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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
    - SupplyScape
  - 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. <u>Presentations and Updates by Manufacturers, Wholesalers and Pharmacies on Implementation of Electronic Pedigrees</u>

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 Blueray, 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 RIFD. 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.