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

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
WORK GROUP ON E-PEDIGREE
MINUTES

DATE: December 5, 2007

LOCATION: Red Lion Hotel Sacramento
1401 Arden Way
Sacramento, CA 95815

BOARD WORK GROUP MEMBERS PRESENT: Stanley Goldenberg, RPh, Chairperson
Ruth M. Conroy, PharmD
Robert Swart, PharmD

OTHER BOARD MEMBERS PRESENT: Susan L. Ravnan, PharmD
Stan Weisser, RPh
Henry Hough, Public Member

STAFF PRESENT: Virginia Herold, Executive Officer
Joshua Room, Deputy Attorney General
Robert Ratcliff, Supervising Inspector
Judith Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Robert Venegas, Inspector
Janice Dang, Inspector
Anne Sodergren, Legislation and Regulation Manager
Karen Abbe, Public and Licensee Education Analyst
Michelle Leech, Administrative Assistant

Note: A number of presentations were made to the work group at this meeting. Copies of these presentations follow the minutes.

CALL TO ORDER

Chairperson Goldenberg called the meeting to order at 9:14 a.m. He acknowledged Susan Ravnan, Hank Hough, and Stan Weisser as board members attending the meeting that were not members of the Work Group.

Mr. Goldenberg noted that the agenda was significant and the board would give everyone a chance to speak. He asked the manufacturers in the audience to identify themselves. Some of the manufacturers (and other pharmaceutical industry companies) represented were Amgen, Abbott, Allergan, 3 Rivers, AstraZeneca, Watson, CV Therapeutics, Smith Labs, Bausch & Lomb, Tap, TEVA, Astellas, Mylan, Precision Dose, Johnson & Johnson, Sigma, Slag Allermed, Sandoz, Wyeth, Apatech, DRX, Biogen, Hospira, Dade, Solstice Neurosciences, GSK, Genentech, Hoffmann-La Roche, Pfizer, Bristol Myers Squibb, Reliant, Schering-Plough, Novartis, Elan, King, Barr, Bayer, MGI Pharma, and Sepracor.

Mr. Goldenberg introduced Diane Furukawa, PharmD, and David Botelho, CPA, as interested parties from the California Department of Health Care Services Medi-Cal Division.

Ms. Herold advised that representatives of the FDA and several other states were participating in the Work Group via conference call speakerphone, but on a "listen-only" status.

PROGRESS OF THE IMPLEMENTATION OF ELECTRONIC PEDIGREES PURSUANT TO THE CALIFORNIA BUSINESS AND PROFESSIONS CODE

1. Presentations and Updates by Manufacturers, Wholesalers, Pharmacies and their Associations on Implementation of Electronic Pedigree by January 1, 2009

- **Alien Technology**

  Victor Vega, Director of Technical Marketing, and Ronny Haraldsvik, Vice President of Marketing of Industry Relations, gave a multimedia presentation demonstrating radio frequency identification (RFID) advancements.

  Mr. Vega noted that RFID technology has improved greatly. The previous hurdles of reading tags in and on water, and around foil and other metal materials have been overcome. He stated that more than 35 states in the U.S. are considering e-pedigree legislation to enhance patient safety. Combating counterfeit drugs is one of the reasons the pharmaceutical industry is motivated to pursue RFID technology, in part, because of its reverse logistics capabilities.

  To perform e-pedigree tracking at the item, case, or pallet level, three technologies could be used: 2-D barcoding, high-frequency (HF) RFID, and ultra high-frequency (UHF) RFID. RFID technology can be used for other wireless infrastructure considerations as well, such as electronic article surveillance (EAS – security), automatic dispense mechanisms, and file management.

  Mr. Vega stated that radio frequency exposure has not been shown to affect the potency, efficacy, or stability of biologics or pills.

Some of the challenges of RFID technology have been reading tags in items with water-based content, gel-packs, limited item-level surfaces, small vial diameters, metal or foil surfaces, and shadowing/shading (close proximity of tags to one another). Mr. Vega said that these challenges have been overcome, and significantly smaller RFID tags are now being manufactured as well. Some of the other benefits of RFID technology are improved transportation and logistics management efficiencies. In addition, temperature tag monitoring can be performed using UHF RFID.

Mr. Vega stated that the price of RFID tags has been reduced from about $1 each to less than 10 cents each. He emphasized that other hurdles have been eliminated including reader collision, short read range, sluggish responses, interference susceptibility, "dumb" readers, inability to filter/mask, unfriendly user interfaces, limited suppliers and support, regional tag design requirements, and wireless access point contention. He added that because of the initiatives of Gen2, companies are no longer held hostage by a single vendor; they can choose from many different vendors.

Mr. Vega emphasized that hardware is no longer an excuse to not adopting RFID technology because Gen2 tags are flexible and scaleable. The technology is stable, robust, and reliable, and there have been developments in silicon as well. RFID silicon now has superior sensitivity that works on farther distances, and has extended user memory, and wide spectral bandwidth alleviates regional tag incompatibility. The pharmaceutical industry can use tags that are now less than one square inch, and read ranges of up to 130 feet have been demonstrated. There is a wide selection of tags currently available. "Dumb" tags used to be read-only, but now have read/write capabilities, and at a lower cost. Access control tags that were near-field are now near-field and far-field.

Mr. Vega noted that with EPC Gen2 RFID, you can ask a vendor to program chips with your identifier in the tag. The technology is available today. Other security options include tamper-proof labels and a 32-bit access password that is "lockable." Tag reader technology has also been emerging, with diverse choices available including handheld and forklift readers.

Mr. Goldenberg asked that industry come forward with their comments on this presentation. He asked that everyone limit their comments to the information presented today. He emphasized that the board wants to understand industry's perspective on this issue.

Mr. Haraldsvik stated that they have been working with different vendors, including Wal-Mart, at the case level. He said it has become clear that the whole industry must move forward in order to deploy the infrastructure necessary.

Mr. Goldenberg stated that board is seeking information about the projects being conducted. The board will need a description about the testing, including when it started, and the resources applied to it.

Mr. Haraldsvik responded that they have tagged cases shipped to retail. He said they are still hearing from retailers who are asking where to go. They are not seeing wide deployment of the technology, but their results so far show good data, promising data. He said that they conducted pilots in France on medical devices. They also have 5-10 hospital pilot projects going on in the United States right now.

Mr. Goldenberg asked what they have done to determine whether biologics were affected by exposure to RFID.

Mr. Haraldsvik responded that they have conducted studies and had conversations on the issue, but the jury is still out, and they want FDA's guidance. He stressed that it is important to choose one technology to go forward.

Mr. Goldenberg stated that the board respects that there are alternative technologies, but that California just needs a safe system. We are now on a one year deadline.

Mike Rose, a representative from Johnson & Johnson, commented that they have conducted a number of projects, but they can't rush the technology. They have made a commitment, but California's law doesn't stipulate a specific technology. Johnson & Johnson is committed to complying with the law, but it is challenging. They have teams working on it, though.

Mr. Room asked whether it was a fair assessment that in 2003 or 2004 RFID technology was not as developed, so they were leaning toward 2-D barcoding instead? He asked if their level of RFID study was somewhat forestalled if it was a couple years old.

Mr. Rose stated that they were driving towards 2-D matrix, and they want it to work in other jurisdictions, including Europe. They have an RFID lab and their work is up-to-date. They believe RFID will have a place and they'll continue to look at ways to adopt that technology, but their use cases are quite different.

Mr. Goldenberg stated that the issue is not "us and them" and that we are all trying to understand the details of the issue. The Enforcement Committee's responsibility is to give a report to the full board on the issue, and information is needed in order to make good decisions.

Lou Kontnik, Director of Brand Protection and Business Continuity for Amgen Pharmaceuticals, stated that Amgen offers a narrower range of products, and the issue of biologics and suitability is the threshold focus.

Mr. Goldenberg noted that more than two years ago, we were discussing this same issue.

Mr. Kontnik responded that Amgen has given taken the matter seriously, and looked in-depth at RFID. Most of their products are biologic, and they have conducted studies on

exposure to their products. Equivocal results have been shown, and in at least one case, they saw a statistically significant difference of the product after exposure to RFID. He said the real issue they're following is that there is not an established and accepted FDA protocol for products. They don't have clarity about safety or a regulatory approach as to whether their products are affected by RFID exposure. He said the work they are doing includes 2-D barcodes, as is Johnson & Johnson. They hope to share information about that work with board shortly. Amgen wants to protect patients, but at the unit level, their work has only been done using 2-D models.

Peggy Staver stated that Pfizer has been doing pilot work since 2004, tagging Viagra at the pallet level. They have been using Alien Technology tags at the unit level and case level. She noted that Pfizer expects to tag and ship Celebrex by the end of December. She said that statements that all issues surrounding RFID technology have been resolved is misleading, and they are still looking at looking at both 2-D barcoding and RFID.

Mr. Goldenberg asked what would happen in one year, if Pfizer's decision was still up in the air. He likened it to revving an engine, but not moving forward.

Ms. Staver responded that as stated to the committee in June 2007, they expected it to take 5-7 years to serialize all their products. She said they would work with industry to see what will work across the supply chain to ensure patient safety and channel security. She said it's not that Pfizer isn't doing anything, it's just very different what they're doing in the U.S. verses what they're doing in Europe.

Mr. Goldenberg said that we just heard a presentation about the advancements of technology, and the board wants a sampling of how manufacturers are dealing with this information.

Jim Dowden, representing Hoffman-La Roche, said he had some impressions of Victor Vega's presentation. He said that Mr. Vega said the right things, but that tagging is just one part of the picture. Mr. Dowden said that you have to bring IT structure and other things into play.

Mr. Dowden stated that Hoffman-La Roche did an initial pilot at the case level in 2003, and tracking at the case level was promising at that time. Their next level of activity was tracking at the item level using vials, blisters, and bottles. They looked at different frequency technologies, and learned that blister packs and vials were a little tricky, and that solid dosage bottles were the least tricky. He emphasized that it's not just about putting a tag on something. They looked at the orientation of tags and other nuances of RFID technology at the case level. On the item level, they have not done quite as much work.

Mr. Goldenberg asked if there were any further questions about the information presented, before they returned to Alien Technology's presentation. There were none.

Mr. Vega noted that there is reader diversification in three categories:

1. OEM modules, adapters, and sensors
2. mid-tier fixed
3. high-end fixed

Mr. Vega stated that a cell phone is much like a reader. He added that Intel and Samsung are silicon leaders, which suggests strong industry stability.

Mr. Vega referred to the attributes of Smart Antenna (ALR-9650) and the High-Performance Enterprise Reader (ALR-9900). He performed a demonstration using the ALR-9900 reader. He said that the cost of readers have dropped to as low as $600 during the past two to three years. He stressed that the stability and performance of readers was poor, but now it's very good.

Mr. Vega stated that downstream partners are driving this industry. He demonstrated the choice between adopting multiple technologies verses one technology by showing a graphic of a large man bulging at the midsection standing next to a slim man. He added that Alien Technology white papers could be downloaded at http://www.alientechnology.com/whitepaperdownload/.

Mr. Vega conducted a demonstration of UHF RFID technology with the objective of showing how technology has advanced. His demonstration showed how RFID technology worked, even under the following conditions:

- Tags in close proximity to one another (shadowing)
- foil blister packs and other products with metal foil
- tags read through and on containers of liquid (water)
- very small vials

Mr. Vega also demonstrated that UHF RFID technology could identify tampered cases and out-of-date products using a hand-held device with an OEM module. His demonstration also included holding bottles with 2-D barcoding in front of a scanner. Each bottle needed to be placed in front of the scanner, one at a time. He emphasized that manpower is not cheap, and reading each bottle would take some time. He then placed a case of RFID-tagged bottles in front of the scanner. Scanning the box showed that 25 bottles were contained in the box. Mr. Vega conducted other demonstrations with blister packs of Benadryl and NyQuil, plastic bottles of Crystal Geyser drinking water, and paper files of different colors.

Mr. Goldenberg stated that the board understands that the technology has advanced, but needs to know how to operationalize the technology. He said we are meeting in the spirit of working together to understand the progress made on the technical side, as well as on the operational side.

Mr. Room noted that questions have been raised in prior meetings about the availability of tags and readers necessary for industry-wide rollout. He asked whether Mr. Vega could comment on the current manufacturing capacity.

Mr. Vega responded that the industry would certainly welcome it, and it's not just about Alien Technology. There are other providers that can ramp up manufacturing right away.

Mr. Room asked about the Department of Defense (DOD) tagging products for defense contractors. He noted that the DOD had 2007 implementation guidelines.

Mr. Haraldsvik said that they are currently working with the U.S. Navy, Air Force, and Marines on projects.

A person from the audience asked whether the military projects are serialized at the unit level, and noted the magnitude of program expenses to conduct these pilot projects.

Mr. Haraldsvik responded that it is at the case and pallet level right now.

- **California Pharmacists Association (CPhA)**

Mr. Goldenberg introduced Kathy Lynch, and asked that the pharmacy community tell the board where their challenges are.

Kathleen Lynch, Esq., Vice President of Government Affairs, emphasized that CPhA members are solution driven and most importantly, they are advocates for patients. She said that as pedigree legislation comes into play, CPhA doesn't know when pedigree will be ready at the pharmacy level because of several issues including equipment, space, budget, and training personnel. She said pharmacies are totally reliant on their upstream partners as to which technology will be used. Different costs estimates have been provided to them including $25,000 to $30,000 per store to ramp up and comply with California's e-pedigree law. Will one reader be needed at each pharmacy, or two readers capturing 2-D and RFID? What about the cost of software? Who will house the software? She also said they need guidance from the board on inference.

Ms. Lynch said that questions about grandfathering also present an issue. For example, if they have stock on hand on January 1, 2009, what about products received from upstream partners after January 1, 2009 without pedigree? They rely on their upstream partners, and last minute decisions will affect them.

Ms. Lynch stated that CPhA has been working towards pedigree compliance by educating their members, meeting with wholesalers, and participating in pilot programs. Pedigree is not the only issue facing their members, though. Other issues they will be dealing with are implementation of AMP, tamper-resistant prescription pads, new

labeling requirements, health care reform, drug disposal programs, and Medicare Part D. All these issues put enormous pressure on independent pharmacies.

Ms. Lynch referred to the visual display of nesting Santas from Ms. Herold, similar to Russian nesting dolls. She said that although the smallest Santa is the manufacturer and the largest Santa is the retail pharmacy at the end of the supply chain, CPhA members actually feel small instead.

Ms. Lynch stressed that CPhA members want to comply with the law, and she recalled only around 10 people in the audience when these meetings first began. Now there are many more people involved, but there is still much work to be done.

- **National Community Pharmacists Association (NCPA)**

  David Wilcox, owner of an independent pharmacy, advised that he was representing NCPA, and he thanked the board for the opportunity to testify. He said that NCPA members represent 23,000 pharmacies, 75,000 pharmacists, and 300,000 employees. He said that millions of patients rely on their members for their prescription care.

  Mr. Wilcox emphasized that NCPA members do not believe the January 1, 2009 deadline of pedigree is possible to achieve. He said that there are circumstances beyond their control including the lack of standard technology implemented at the manufacturing and wholesale level.

  Mr. Wilcox stated that NCPA is supportive of a safe chain of custody of drugs to minimize illegal diversion of drugs as well as counterfeits, but their number one concern is standardization so that retail pharmacies will not be forced to maintain multiple technologies. California's law requires capability between all distribution channels, and without standardization, costs could be $10,000 to $40,000 per location. Without the state supporting that financial burden, it constitutes an unfunded mandate.

  Mr. Wilcox advised that a delay in pedigree implementation is justified, and that NCPA is requesting that the board extended the pedigree implementation deadline to January 1, 2011. He further stated that e-pedigree technology is not ready for purchase and operation at an affordable price, and the public would be best served by delaying implementation to ensure a system that will prevent counterfeit drugs from entering the system.

  Mr. Wilcox suggested that independent pharmacists be compensated for the costs associated with the purchase of multiple technologies. He also said that NCPA supports grandfathering so that pharmacists can be dispense drugs up to one year after pedigree implementation. In addition, they are asking the board for a hold harmless provision if inference is part of the process.

Mr. Wilcox said NCPA members are very concerned about costs put on to pharmacists at the retail level. He referenced P.S. 110-085, Sec. 913 that will require the FDA to develop a standardized numerical identifier by March 2010. If independent pharmacists implement a California standard in 2009, they may face a different federal standard in 2010.

Dr. Swart acknowledged that the board understands the end user at the pharmacy level is a dumping pool of upstream partners, and the board would look at the issue of grandfathering.

Mr. Goldenberg thanked Mr. Wilcox for his presentation. He said that the key factor we need is a timeline ensuring that the consumers of California will be protected. We are all in this together to protect consumers, and our worst nightmare will be body count legislation. People will be hurt while waiting. He said we must protect consumers and move forward to a safer line of pharmaceuticals.

Dr. Swart warned that a "timeline" does not mean 5-7 years, which really means never. He said he would feel terrible if people died because there was no sense of urgency.

- **Generic Pharmaceutical Organization (GPhA)**

Shawn Brown, Director of Policy for GPhA, thanked the board for the opportunity to make a presentation. He said that GPhA's members manufacture more than 90 percent of the generic medicines dispensed in the U.S., and that generic medicines comprise 63 percent of all prescriptions. Mr. Brown said that public health is sustainable through generics.

GPhA recognizes that counterfeit products entering the U.S. supply chain would pose a serious threat to public health. The U.S. drug supply is approximately 1 percent or less counterfeit, and 10 percent worldwide. Mr. Brown stated that generics are not likely targets for counterfeits, and no instances have been reported during the last five years. He said that generics compete on price and that is the benefit of competitive market, whereas other countries have price controls.

Mr. Brown noted some of GPhA's efforts toward pedigree compliance included conducting a survey of GPhA members, and working with Wal-Mart in package-level serialized products on a subset of SKUs.

Mr. Brown said that GPhA's economist supplied serialization start-up costs, with a conservative estimate of $500 million for equipment needed to modify packaging lines of generic producers (i.e., middleware, testing new packing lines, etc.). Item level serialization adds costs to the production of individual packages. Serialized labels will be more expensive than those currently in use. He said that labels with RFID technology are 24-30 cents more than labels currently in use, and labels with pre-printed 2-D barcodes are 2-3 cents more than labels currently in use.

Mr. Brown stated that generics have narrow profit margins on products, though they have higher volumes. Whatever affects the generic market will have direct repercussions on public health and access to affordable medicine in California and throughout the U.S. Unit level serialization on generics will have competitive disadvantages, ultimately resulting in fewer competitors and less competition. Wholesalers have informed manufacturers that they expect products to be pedigreed and serialized by June or July of 2008.

Mr. Brown stated that unit level serialization will significantly increase the production cost of generic medicine, and large-scale withdrawal from the market of low-cost/low-margin products is possible. Case or pallet level pedigree would cause fewer interruptions. He asked whether unit level serialization was shown to counter counterfeit drugs.

Mr. Brown emphasized that there is a lack of agreement among stakeholders on one technological standard that will support interoperability, and that the cost of "experimentation" is not an option. There is no guidance for implementation of track and trace as there is currently no agreement on EPCIS usage. He also referred to possible consumer/patient privacy issues, and whether vendors have the technical expertise to implement and manage the IT infrastructure by January 1, 2009.

Mr. Room emphasized that terminology is important, and that e-pedigree serialization means tracking at the unit level, not case or pallet level.

Mr. Brown stated that access to low cost generic medicine is at risk because high implementation and operational costs of pedigree requirement will raise production costs. He said that GPhA encourages an industry-wide review of the weak points in the pharmaceutical supply chain. GPhA does not believe industry can implement unit level serialization widely by January 1, 2009.

Dr. Swart asked Mr. Brown about studies they've done.

Mr. Brown responded that challenges to implementation are holding the process up. Generic manufacturers can't talk about a single solution because these documents would violate anti-trust laws. They want to see how pilots play out, but will come back to the board with findings when their economist looks at the pilot studies. They expect to come back to the board with their findings in Spring 2008.

Dr. Conroy noted that GPhA's economist is saying what it will cost to do pedigree, but doesn't offer a timeline as to when it can be done.

Mr. Goldenberg asked about the total sales of generic medicine.

Mr. Brown said that generics represent 65 percent of total national sales, but he doesn't have a dollar figure. He said they would come back to the board with information.

Mr. Goldenberg noted that hard data should be provided.

Mr. Room asked about Mr. Brown's suggestion that there is a market disadvantage caused by the need to segregate products compliant with pedigree.

Mr. Brown clarified that he meant to say that California's requirements are the most demanding. A product meeting California's requirements could be distributed anywhere. Products not meeting California's requirements could not be distributed in California.

- **Three Rivers Pharmaceuticals**

Christine Sheehy, Vice-President of Operations for Three Rivers Pharmaceuticals, stated that patient safety is their number one priority. Three Rivers supports state and federal legislation to ensure supply chain security, but is overwhelmed by the complexity of the technology.

Ms. Sheehy stated that Three Rivers Pharmaceuticals contracts out to third party operations for their manufacturing/analytical/packaging; it is not done in-house. Ribasphere Capsules in the 200-milligram dose is their flagship product.

Ms. Sheehy said Three Rivers is at square one, with regard to their pedigree readiness strategy. They are still trying to understand the requirements and monitor the development of standards. Three Rivers has an IT staff of only three people. They work collaboratively with vendors, customers, and trading partners. Though a small company, Three Rivers doesn't see pedigree as an insurmountable challenge, but they must develop a standard, cost-effective solution. They would have to integrate an e-pedigree solution with a validated distribution system, and there is a lot of work to be done in that area as well.

Ms. Sheehy said that CFR 21 requires distribution records; you must test distribution processes so that you have accurate records throughout the process. For those records, they must write test scripts and final reports, which take several months. She referenced an April 2007 FAQ document with a question as to how a sample implementation would work for a small company. She said it's a mouthful to implement in 12 months.

Ms. Sheehy said that the State of California is driving industry to what will become a national standard. The challenge for Three Rivers is that trying to comply with e-pedigree initiatives will consume 100 percent or more of their 2008 IT budget. There is a wait and see approach, and they'll have to be on the same page as everyone on both sides (suppliers and customers). They are also getting direction that whatever money they spend in 2008 will have to be for technology for the long-term solution.

Ms. Sheehy said Three Rivers is concerned about understanding the requirements, and they can't send three IT people around the country learning. They have great vendors, but it takes time to work with vendors as well.

Ms. Sheehy reiterated that patient safety and the security of the supply chain is their priority, but they respectfully ask for an extension. She added that they have not done pilot studies, as there has not been time to do so.

Mr. Room asked how their contract manufacturing was set up, and whether they were exclusive to Three Rivers.

Ms. Sheehy responded that they use two contract manufacturers, and Three Rivers is small fish to them.

Mr. Goldenberg asked whether there is an industry group representing outsource manufacturers. Three Rivers is like a boutique firm, and the board considers small companies to be an integral part of this process.

Ms. Sheehy noted that Contract Pharma Magazine could identify different outsourcers.

Mr. Goldenberg asked Ms. Sheehy to forward information about the magazine to Ms. Herold.

Mr. Room stated that there is a lot of information as well as disinformation out there regarding anti-trust. He invited anyone with opinions given to them by counsel be shared with him, and he'll see what can be done to provide clear information. It will be helpful to drill down on actually what the anti-trust restrictions are on communications.

- **TEVA**

Brian Shanahan and Michelle Keller appeared representing TEVA Pharmaceutical. TEVA supports the goal of securing the integrity of the pharmaceutical supply chain to ensure provision of safe prescription drug products to the public. TEVA is the leading generic pharmaceutical company in the world, with the largest pipeline in the industry. TEVA has 8 U.S. manufacturing sites, 8 international sites, 68 unique internal packaging lines, 50 outsourced manufacturers, 5 contract packagers, and 1 U.S. distribution site. They depend on a seamless distribution network.

Ms. Keller stated that TEVA complies with existing federal and state-level pedigree laws, and they seek standardization of supply chain integrity and track and trace interoperability. They are concerned that early adopters risk investing in technology that may not prevail. Some of the challenges of item-level serialization include:

- Lack of unified standards for track and trace interoperability
- Long implementation timeline

- Disruption to ongoing operations
- Significantly more expensive than lot-level e-pedigree

Mr. Shanahan emphasized the impact of requiring item-level serialization and track and trace capability on generic manufacturers, and that it will increase the production cost of generic medicine to patients. He said that generic manufacturers have lower revenues and profits and are, therefore, less capable of absorbing such costs. Generic manufacturers may be forced to increase prices or even discontinue certain product lines. Mr. Shanahan stressed that patients receive treatment with generic medicines that they would not otherwise be able to afford.

TEVA's actions to date include forming a global, interdisciplinary project management team specifically focused on compliance with California pedigree. They are also planning to conduct pilots with wholesalers, chain drug stores, third party manufacturers, private labelers, and re-packagers. TEVA does not have a pedigree implementation timeline, though they report that they are formulating one. They noted various challenges to formulating their timeline including equipment availability and potential labeling changes. TEVA reports that because their customers are imposing multiple requirements and there is no agreement about standards, they are "stuck." An estimated figure of $35 million to install equipment capable of 2-D serialization on packaging lines was given, but did not include the costs associated with distribution centers or ongoing operating.

Mr. Shanahan concluded the presentation by stating that TEVA supports a multi-faceted, risk-based and phased-in approach involving business practices, legislation/regulation, enforcement and technology to address issues that impact patient safety. They asked the board to postpone, as soon as possible, implementation of the California Pedigree law to ensure a continued supply of generic to citizens of California and to enable the industry to adopt a standardized system at a reasonable cost.

Dr. Swart asked about TEVA's annual sales.

Mr. Shanahan responded that it is $8 billion globally.

Dr. Swart noted that, on a percentage basis, the cost to implement is not as onerous, looking at it on a grand scale.

Mr. Shanahan stated that they are not limited just to implementation costs. They want to put capital resources into something that will work with everyone in supply chain.

Mr. Goldenberg stated that the board understands the Beta/VHS challenge, about selecting the technology to carry out e-pedigree requirements.

Mr. Room said this comment was for everyone present because it's about timing and attention to the issue. Statements made today by some of the presenters didn't strike him as anything that couldn't be said two years ago. He also wanted to correct a

misperception – the initial law required unit level serialization. So there is nothing new. The board has only given more structure to the law with the 2006 amendments.

Mr. Room stated that he has repeatedly advised the board that they must have a factual record of what the obstacles are and what industry has actually done, so the board can take into account whether a delay is in order. The board cannot delay the implementation date without those specifics and if a good faith effort cannot be demonstrated.

A person from the audience stated that by Spring 2008 they would have the results of a pilot study conducted.

Ms. Herold noted that there were early adopters who have moved forward and did not hold back implementation and pilot studies.

Mr. Goldenberg stated that if the board moves without a conviction to the January 1, 2009 implementation date, we will be sitting here talking about the same thing in 2011, 2013, or 2020. The board is clear in its needs. If TEVA has other information to present, he asked that it be forwarded to the board before the next general board meeting.

- **Watson Pharmaceuticals**

Mary Woods, Executive Director of Call Center Operations for Watson Pharmaceuticals, thanked the board for the opportunity to speak. She said that Watson is committed to patient safety and they do not take the matter lightly. Ms. Woods gave an overview of Watson's corporate profile. Watson is the third largest supplier of generic pharmaceutical products in the U.S., based on prescriptions dispensed.

Ms. Woods stated that Watson's actions to date regarding e-pedigree include a two-year RFID pilot with a Watson customer. The pilot included a modified packaging line, UHF Gen1 and Gen2 RFID pre-serialized labels, scanners, readers, and licenses. She said these actions show their significant commitment to technology.

Ms. Woods said the challenges they see include standards that are still being developed, and timeline constraints for equipment installation, testing, and validation. She said it's not just the cost element; it's trying to get technology decisions to be made just once, instead of over and over again. Watson has 32 packaging lines and their vendors have advised that they cannot have their packaging ready in time to be compliant.

Ms. Woods said that Watson's next steps toward e-pedigree implementation include trading partner testing. They asked the board to consider an extended implementation date to ensure that standards are in place and to protect the integrity of the supply

chain, while continuing to provide lower cost alternative pharmaceutical products to patients.

Mr. Goldenberg asked Ms. Woods if Watson had any information to share with the committee as to when they could comply.

Ms. Woods responded that they will have a "timeline for a timeline," but only if they have the standards. She said it was a Catch 22 until they agree on data collection and methodology. At that point, they can "work backwards into a timeline" but until then, they will get stuck in loopholes. Ms. Woods said their customers were confused as well, and they are reaching out to them. She said it saddened her to see so much confusion.

Mr. Goldenberg asked whether Shawn Brown could help Ms. Watson prepare something for the January 23, 2008 board meeting. He suggested that Shawn get information from their constituents regarding the timeline of the timeline. He emphasized again that we do not want to be talking about the same thing in 2020, and that any information to present on January 23rd should be sent in advance for inclusion in the board packet.

Mr. Room stated that the board would agendize all requests for delay of implementation, and all requests must be submitted in writing. Requests must be supported by data demonstrating compliance efforts thus far, including compliance studies, what that particular segment of the industry has done, and when that segment of the industry will be compliant. A request to delay must show what the requester has done so far, what steps will be taken, what products are in their portfolio, and the logical requirements to modify their packaging line. Mr. Room asked Mr. Brown what data was submitted to their economist.

Mr. Brown responded that he couldn't give specific information on companies. He said there is fierce competition among companies, and that's why they didn't aggregate the information.

Mr. Room said that the decision the board will make must reflect their duty to provide the highest degree protection to the public. To delay implementation, the board must be satisfied that the technology is not ready. To secure an extension, the board needs data demonstrating that another date is a more appropriate date than January 1, 2009. If the cost would be prohibitive or supply would be interrupted, that must be specifically spelled out in the request.

A person from the audience asked the board to provide a template for the requests. She said that they want to give the board the information in a collaborative spirit, and a template will advance their ability to give the board the information it needs.

Ms. Herold said a template would be posted on the board's Web site.

Mr. Room said that in the last 10-12 months the board has been clear about the data that the board will need to delay implementation.

Mr. Goldenberg stated that we've all been working together very hard on this, and it is one of the priorities of the board. The board cannot justify a delay without information, and cannot place the consumers of California in harm's way. This is a significant meeting today, and January 23, 2008 will be a watershed meeting.

- **Pharmaceutical Research and Manufacturers of America (PhRMA)**

  Marjorie Powell, Senior Assistant General Counsel for PhRMA, presented findings from a survey of their members. PhRMA is a trade association representing research-based pharmaceutical and biotechnology companies in the U.S.

  Ms. Powell stated that PhRMA conducted a survey to determine what pilots their members had done. She said they did not send the survey to all their members because they did not have correct contact information for all of them. They sent the survey to the companies they knew were actively working in the area. The survey asked questions about e-pedigree without serialization and with serialization.

  Ms. Powell said that PhRMA received responses from 21 companies, 16 of which have been engaged in pilot studies. For pilots conducted at the item level, these companies used 2-D barcoding. The majority of the companies tagged a limited supply of a particular product.

  Ms. Powell advised that she would compile information from the survey and provide it to the board in a letter, prior to the January 23, 2008 meeting.

  Ms. Powell noted that the survey revealed a number of issues regarding exchange of information. She said those issues need to be worked out because it's like peeling an onion where each layer shows subsequent issues. Ms. Powell referred to the nesting Santas and Russian dolls as an example. If a pilot is conducted with the first two entities, the decisions at the first and second level could cause problems at the third and fourth levels. Companies must change their processes, including software and computer systems.

  Ms. Powell said that entire packaging lines could be out of use for two to four months during modifications. Companies must get FDA approval for changes in packaging lines, so FDA resource issues will occur. They have been in contact with the FDA to identify what resources will be needed, but modifying one packaging line does not readily translate into faster implementation in other packaging lines. Three to four years of pilot projects show lot level itemization, is enough to authenticate products in the distribution system.

Ms. Powell said that to avoid dealing with the same issues in the year 2020, PhRMA urges the board to think about a system that involves everybody in the distribution chain, including the downstream partners. They suggest fewer details initially, starting with lot level or case level, tagging, then moving to unit level serialization. She said it would be best to phase in this process to eventually get to unit level serialization, starting with those products with the greatest risk.

She asked the board to consider a timeline looking at high-risk products by a certain date, and lower risk products at later dates. She said that high-risk products included both patented and generic products.

Ms. Powell questioned the effect of RFID on biologic products, and how testing should be done on those products. She noted that there could be a problem if they go forward with RFID and effects are later shown on biologics. She urged the Enforcement Committee to give FDA the benefit of everything learned because California has moved more quickly than the FDA. In the end, there must be a uniform system, not just one system for California, and for the country.

Ms. Powell said she would get back to the board with more details, but not necessarily a timeline for all companies. She said that in response to Mr. Room's request for copies of opinions about antitrust issues, she would forward to him information that she is waiting for from their antitrust lawyer.

Mr. Goldenberg thanked Ms. Powell, and said he looked forward to the information she will provide for the board's packet. He advised that all board members receive meeting materials for their review, prior to the public meetings. Part and parcel of that review is a full disclosure of information that is understandable by professional members of the board and public members of the board. He suggested it would be helpful if information presented to the board is in English, instead of pharmaceutical or legalese.

Ms. Powell stated that PhRMA wants to prevent patients from products that are counterfeit, but the focus at the manufacturer level should be on high-risk pharmaceuticals.

Mr. Goldenberg asked whether PhRMA had a person dedicated to this issue, due to their importance to manufacturers.

Ms. Powell responded that there is not a particular person that she knows that is dedicated to this issue. She said that PhRMA asks their members to work on various committees, and PhRMA has had a technical committee working on this issue for five years. That committee is comprised of companies that have resources, but she doesn't have a contact person to reach out to. She said they extended the time for their members to respond to the survey because all of their member companies have an interest in pedigree, but do not necessarily have someone working on it.

Mr. Goldenberg noted that the board looks to PhRMA to help the board understand, and he understands that the FDA has resource issues. He is hoping to receive information from the FDA as well.

Ms. Herold noted that with respect to risk-based products, some of PhRMA's members have already tagged products, but those products can only be read by certain people. She added that some companies have already done risk-based assessments and in the absence of any requirements, they are already doing a number of things to protect their drug products. She added that industry advised the board in 2006 that they could readily tag products at the case and pallet level and asked whether this first step had been taken.

Ms. Powell responded that she was not sure how to answer, but she is aware of two companies with tagged products at the unit level, one of which was read all the way down to the pharmacy level.

Mr. Room noted that at the time of enactment of this legislation, PhRMA members said they didn't want a list of "dirty" drugs. If the board adopted a risk-based approach, which would require legislation, what drugs would be on that list? How could the board allocate the costs if some companies had multiple drugs while others had none – manufacturers without high-risk drugs, would they be expected to share in costs anyway? What criteria could be used to develop such a list and would all PhRMA companies support the resulting list? Would the board legislate that list? Would each manufacturer volunteer three drugs to place on the list? Are PhRMA members willing to do that?

Dr. Swart commented that pedigree only for certain drugs would definitely affect end users. In the pharmacy, they would have to check some drugs but not others, which would be problematic.

- **Pfizer**

Peggy Staver, Director of Trade Product Integrity for Pfizer, stated there are a couple companies that have serialized SKUs. For example, Viagra can be read with HF and UHF. Albertson's has stores in the Chicago area that were reading tags at the pharmacy level, and at one point Rite-Aid was involved in a pilot as well.

Ms. Staver stated that in order to read the serialized tags, a pharmacy would have to have access to their system and have an account. It will enable a company to read, but not to authenticate back. Pfizer does not have agreements in place with anybody. She added that serialization requirements are different than pedigree requirements.

Ms. Herold suggested that field tests could be conducted, but she heard from the pharmacy end that nothing is coming through that they could pre-test. As a result,

pharmacies can't train their staff, though this would provide a perfect opportunity to do so. She asked that Pfizer take an extra step further to see how it will work in California.

Ms. Staver responded that Pfizer will need to work with each trading partner, aligning with each trading partner from end to end to implement e-pedigree.

Heather Zenk, from AmerisourceBergen, commented that authentication of a serial number is different than a chain of custody.

Mr. Room asked for clarification as to whether they are accessing data, not adding to the data.

Ms. Zenk responded, yes, they are accessing the data only.

Ms. Staver said that Pfizer is hearing from companies that are reluctant to make a significant investment in technology until there is common agreement.

Ms. Herold asked whether a pharmacy could request access from Pfizer, and Mr. Room asked whether access would occur through a web portal.

Ms. Staver responded yes to both questions. On a separate issue, Ms. Staver stated that manufacturers know best which products are best identified as high-risk.

Mr. Room said that his comment was not directed just to Pfizer, but that companies can generate a list of high-risk products and it shouldn't be that hard. His advice to the board is that it is not sufficient for the board to identify criteria for a list, but an actual list would have to be developed. It would result in a huge issue for litigation, and the board would not want to litigate each drug applied to a list. He added that regarding common agreement about technology, as the board and staff have repeatedly advised, companies do not want the board to legislate which technology should be used.

- **Distribution of Revenue for Filled Prescriptions in 2006**

Ms. Herold provided information and statistics from a report provided by NACDS. A chart from the report showed that the average cost of prescription drugs dispensed during 2006 was $68.26. This was for brand name and generic drugs. The chart revealed that 77.6 percent of the cost of a filled prescription ($52.97) went to manufacturers of which $8.58 was net profit and wholesalers made an average profit of $0.72 for each sale, and pharmacies made $0.96.

Ms. Herold cited other statistics the NACDS report including:

- 3.4 billion prescription drugs were dispensed in the U.S. during 2006
- Average price of a generic drug dispensed in the U.S. during 2006 was $32.23

- 54.3% of all prescriptions drugs dispensed in the U.S. during 2006 were generic
- Average price of a brand name drug dispensed in the U.S. during 2006 was $111.02
- 45.7% of prescription drugs dispensed in the U.S. during 2006 were brand name
- Average price of a prescription drug dispensed in California during 2006 was $76.72

- **California Health Care Institute (CHI)**

  Mike Carpenter presented results of a survey of CHI members. CHI is a statewide trade organization representing the life sciences industry. Mr. Carpenter said that CHI advocates for policies that promote medical innovations, access to the best medicines and therapies, and the health and well being of patients.

  Mr. Carpenter stated that a survey of their members was conducted in conjunction with the Biotechnology Industry Organization (BIO). The purpose of the survey was to get a picture of what their members are doing to get ready for implementation of e-pedigree.

  The results of the survey revealed that 71 percent of their members had begun some type of "planning" for e-pedigree, but they are facing many challenges. For example, they cite no consensus among supply chain members regarding RFID technology vs. 2-D barcoding. There is concern about setting up the infrastructure necessary (data storage and ownership issues), and whether there is time left to meet the implementation date. Regarding production, there must be a continuous supply of products while packaging lines are being reconfigured for unit level serialization.

  Mr. Carpenter also noted concerns about third party business partners because a majority of CHI members rely on third party manufacturers, packagers, labelers and carton suppliers to get their products into distribution. Cost is also an issue for smaller companies because product serialization at each step of the drug distribution chain will require significant upfront and ongoing costs, and they must dedicate human resources to that effort.

  Mr. Carpenter's summary of the findings revealed that only 10 percent of respondents believe they can be prepared to implement serialization across all or some of their product lines. The vast majority of respondents are only in the planning phase. He emphasized that CHI members support the law's goal of product integrity and patient safety.

Mr. Goldenberg noted that the companies that CHI represents are the small research companies for different diseases. He asked whether the ownership of these companies was in part by large pharmaceutical manufacturers.

Mr. Carpenter responded that he did not know.

Dr. Swart noted that this group of companies produces the products that are probably at higher risk to have counterfeits.

- **Healthcare Distribution Management Association (HDMA)**

  Liz Gallenagh, State Government Affairs Senior Director of HDMA, commended California in trying to facilitate progress towards e-pedigree. She said that the California model offers the best framework and will preserve the integrity of the supply chain, but HDMA has concerns about the robustness and the timeline.

  Ms. Gallenagh said that much progress has been made and that there is better software and hardware available now. Supply chain partners have been discussing track and trace, but they need to understand more in order to achieve track and trace and comply with California law. HDMA has helped design pilots, but they need more time to do testing. Products have been tagged by manufacturers, but they are just now testing the storage and collection of information.

  Ms. Gallenagh said that HDMA would submit their recommendations to the board regarding inference and grandfathering issues. She emphasized that HDMA continues to try and work through these obstacles, and they must work with their supply chain partners to get more data to the board. If the board grants an extension, HDMA wants the board to act sooner rather than later.

  Mr. Goldenberg asked whether she had any thoughts regarding implementation issues for all drugs vs. implementation for only a few drugs.

  Ms. Gallenagh said that when talking about implementation for high-risk drugs vs. full implementation of everything at once, the systems put in place for a limited numbers of products would require the same systems that would be needed for full implementation.

- **EPCglobal**

  Bob Celeste, from EPCglobal North America, provided an update on standards. He noted that item level tagging for the EPCIS system is in its second 30-day intellectual property review.

  Mr. Goldenberg commented that the graphic presentation from EPCglobal is an example of what would be useful to the board to make an informed decision.

Mr. Celeste spoke about the pedigree messaging standard, item level tagging, serialization, supply chain integrity, and track and trace, and tag data standards. He noted that the GS1 Healthcare taskforce would be assembling.

Mr. Celeste emphasized that the EPCglobal pedigree messaging standard is the only ratified standard that meets FDA, Florida, Nevada, and California pedigree requirements. He outlined what information is contained in a drug pedigree. He also spoke about EPCIS events, and that they answer five questions (who, what, when, where, and why). He also spoke about possible recommendations including U.S. guidelines or a global standard for how to use both the pedigree messaging standard and EPCIS to satisfy pedigree regulations.

Mr. Celeste stated that EPCglobal is working on the assessment on how the pedigree messaging and EPCIS standards will be interoperable.

A person from the audience asked whether the board accepts EPCIS as a tool to meet pedigree requirements.

Ms. Herold responded that this is what EPCglobal is working on.

Mr. Room added that it appears that the infrastructure allows trading partners to pass information, but we don't know if that meets the interoperability requirement. The board is not here to endorse any particular technology solutions.

- **Aegate**

Graham Smith and Gary Noon gave a presentation regarding an electronic product authentication system used in some countries in Europe. Mr. Noon emphasized Aegate's commitment to patient safety and stated that the current distribution system is not conducive to patient safety. They have approached patient safety from a different point of view because they are looking at pharmacies, and authentication of drugs within the pharmacies before a product is dispensed to a patient.

Mr. Noon stated that complexities exist with the current e-pedigree approach because of the requirement to establish e-pedigree for each saleable unit inside a pack/case inside of a pallet. He emphasized the need for standards because we are using new technologies that are unproven.
Mr. Noon stated that authentication and case level e-pedigree could help resolve these complexities until the technology is implemented by the supply chain. He described authentication as the process to verify at the point of dispensing that the goods being dispensed have the same manufacturer's identifier displayed as present on the secure data base provided by the manufacturer.

Mr. Noon stated that manufacturers can mass serialize the products and provide this data into a central database. Later in the pharmacy in real time, a pharmacist scans the product, which doesn't interfere with pharmacist's workflow because he/she already scans the products. Data is sent back in less than one second during scanning and if something is wrong (i.e., out of date drug, recalled drug), an 'alert' will display via a screen prompt. The pharmacist must touch the screen to acknowledge the alert. This process has resulted in expired medicines being identified in Belgium.

Mr. Noon stated that 18 major pharmaceutical companies are currently involved with the authentication of drugs, with 1,300,000 authentications being performed each month in Europe. In Belgium, 5,300 pharmacies are participating; in Greece, 9,500 pharmacies, and in Italy, 17,400 pharmacies are currently performing authentications.

Aegate reported that pharmacists find the drug recall and expiration information provided during authentication very useful. Products have been intercepted during this process, preventing recalled products from reaching patients.

Aegate proposed that if every saleable unit is authenticated in the pharmacy, and inference between case level and the saleable unit can be justified, then the existing legislation requirements can be met with their system. To make that approach happen, however, California's Board of Pharmacy would need to accept the principle of inference from case level to saleable unit, provided it is supported by authentication in the pharmacy. He added that California's Board of Pharmacy would also need to endorse a coding standard, such as GS1.

Mr. Noon suggested formation of a task force to evaluate this proposal and generate a road map. The working party of the task force would consist of solution providers, manufacturers, wholesalers, pharmacy chains, and Board of Pharmacy representatives (as an observer). He recommended that the task force, if formed, report back to California's board on January 23, 2008.

Mr. Goldenberg asked for clarification regarding how security works in this system, and what percentage of products are included. He also asked how many computer systems they are integrating, given that California has many systems to deal with. Mr. Goldenberg also asked about motivation for these efforts, and if it began because the government pays for the drugs in Europe.

Mr. Noon stated that Aegate's system tracks products containing a large random number (serialized key) on the pack. The product is scanned and information goes back to the central database and the number tries to "find itself." The process takes only about one-third of one second. If a duplicate is identified, the first pharmacy where the product was sold is notified, as well as the pharmacy that has scanned the same number for the second time.

Mr. Noon referred to their pilot efforts in New York, and that they learned to embed the authentication process in the existing scanning process. He noted that scanners

reading more than one technology (2-D and RFID) ran too slow. He said he would share the data set from their work in New York with California's board.

A person from the audience asked whether the database is a web-based repository or if it's proprietary.

Mr. Noon responded that it is a high-level security database. He added that speed and security could only be ensured by putting it in one secure place.

Mr. Goldenberg asked whether Aegate is willing to do a pilot study in California.

Mr. Noon responded that he wants a task force to see if all players want to go in that direction first. Otherwise, it will be a waste of time.

PUBLIC COMMENTS

- **National Coalition of Pharmaceutical Distributors (NCPD)**

Gene Alley, Vice President of Regulatory Affairs, spoke on behalf of NCPD. He said their organization represents and supports independent drug wholesalers nationwide. NCPD members distribute to physicians, clinics, pharmacies, long-term care facilities, surgery centers, dentists, and government entities, and almost half of their members are VAWD (Verified Accredited Wholesale Distributor) certified.

Mr. Alley said that small distributors benefit end-users; for example, they can source products for hospitals that hospitals cannot get through their regular chains during an emergency.

Mr. Alley noted that NCPD members have been dealing with paper pedigree requirements for two years, and they can serve as a resource to the board regarding what has and has not worked in Florida. He said that NCPD supports measures that increase the security of the nation's pharmaceuticals, and urges California to involve all stakeholders in the pedigree implementation process.

Mr. Alley spoke about surety bonds, and said California's current requirements burden small distributors. NCPD suggests that one national surety bond (proportionate to revenue generated by sale Rx drugs) be permitted for all states nationwide.

Mr. Alley stated that though patient safety must be the primary concern, serialization is a big problem. Meeting the January 1, 2009 deadline will be challenging. Mr. Alley stated that pharmacies are dependent on manufacturers to determine which technology to buy. Therefore, a delay should be granted to pharmacies. He further stated that an electronic pedigree without serialization would be better than no pedigree for another two years in California.

Mr. Alley emphasized that NCPD supports a phased-in approach, implementing e-pedigree except for the bonding and serialization requirements. NCPD asks for a delay in serialization until 2011 and then only implement it on a risk-based approach for high-risk drugs. He asked that NCPD be included as one of the board's many resources to help determine the best method to protect consumers.

- **Stephanie Feldman Aleong**

  Ms. Aleong introduced herself as a former statewide prosecutor in Florida. She planned and directed Operation Stone Cold, a pharmaceutical racketeering prosecution, which became the subject matter for the non-fiction book by Katherine Eban, Dangerous Doses.

  Ms. Aleong said what happened in Florida was that lot level pedigree was a "sham" pedigree. In her experience, what you demand of the industry is what will be possible. She advised that people show the board why no delay in implementation is necessary, instead of arguing that a delay is necessary.

  Ms. Aleong said the board has initiated a forum that also will encourage written comments from people who say don't delay. She is encouraged by California because Floridians listened to the fears instead of forcing industry to come forward with hard data. She said industry has been talking about this issue since 1987, and she urged the board not to delay implementation.

- **Siemens Corporation**

  Jeff Schaengold, Traceability Internal Consultant, spoke on behalf of Siemens Energy & Automation, Inc. He also provided a written statement of his testimony to the board.

  Mr. Schaengold noted that the cost to modify one packaging line has been overestimated when stating it will cost $500,000. He said actual costs are lower, with higher costs usually incurred during pilot projects. The "cloning" of packaging lines brings the actual cost down quite a bit.

  Mr. Schaengold recalled previous warnings that every company would be put out of business if they had to computerize. Later came warnings that every company would (again) be put out of business, this time because they had to put barcodes on their products. E-commerce was the latest thing that was going to put every company out of business. Despite the warnings, no traumatic events occurred. He emphasized that businesses adapt and conform, and he strongly recommended that California's e-pedigree implementation date not be delayed.

  Mr. Schaengold said that Siemens supports patient safety, and that delaying e-pedigree implementation beyond January 1, 2009 would jeopardize that patient safety. He said

that traceability is 95 percent adoption of the principle and 5 percent deciding on standards. Delaying adoption of drug traceability is unjustified, considering that traceability and serialization have been used in the aviation, automotive, and electronics industries for the several decades.

Mr. Schaengold stated that the concept of serialization is not new or expensive, and serialization of a drug would cost a fraction of a cent per unit. Siemens is making their resources available to companies that need to fast-track their package serialization to meet California's deadline. They have worldwide resources ready and able to support any drug manufacturer in order to meet the January 1, 2009 implementation date. Siemens IT services and employees stand ready to improve the delivery of drugs, prevent counterfeit drugs from entering the marketplace, and prevent drug dispensing errors.

Mr. Schaengold said that Siemens is capable of marking, reading, and verifying products on a conveyor line faster and better than any other company in the world. In addition, Siemens will not provide grandfathering exceptions or waivers.

Mr. Schaengold gave an example of buying a $25 printer from a Wal-Mart in Connecticut. When the clerk scanned the product UPC code, a screen-prompt directed the clerk to scan the serial number as well. If ink jet cartridges and printers can be serialized, why are oncology drugs not serialized? Mr. Schaengold urged that there be no delay of implementation for California drug pedigree.

2. Possible Use of Inference for Serialized Drug Products in the Supply Chain or Grandfathering of Unserialized Drug Products Already in the Supply Chain on January 1, 2009

Mr. Room stated that the way in which the board had hoped the discussion would proceed was that presenters would use the Implementation Submission Statement Template posted to the board's Web site. The template was developed to help industry communicate how they perceive grandfathering or inference would look within their system.

One template was submitted regarding inference from EPCglobal, and there were no submissions from industry. The board understands generally what inference is, but was interested in what inference means to industry, and how and when they would use it. Would they use inference at the front end or the back end of the supply chain?

Ms. Herold referred to EPCglobal's template submission on inference (attached to these minutes). Slide 4 included three serialized inference definitions as follows:

- **Infer:** Conclude from evidence (Webster's Dictionary).
- **Working definition:** To infer the serialized number, based on information provided by the upstream supply chain, reasonable inspection of the product,

and application of the Serialized Inference Rule by the Shipping and Receiving partners.

- **Serialized Inference Rule:** The process a supply chain partner uses to ensure there is enough evidence to infer the serialized number without physically reading ALL serialized numbers. A Serialized Inference Rule should be defined for each packaging unit (e.g., pallet, case, item, etc.) for the key process steps of Commission/Aggregation, Ship, and Receipt.

Mr. Celeste spoke on behalf of the EPCglobal's HLS Industry Adoption Task Force. He provided excerpts from a body of work containing general material on inference.

Mr. Celeste stated that California's Business and Professions Code Section 4034(b)(3) requires the name and address of each person certifying delivery or receipt. The business problem presented is that serial numbers, especially on a 2-D bar code tag, are not always visible and opening each case to certify individually tagged items would be time-consuming. 'Inference' is one suggested solution to this business problem.

Mr. Celeste said that serialized inference would assume that each trading partner is following good business practices such as:

- Good manufacturing and good distribution practices.
- Documented controls and Standard Operating Procedures.
- Uses quality metrics to minimize "defects" of inbound and outbound product.
- When process errors are detected, implements changes to those processes to prevent future errors.
- Processes are periodically reviewed for improvement opportunities.

Mr. Celeste summarized that serialized inference is possible when the following conditions have been achieved:

- A collection (item, full or mixed case, tote, pallet, etc.) is present.
- The collection is identified with a unique serial number, and each member of the collection (item, case, tote, pallet) is also identified with a unique serial number.
- The received trading partner receives an electronic communication containing the serialized numbers and the hierarchical relationship of those serialized numbers within the collection ("parent to child" relationship).
- The receiving trading partner must have assurance that the collection has remained intact since leaving the last trading partner.

Mr. Celeste noted that this information is intended to provide trading partners with an understanding of how inference can be used, but the application of inference remains an individual business decision.

Mr. Celeste also provided serialized inference scenarios including:

- Single Item Commission – apply serial number to one single item
- Item in Case Commission/Aggregation – apply serial number to case and build item-to-case hierarchy
- Case to Pallet Commission/Aggregation – apply serial number to a homogeneous pallet comprised of cases of all one product and build case-to-pallet hierarchy (may be a full pallet or a partial pallet)
- Tote or Mixed Case Commission/Aggregation – apply serial number to cases or tote containing either a mixture of SKU's or one or more items of a single SKU, and build item-to-case hierarchy (typically conducted as part of a pick/pack/ship operation)
- Mixed Pallet Commission/Aggregation – apply serial number to pallet of mixed cases or totes, and build case-to-pallet or tote-to-pallet hierarchy (pallet could contain mixed cases and/or full cases, and the full cases could be from one product or from multiple products)

Mr. Celeste acknowledged that inference is a risk because each item in an inference case is not specifically checked. He noted that inference is common in everyday life (a bottle of 100 tablets is purchased without verification that there is actually 100 tablets in the bottle).

- **DDN Pharmaceutical Logistics**

Bill Von Rohr spoke on behalf of DDN Pharmaceutical Logistics. Mr. Rohr stated that DDN represents 50 manufacturers. He said that per the regulations, pedigree must be authenticated when there is a change of ownership. For example, a manufacturer has a partner and that partner ships a pallet to that manufacturer; it will show the address of one partner and the name of the other. He asked whether they would need to authenticate the physical product against the record. He said as product moves down the supply chain, will they be told they're not authenticating enough, or just go back to manufacturer? What if they pull 50 cases off a pallet and compare that authentication to be the same as the physical products? Mr. Rohr suggested that for the agent of a person buying the goods, it would be a challenge to open every case to scan each unit.

Mr. Room responded that this is exactly the kind of data the board needs in writing in the template. The board does not know exactly how people will put this inference into practice and what kinds of problems they perceive.

Mr. Von Rohr said that he would be happy to write up the issue, and submit it to the board.

- **Walgreens**

Emily Stamos and another person from Walgreens commented on the issue of inference. They said inference is important because they see it as an interim step until

there is “no-line-of-sight” technology. In answer to the board’s question about how inference would be used, Walgreens wants to use it in their distribution centers. Without inference, they will have to read every item to accommodate items where there is no line-of-sight. They would conduct “100 percent audits” initially for a particular manufacturer, then later read fewer items from the same manufacturer (or the three large wholesalers). They believe that ultimately a full read of everything could be done, but until that day comes, inference would allow them to use their good practices and make good business decisions, ensuring that people in California receive quality medications.

Mr. Room asked Walgreens to submit their comments in writing, including their trust with manufacturers, internal protocols, and ways to apply inference. He said that scenarios would be useful to the board. He added that inference is not risk free, and it cannot be hold-harmless.

Ms. Herold noted that it would be very helpful to know if a product is inferred all the way through to the pharmacy.

Ms. Stamos said that she would put together a visual presentation on the subject of inference, for the board’s meeting on January 23, 2008. Regarding the subject of grandfathering, there is a challenge if they cut off orders waiting for tagged products. There would be empty spots on the shelves because certain products would not be ready at a certain time.

Ms. Stamos suggested that grandfathering be staggered. She gave an example of requiring manufacturers to grandfather until a certain date, then wholesalers would add six months to the original date, and so on, so that everyone can bleed out their inventory.

Mr. Room asked that these proposals be put in writing for the board.

Ms. Herold noted that the board would need to provide some enforcement discretion.

Ms. Stamos stated that some products have a long shelf life, and retail pharmacies may run the risk of destroying inventories, and it is costly to replace that inventory. For example, a product that is not due to expire before 2012 may be wasted.

Dr. Swart asked how much supply a pharmacy would have, for example, three months or a year.

Ms. Stamos responded that it’s product specific. For example, they have some products that wouldn’t expire until 2013. There is a wide spectrum as to how long product supply will last.

- **Safeway**

  Ron Bingaman spoke on behalf of Safeway. Regarding grandfathering, Mr. Bingaman supported the comments made by the representatives of Walgreens. He also said that in retail pharmacies, inventory goes through at different rates. He said he would provide written comments to the board. He supports a tiered approach by category.

  Mr. Bingaman also supported the use of inference with spot check oversight, until industry comes together and the system standardizes itself. After industry finalizes track and trace standards, they will put together a system, dependent on track and trace serialization being adopted. Assuming a product is serialized, whether it's 2-D barcode or RFID, they could have a working pilot going within 120 days.

- **Longs Drugs**

  Jeff Beadle spoke on behalf of Longs Drugs. He said he supported Walgreens comments regarding a phased-in approach.

  Mr. Beadle said that products become more suspect once they are out of the case. As a case moves downstream, it's been opened by multiple parties in the supply chain. By keeping a container in tact, you keep an additional barrier for an added layer of security.

  Mr. Room noted that is what he meant by identifying which transactions may or may not be appropriate for inference. Products sold as whole cases all the way down to retailers would be an example.

- **Kaiser Permanente**

  Steve Gray spoke on behalf of Kaiser Permanente. He said that pharmaceutical quality is based on inference. For example, they assume what's it says on the bottle is what is in the bottle.

  Dr. Gray gave an example of an advance shipping notice of cases arriving by air or freight. Those kinds of shipments are inferred because containers are not opened.

  Regarding grandfathering, Dr. Gray said enforcement discretion should be category specific. He gave an example of a drug for black widow spider venom that may not be dispensed to a pharmacy, but can be delivered in a couple hours. It is similar to medication for rattlesnake venom. Dr. Gray suggested that long-term grandfathering may be needed because some these products have only a few manufacturers and are manufactured very infrequently.

  Mr. Room asked Dr. Gray to include these examples as part of a written submission.

Dr. Gray clarified that if patients needed a product, that product should be able to be brought in to the state during an emergency, and that there should be enforcement discretion. He asked the board to support that type of legislation. He also suggested that if there was a domestic supplier not in compliance, but they have a product we need, grandfathering would be in order.

ADJOURNMENT

Mr. Goldenberg emphasized that the board has heard presentations on what industry cannot do, and wants to know what industry can do to ensure the safety of Californians.

Ms. Herold stated that a template would be developed for submissions regarding implementation of California's pedigree. The template will solicit comments requesting delay as well as requests not to delay implementation. It will be posted on the board's Web site.

There being no further business, Chairperson Goldenberg adjourned the meeting at 5:12 p.m.