, integration with existing systems, integration with wholesalers/pharmacies still being tested
 - Stability of the current end to end solutions for tracking the EPC number through the supply chain are not ready for Pharmaceutical Validation requirements
 - No requests have been received to initiate serialized pedigree
- GSK along with many industry partners have been working together to address the role of serialization in supply chain security issues (i.e. EPCglobal, PhRMA, HDMA, NACDS, GS1)

Implementation at scale will rely on end to end processes and technology standards, together with robust solutions being available



Do more, feel better, live longer.

5

Actions Needed

- Active standards and solution development needs to continue
- Manufacturer/Wholesaler/Pharmacy Pilots are needed to test standards and develop ways of working across the end-to-end process
- Consistent set of requirements across US, e.g., pedigree standards, 2D sizes
- Guidance from the FDA regarding:
 - Expand Compliance Policy Guide to include all forms of serialization and extend date to encourage pilots
 - Use and protocols of RFID on liquids, biologicals



Do more, feel better, live longer.

6

Next Steps

As we progress implementation of the CA Law, our approach includes...

- A prioritized approach to start with the higher risk products
- A focus on industry adoption
 - **Unit Serialization:** Maintain Trizivir serialization using RFID and adding 2-D barcode. Implement other products using our prioritization methodology utilizing 2-D barcodes.
 - **ePedigree & Authentication:** Build an infrastructure to facilitate early implementation and flexibility in deployment, including item-level, case-level, and lot-level ePedigree and product authentication. Agree on standard processes among Manufacturers/Wholesalers/Pharmacies.
- Ongoing work with the Manufacturers/Wholesalers/Pharmacies and regulators to enhance the security of our products in the supply chain



Do more, feel better, live longer.

7

Summary

- GSK has a strong commitment to patient safety and continues to explore opportunities to enhance supply chain security
- Standards, business processes and serialization solutions are essential
- Successful implementation of ePedigree and Serialization requires coordination across Manufacturers/ Wholesalers/ Pharmacies



Do more, feel better, live longer.

8



GlaxoSmithKline



Do more, feel better, live longer.

9

GSK Serialization Experience Update to the California Board of Pharmacy – September 2007



Tim Kvanvig
VP, US Pharmaceuticals



GSK Around the World

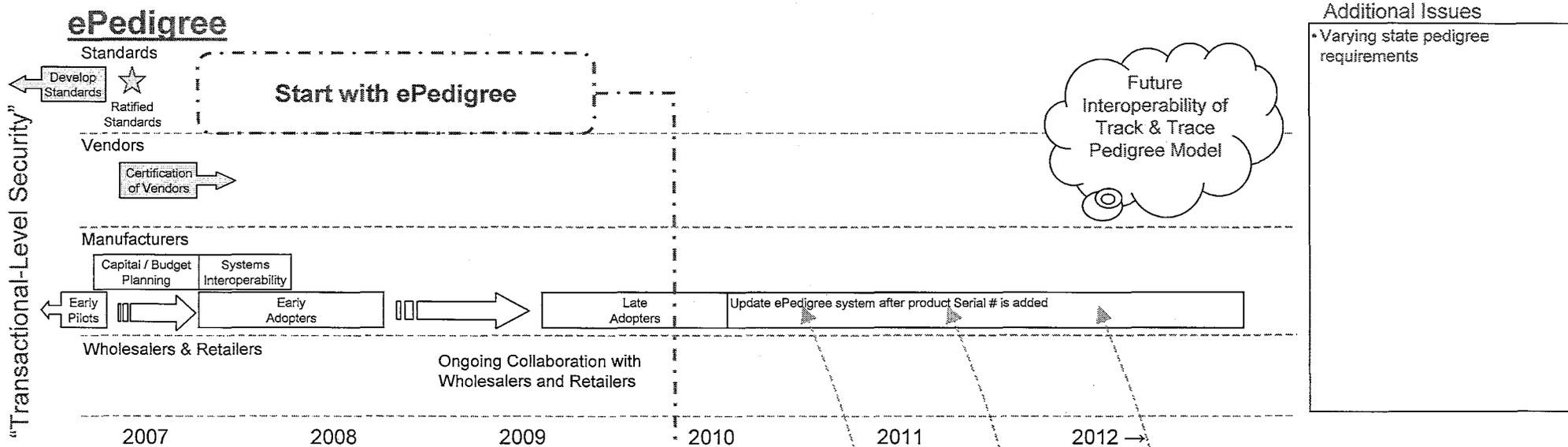
- We make almost four billion packs of medicines and healthcare products every year
- We supply one quarter of the world's vaccines and by the end of February 2007 we had 23 vaccines in clinical development
- In 2006 we shipped 206 million tablets of preferentially-priced Combivir and Epivir (our HIV treatments) to developing countries - including 120 million tablets supplied by generics manufacturers licensed by GSK
- In 2006 our global community investment was \$600 million, 3.9% of profit before tax



Do more, feel better, live longer.

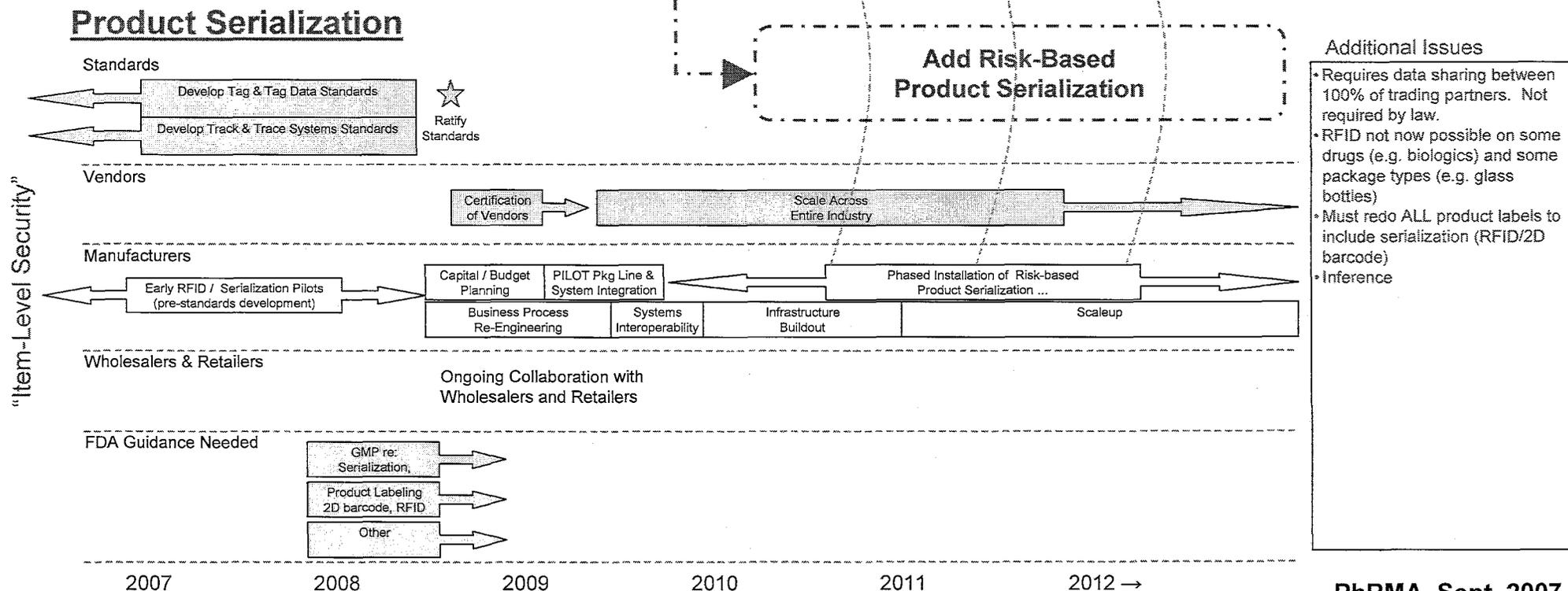
2

Industry-Wide E-Pedigree and Serialization Timeline (Start with e-Pedigree / Add Risk-Based Serialization)



Additional Issues

- Varying state pedigree requirements



Additional Issues

- Requires data sharing between 100% of trading partners. Not required by law.
- RFID not now possible on some drugs (e.g. biologics) and some package types (e.g. glass bottles)
- Must redo ALL product labels to include serialization (RFID/2D barcode)
- Inference

California ePedigree Work Group Presentation

September 20, 2007



Bracco Diagnostics Inc.



- Bracco manufactures and sells injectable and oral diagnostic imaging contrast agents and nuclear medicine imaging agents
- Our products are distributed through authorized distributors or directly to customers (hospitals, imaging centers).
- All of our products are administered by healthcare professionals.
- Products are distributed in sealed boxes of 5-10 vials or bottles through the supply channel and received by the end user department intact and unopened.



Current Market Unit Label Details

Product Name & Concentration

Eaches per Box

Product Number

Volume per bottle or Syringe

Lot Number & Expiration Date

Bracco Diagnostics

ISOVUE-300
Iopamidol Injection 61%
Rx only

For Intravascular Use
SEE PACKAGE INSERT FOR INDICATIONS AND
DOSAGE INFORMATION
Single dose syringes for use with power injector.
Discard unused portion and syringe.
Do not use if leaking is observed.
Protect from light.
Store at 20-25°C (68-77°F) [See USP]

LOT 7A16725
EXP Jan 2010

BRACCO
LIFE FROM INSIDE

Injectables Exception Questions

- According to the exception for injectables (4034 (g) (2)) all direct manufacturer shipments are exempt from ePedigree requirements until 1/1/2010.
- Today, all Bracco contrast media agents are dispensed only by the administrator of the entity but these customers are supplied by both Authorized Distributors or directly from Bracco.
- Questions:
 - Can the injectable dangerous drug exception be extended to include Bracco's authorized distributors?
 - Can the injectable dangerous drug exemption be applied to both oral as well as injectable contrast media since they are all administered by only healthcare professionals?
 - What are your plans for the administration of nuclear medicine imaging agents?
 - How does Bracco obtain an exception certificate?



Serialization Questions

- **Serialization will enable Bracco and its customer to track and trace our products through the supply channel.**
- **Bracco will provide serialization at the market unit level which is the box.**
- **Question:**
 - Given that the cost for serialization will greatly increase our cost of goods, would an ePedigree provided from the point of manufacturer be acceptable?
 - Knowing that Bracco will meet your regulations, how does the Board ensure compliance is enforced?

5



Summary

- Bracco plans to support and meet all regulations for ePedigree in the State of California.
- Bracco would like to have clarification of our obligations for compliance with regards to the distribution of our products administered by healthcare professionals and with regards to the serialization requirement.
- Thank you for the opportunity to request clarification and for the time you have given us today!
- Please feel free to contact me for questions:
Robert.Zachow@diag.bracco.com
609-514-2383

6



Lot Number Tracking in the Pharmaceutical Supply Chain

California Board of Pharmacy
Enforcement Committee
September 20, 2007
Los Angeles, CA



Overview and Purpose

- Follow up to points raised at June meeting.
- Identify issues with lot number tracking and aspects of "risk-based approach."
- Affirmation of HDMA's commitment to patient safety, as well as our position on item-level serialization and California law.



Lot Number Limitations

- Lot numbers identify batches, not individual units.
- Lot number can't identify additional (counterfeit) items.
- Lot number can't link electronic transactions to specific products with certainty.



Lot Number Limitations

- In previous cases, counterfeit products have had counterfeit paper pedigrees with valid lot numbers.
- Lot numbers can not be used to identify stolen product unless the *entire* lot is stolen.
- Some products are only manufactured in a single batch per year. Lot number = a year's supply of product.
- There are no standards for lot number
 - Location on label / case / item
 - Human vs machine readable



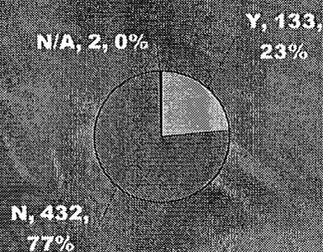
Distributor Case Study: Operational Issues

- Three large and three small manufacturers
- Total sample size = 567 SKUs
- Entire product line of a manufacturer examined



Case Lot # Does Not Always Match Item Lot

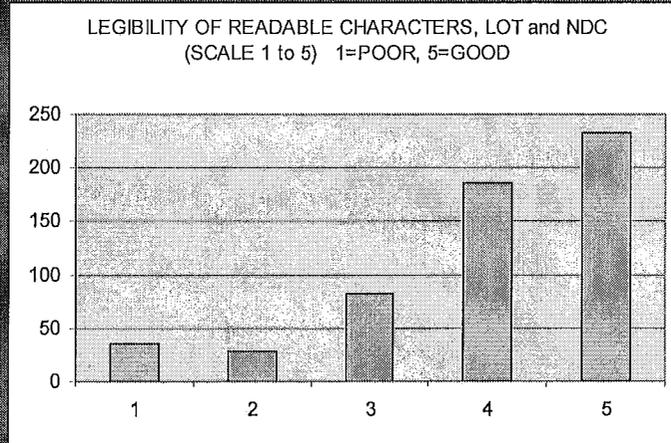
INNER LOT # DIFFERENT THAN OUTER
CASE LOT #



23% of item lot numbers do not match
case lot #



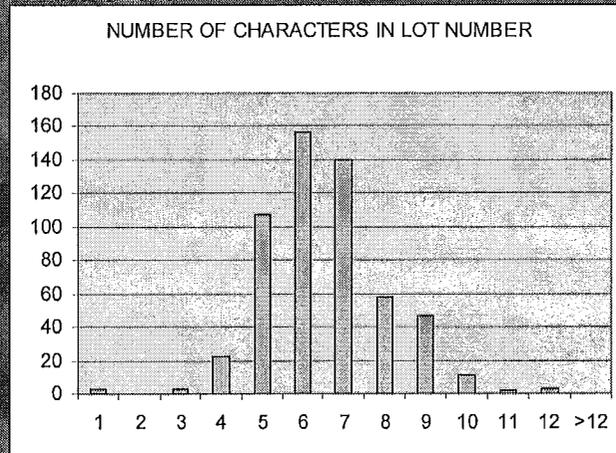
Lot Numbers May Not Be Readable



9% of lot # errors may be due to readability of lot #

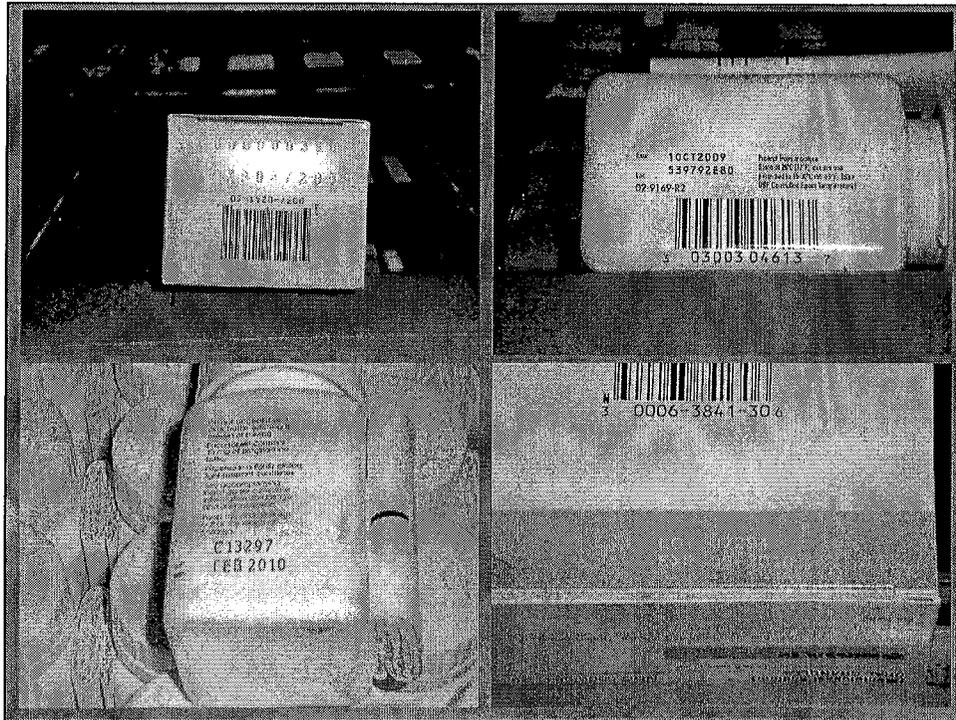


Inconsistencies in Lot # Length



Inconsistent lot number length contributes to data collection errors





Lot Number Frequency in Multiple Locations

HDMA members collected data to examine how frequently the same lot number could be found in multiple locations, at different points in the supply chain

- Two different companies' distribution centers in Florida sold 2,640 cases of a single high-volume product to pharmacy customers. 325 of the 2,640 cases (12.3%) had the same lot number.

Case Study #1

- One distributor recorded 116 transactions for a single product sold to 49 customers over the course of a two week period (May 1-17), all with the same lot number.



Lot Number Frequency in Multiple Locations

Case Study #2

- From April 4 to May 5, one distributor sent 93 units of product in 14 shipments to a single customer. All 93 units had the same lot number.

Case Study #3

- From March 6 to May 9, one distributor completed 14 shipments of a single product to a single customer. A total of 14 units were shipped to this customer over those 14 orders, all with the same lot number.



Summary of Analysis

- Lot number is unreliable and results in errors when used as primary identifier for ensuring supply chain integrity.
- Lot number entry errors will be caused by:
 - Inconsistent lot number data length
 - Variability in size and font of printed lot numbers
 - Inconsistencies between case and item lot numbers
- A lot number manually entered with characters alpha "l" vs. numeric "1" has better than 50% chance of error.



Lot Number vs. Item-Level Serialization

Lot #		Item Serial #
<input type="checkbox"/>	Unique Item Identification	<input checked="" type="checkbox"/>
<input type="checkbox"/>	Link Physical Item to Data	<input checked="" type="checkbox"/>
<input type="checkbox"/>	Detect Counterfeit	<input checked="" type="checkbox"/>
<input type="checkbox"/>	Track & Trace Products in Supply Chain	<input checked="" type="checkbox"/>
<input type="checkbox"/>	Efficient Recalls	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	Standardized Lot Number	<input type="checkbox"/>
<input type="checkbox"/>	Detect Stolen Products	<input checked="" type="checkbox"/>



California Pedigree & Beyond

- To further enhance patient safety and effectively track & trace through the supply chain, unique identification at the item level is required.
- Because of the operational challenges that lot number tracking presents, it is not a viable option for pedigree.
- Lot number tracking as a method of pedigreeing Rx product adds no safety value and erodes supply chain efficiencies.



Walgreens

California Pedigree Law: Store Level Impact

Emily Stamos, RPh, PharmD
Associate Category Manager
Pharmaceutical Strategy
September 20, 2007

Agenda

- Background
- Safeguards Walgreens currently has in place
- Impact of upcoming pedigree legislation on patient care
- Additional considerations
- Potential solutions

Walgreens

Walgreens Patient Safety Philosophy

- Walgreens prides itself on being "The Pharmacy America Trusts"
- Our patients rely on us to provide them with medications that are safe and effective.
- As an industry leader, we strive for standards that ensure patient safety regardless of the requirements of the law.

Walgreens

Safeguards Currently in Place

- At a corporate level:
 - Walgreens purchases the majority of its drugs directly from the manufacturer.
 - When buying from the "Big Three" wholesalers, we contractually require them to sell us product that they purchased directly from the manufacturer.

Walgreens

Safeguards Currently in Place

- Individual pharmacies are prohibited from:
 - purchasing drugs from outside of Walgreens DC or the company's DSD wholesaler.
 - trading drugs with non-Walgreens entities.

Walgreens

Implementation Status

- Walgreens has taken the following measures to ensure timely compliance with CA law:
 - Communication with trading partners
 - Internal determination of course of action and time to implement
 - Design of procedures, software updates, etc

Walgreens

Estimated Timeline

- Once we know the concrete plans of our upstream partners:
 - 9 months to code new programs
 - 6-9 months to train staff and troubleshoot
- Total implementation time once parameters are set: 15-18 months *Walgreens*

Estimated Time Impact

- Every member of pharmacy staff will need to be trained on:
 - Utilization of hardware and software applications
 - Understanding which hardware and software to use, depending on what technology each manufacturer has chosen
 - Troubleshooting and contingency plans when technology malfunctions *Walgreens*

Estimated Cost Impact

- Estimated cost of implementation: \$25-30 K per store
 - Corporate Investment ~\$2K
 - Labor ~\$3K
 - Software ~\$2K
 - Hardware ~\$21K
- Ongoing costs: \$5-6K per store per year
- Costs could be lowered by standardizing processes across supply chain
 - Reduction of hardware investment *Walgreens*
 - Reduction of personnel training

Impact of Time on Patient Care

- Patient consultation
- Order verification and accuracy
- Technical/customer service questions
- Staff now must be pedigree "experts"
- Potential to decrease patient utilization of pharmacy staff and services *Walgreens*

Impact of Cost on Patient Care

- Costs might be passed on to patients
 - Not reimbursed by third party payors
- Greatest impact on most vulnerable, cash-paying, uninsured patients
 - Limited access to needed meds
 - Decreased compliance
 - Pts may seek alternative sources
 - Unregulated internet pharmacies *Walgreens*
 - Potential for counterfeits to enter system

General Assumptions

- No pedigree required for intra-company movement of product
- Accurate flow of data from manufacturers and wholesalers
- Need clarification on risk-stratification concept from previous meeting *Walgreens*

Other Considerations

- Patient privacy issues
- Pharmacy buyouts
- Potential delay in patient care
- Technology still emerging
 - Still unreliable
 - Still not studied for all drug products

Walgreens

Suggested Solutions

- Universally interoperable standards
- Inference
- Pooling
- Grandfathering existing inventory
- Phased implementation

Walgreens

Questions?

Thanks for your time!

Walgreens

Work Group on E-Pedigree
California State Board of Pharmacy
September 20, 2007
David Vucurevich R.Ph.
Group Vice President
Pharmaceutical Purchasing and Clinical Services



Agenda



- ✓ Historical overview of Rite Aid activity in pharmaceutical supply chain integrity
- ✓ Cost analysis to meet CA Pedigree statutes
- ✓ General Concerns and Considerations.

Rite Aid Corporation Commitment



- ✓ Project Jump Start
 - ✓ Rite Aid was an active participant in the project conducted by Accenture in 2003-04
 - ✓ Focus was proof of concept for track and trace technology and an end to end solution for supply chain authentication
 - ✓ Findings were mixed. Concept was feasible and scalable; however, technology needs improvement and costs were deemed prohibitive to meet the long term industry goal

Rite Aid Corporation Commitment



- ✓ Rite Aid RX Supplier Advisory Board
 - ✓ Collaborative project started in Fall 2005 with open invitation to over 20 pharmaceutical suppliers represented on the board
 - ✓ Project goal was to collaborate with suppliers utilizing RFID track and trace technology for products in a live supply chain environment to evaluate technology, impact on productivity and costs
 - ✓ Established pilot at the Rite Aid Perryman, MD DC
 - ✓ Initial focus on reading tags at the case level
 - ✓ Challenged with not having adequate numbers of participating suppliers

Rite Aid Corporation Commitment

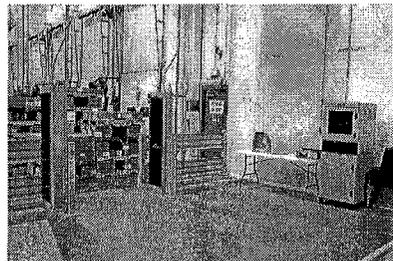


- ✓ On Track
 - ✓ Charter participants in McKesson project
 - ✓ Integrated RX SAB project into On Track initiative
 - ✓ Active participants in the Perryman DC pilot are Pfizer (Viagra) and GSK (Trizivir)

RFID/EPC Phase I: Case Level On Track



Rite Aid RFID Innovation Center



RFID/EPC
Phase I: Case Level
On Track
Tag Metrics



Through our testing of case tags from both Pfizer and GSK we have been able to achieve a ~98.5% read rate.

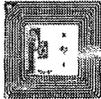
- Manipulation of cases
- Broken case quantities (no tag on shipping container)
- Broken case quantities (more than one case with tag on shipping container)



RFID/EPC
Phase I: Case Level
Tag Metrics
Comparison to Total Volume



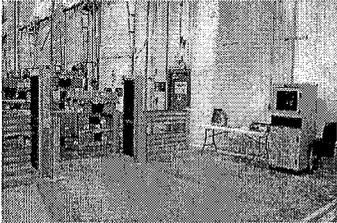
- Since September 2006 we have received approximately 2,200 cases of Viagra & Trizivir.
- Since September 2006 we have received approximately 3,200,000 total cases of RX product

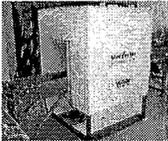


- 0.07% have been handled through our RFID process

RFID/EPC
Phase II: Item Level
On Track 2
Rite Aid RFID Innovation Center







RFID/EPC
Tomorrow
On Track 2
Pedigree/E-Pedigree



- Serialized ASN information
 - Currently receiving ASN from most but not all suppliers
 - Expansion of EDI transaction information or similar medium to carry E-Pedigree information
 - Incorporate into multiple existing WMS operating in Rite Aid DCs
- Currently evaluating E-Pedigree solution providers
- Rite Aid replenishment/logistics and operations evaluating cost and productivity impact at DC and pharmacy level to achieve compliance

Rite Aid Cost Analysis for End to End Serialization Compliance 

- ✓ Analysis based on Accenture/On Track 2 Cost Template allowing capability to meet pedigree and 2D/UHF/HF serialization formats
- ✓ Year 1 investment costs limited to single Rite Aid DC in Woodland, CA and 591 pharmacies is estimated at \$53.2 million
 - ✓ Global corporate data center: \$887,000
 - ✓ DC expenditure: \$484,000
 - ✓ Pharmacy expenditure: \$51,800,000

Rite Aid Cost Analysis for End to End Serialization Compliance 

- ✓ Estimate excludes financial impact related to:
 - ✓ Decreased DC productivity resulting in increased labor costs
 - ✓ Incremental distribution equipment to leverage potential technological efficiencies
 - ✓ Need for upgrading scanners to meet serialized barcode requirements and associated software
 - ✓ Incremental pharmacy labor

General Concerns



- ✓ Pharmaceutical Manufacture Preparedness
 - ✓ There are few active suppliers engaged in pilots today
 - ✓ General internal lack of expertise within the supplier community
 - ✓ Implementation of pedigree/track and trace is a complex process involving the retrofitting of production lines while meeting existing demand
- ✓ Generic industry is a particular concern with very little feedback or inquiries from suppliers
 - ✓ Cost benefit to meet CA pedigree and serialization requirements may lead some generic suppliers to abandon sales and marketing of their product within the state
 - ✓ Reducing competition for multi source products leads to higher costs for compliant products or increase use of corresponding brands
 - ✓ AMP is a concern if implementation moves forward as described in the BRA with reimbursement for Medicaid beneficiaries based on products that may not be available in CA

General Concerns



- ✓ Interoperability testing is very limited
- ✓ Serialization
 - ✓ Standards are not yet established
 - ✓ Multiple data carriers will multiply the cost and complexities for community pharmacies
 - ✓ In the absence of serialized inference, barcode data carrier used at lower packaging levels will significantly decrease the productivity of retail distribution centers
 - ✓ Trading partners may choose serialized hierarchy and/or pedigree in different formats i.e. pedigree built at item or per-lot level

General Concerns



- ✓ Existing inventories
 - ✓ DCs and pharmacies combined carry approximately 60 days of inventory
 - ✓ Segregation of inventory is not feasible
 - ✓ Will documentation guidance for existing inventories be established?
 - ✓ Will there be an inventory transition period?

Recommendation



- ✓ At a minimum extend compliance date to 1/1/11
- ✓ Consider legislative action to adopt model wholesale language reflective of "normal channel of distribution" pedigree exemption until complete technical and economic evaluation of a long term solution can be determined

Thank You!

Questions???