



California State Board of Pharmacy

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

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES**

DATE: January 23-24, 2008

LOCATION: Town & Country Resort and Convention Center
500 Hotel Circle North
San Diego, CA 92108

**BOARD MEMBERS
PRESENT:**

William Powers, Public Member, President
Ruth M. Conroy, PharmD, Vice President
D. Timothy Dazé, Esq., Public Member, Treasurer
Kenneth H. Schell, PharmD
Stanley Goldenberg, RPh
Robert Swart, PharmD
Andrea Zinder, Public Member
Susan L. Ravnan, PharmD
Henry Hough, Public Member
Robert Graul, RPh
Stanley C. Weisser, RPh
Shirley Wheat, Public Member
James Burgard, Public Member

**STAFF
PRESENT:**

Virginia Herold, Executive Officer
Karen Cates, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judith Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Janice Dang, Supervising Inspector
Joshua Room, Deputy Attorney General
Spencer Walker, DCA Staff Counsel
Anne Sodergren, Legislation and Regulation Manager
Karen Abbe, Public and Licensee Education Analyst
Tina Thomas, Staff Analyst

Wednesday, January 23, 2008

CALL TO ORDER

President Powers called the California State Board of Pharmacy (board) public meeting to order at 8:54 a.m.

GENERAL ANNOUNCEMENTS

Mr. Powers welcomed attendees and made announcements regarding sign-in sheets, joining the board's e-mail list, and earning CE credits. He acknowledged the presence of former board members Raffi Simonian, Richard Mazzoni, and Clarence Hiura. He also introduced new board members Stanley Weisser, Shirley Wheat, and James Burgard, as well as newly appointed Supervising Inspector Janice Dang.

A presentation was made to former board member Clarence Hiura. Mr. Powers thanked Dr. Hiura for his service and dedication. Mr. Goldenberg expressed his appreciation and deep respect for Dr. Hiura. A clock was presented to Dr. Hiura as an acknowledgement for his service as a board member over 16 years.

Dr. Hiura stated that it had been a privilege to serve on the board. He spoke about serving under four governors during his tenure. He also expressed his admiration and respect for the four female executive officers he served with. Dr. Hiura acknowledged the leadership of current Executive Officer Virginia Herold and the work of her staff.

I. APPROVAL OF THE FULL BOARD MINUTES OF OCTOBER 24-25, 2007

Mr. Powers referred to the draft board minutes of October 24 and 25, 2007 provided in the meeting materials.

MOTION: Approve the board minutes of October 24-25, 2007

M/S: DAZÉ/RAVNAN

SUPPORT: 12 OPPOSE: 0

II. WORK GROUP ON E-PEDIGREE SUBCOMMITTEE

Enforcement Committee Chairperson Goldenberg asked Deputy Attorney General Joshua Room to summarize the history of the Work Group, and outline the board's objectives and commitment to e-pedigree.

Mr. Room advised that he serves as liaison counsel to the board, and he would provide the legal perspective on the issue. Pedigree requirements in California law were enacted by statute in 2004, with an original implementation date of 2007. In 2006, the board and industry stakeholders returned to the Legislature to clarify some points in the law and to forestall the implementation date to 2009. At that time, the Legislature also delegated to the board some of the authority that would otherwise reside in the legislature, under limited conditions.

Mr. Room emphasized that the legislature holds the ultimate policymaking authority for writing laws that are enforced by the executive branch. The board is a member of that executive branch, and also has some of its own policymaking authority in terms of regulations. The board is constrained to act within the laws passed by the legislature and signed by the Governor. The power delegated to the board was to act to delay implementation of the pedigree law under the conditions set in statute. Those conditions are set forth in Business and Professions Code § 4163.5. A template posted on the board's Web site in December 2007 provided an outline for submissions regarding the implementation date of California's e-pedigree law.

Mr. Room reminded the board that there are two criteria to consider with regard to making any decision to delay the implementation date. First, public protection is the board's highest priority and responsibility under Business & Profession Code § 4001.1, as it is for all boards within the Department of Consumer Affairs. Second, the board may act to delay implementation of the law if the board determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within California.

Mr. Room stated that the board may decide, based on the facts presented to the board, that additional time is required. The template document provided by the board made clear that a decision to delay can only occur if the industry as a whole, or a substantial proportion of that industry, will be unable to meet the 2009 deadline, and that developments between 2009 and 2011 would enable the industry to meet a new deadline of 2011. The board's only authority as set forth by statute is to either take no action and have the law be effective as of 2009 or take a vote of the board to delay implementation of the law until 2011. To delay implementation, the board must be satisfied that the delay would not harm the public interest or the safety of the public, and that the standards of Business & Professions Code Section 4163.5 have been met in terms of the two years (2009-2011) being significant to the development of the necessary electronic technology.

Mr. Goldenberg noted that he read the submissions from industry that came as a result of the board's template. He questioned why so few people from industry responded to the board.

Mr. Room said that the board members must ultimately determine whether the evidence presented satisfies the requirements of the statute. Board members must decide whether the submissions received are sufficiently representative of the breadth of the industry. Board members must determine whether they have heard from enough people in order to say that the evidence before them actually represents the industry's perspective on implementation

readiness. Board members must also determine whether individual presentations have the depth required by the statute, and whether they present sufficient factual evidence to justify a delay of implementation.

Mr. Room advised that the board is sitting as a fact-finder in an evidentiary hearing to determine whether those criteria set forth by the Legislature have been met. Only if those criteria have been met does the statute authorize the board to act to delay implementation.

Mr. Powers gave his perspective as a consumer. He thanked the groups who responded to the board's template with their written submissions, but noted that only three or four submissions conformed completely to the template and answered the questions fully. Overall, he was disappointed in the limited responses from other groups. He said that some groups did not appear to take the matter as seriously. He emphasized that the limited number of responses to the board was disappointing, considering an industry and profession dedicated to protecting the public and consumers.

Mr. Goldenberg echoed Mr. Powers' comments and expressed his disappointment in the limited responses. He emphasized that the board needs to understand the milestones that industry can present to the board regarding the 2009 implementation date. He strongly encouraged industry to be forthcoming with information.

Mr. Goldenberg stressed that the board needs to fully understand how consumers of California will be protected. He advised that testimony will be presented, and the board will need more than mere statements from industry that they cannot meet the 2009 implementation date. He reminded attendees that the board was giving industry and stakeholders the time and the platform to present critical information to the board.

Mr. Goldenberg stated that the pedigree law will provide the consumers of California every protection possible, and this protection will eventually spread beyond California. The board's current focus is to look at 2009, and cannot make a decision to delay beyond 2009 without convincing evidence and data. He reminded board members and those in attendance that the issue of drug pedigree had been discussed on a national level since approximately 1988.

Mr. Dazé reiterated that the board sits as a judge on this issue. He stated that he read the submissions provided to the board for consideration, as well as considering the previous presentations to the board. He noted that the information provided to the board consisted of conclusions that were not evidentiary-based. Mr. Dazé emphasized that the board wants to help consumers and industry, but the board's number one priority is to help consumers. He noted that technology exists for e-pedigree, and he is concerned by the reluctance for industry to make use of that technology. Mr. Dazé stressed that if industry cannot implement e-pedigree by 2009, providing only simple conclusions as occurred in many letters that the deadline cannot be met will not sway him to support a delay.

Mr. Hough stated that, as a consumer, he believes that prescriptions drugs enable seniors to live longer, better, and stay out of hospitals. Patient protection is the paramount issue. At the

same time, he reviewed the responses forwarded to the board members, and only two of the responders indicated they will be able to implement e-pedigree by 2009.

Mr. Hough recognized the urgency of protection of the consumer. He also said that the board must consider the free-market, free-enterprise aspect of the issue.

Dr. Ravnan expressed her disappointment with the lack of depth in the written submissions to the board as to why industry could not meet the 2009 deadline. She was also concerned with the lack of depth as to how industry would meet a 2011 deadline. Dr. Ravnan stated the board needs more information than had been provided.

Mr. Goldenberg noted that a few more than 40 letters were sent to the board, despite an industry that has thousands of people serving consumers of California.

A. Report and Action on Items Discussed at the Work Group on E-Pedigree Subcommittee Meeting of December 5, 2007

The meeting materials contained information summarizing the Work Group on E-Pedigree Meeting held on December 5, 2007. Minutes of that meeting, as well as copies of the PowerPoint presentations, were provided in the meeting materials.

B. Presentations to the Board on Electronic Pedigree Implementation

- Bob Celeste, Director, Healthcare, GS1 US, gave a presentation entitled, "GS1/EPCglobal Standards Update – State of Pedigree Related Standards and Adoption Efforts."

Mr. Celeste's remarks discussed on name changes that occurred within EPCglobal and GS1, an update on the state of the standards, and the state of adoption efforts in the U.S. related to GS1 and EPCglobal.

Mr. Celeste stated that EPCglobal is part of the larger standards body of GS1, an international standards body. He referred to his previous presentations during past 18 months speaking about pedigree from an EPCglobal standpoint, and now they come together under one banner for GS1 Healthcare internationally, as well as in the U.S. with "GS1 Healthcare US."

Mr. Celeste clarified that for global standards, GS1 Healthcare is the parent company. In the U.S., GS1 Healthcare US is dedicated to adoption of those standards in the U.S.

Mr. Celeste spoke about global standards and need for local support. His presentation included a graphic display of labeling of a pharmaceutical product called Pedia in a 5mg dose. He said the product's container was a good example of when standards "go wrong." The manufacturer of Pedia sells this product in many countries, resulting in six

different machine-readable codes. This results in frustration at the pharmacist level when trying to determine how to read the codes.

Mr. Celeste emphasized that choices need to be pared down in order to make compliance with regulations possible. He said that that is why they have been working with California, the FDA, and several other states in the U.S. regarding consolidation of markings as well as one pedigree standard.

Mr. Celeste provided an update on the pedigree messaging standard, noting that the pedigree standard was ratified in January 2007. The standards were built around all of the regulations available at the time, including the FDA, Nevada, and California. He also provided updates on item-level tagging, serialization, supply chain integrity, track and trace, and tag data standards. Mr. Celeste's detailed timeline was displayed in a chart. The chart was included in a copy of his presentation, provided as an attachment to these meeting minutes.

Ms. Herold noted that the discussion regarding inference was left at the initial stages at the last meeting of the E-Pedigree Work Group held on December 5, 2007. The board has not yet taken any action regarding inference. She noted that Bob Celeste provided information regarding inference on December 5th. Following that meeting, additional comments were provided to the board regarding inference, as part of the readiness template submissions. Ms. Herold stated that the board may still not have enough detailed information to move forward on that issue, lacking a good grounding of what industry needs and wants, other than statements requesting inference. She stated that the next Work Group on E-Pedigree Subcommittee scheduled for March 26, 2008 would include a discussion regarding inference.

- Mike Celentano, Associate Director, Supply Chain Systems, Purdue Pharma L.P, gave a presentation entitled, "A case Study in RFID-Based Serialization and Pedigree Preparation." Purdue Pharma is a privately held pharmaceutical manufacturer with several manufacturing and distribution facilities. Purdue produces prescription products as well as over-the-counter products.

Mr. Celentano summarized Purdue's pilot efforts in RFID tagging and serialization. He emphasized the importance of open and interoperable standards, particularly the UHF Gen2 standard.

He spoke about Purdue's efforts that began in 2004 with RFID-tagged OxyContin® tablets (UHF Gen1, Class 0). In October 2005, Purdue engaged in a pedigree pilot with SupplyScape and HD Smith. In June 2006, they converted to UHF Gen2 technology, added case-level tagging capability targeting all domestic bottles and cases of OxyContin®. In June 2007, Purdue started manufacturing and shipping products with UHF Gen2. They have tagged and data-collected over 1.3 million bottles to date.

Mr. Celentano spoke about what influenced their decisions about serialization. He noted different data carriers and standards:

| | | |
|---------|----------------|-----------|
| Item: | RFID UHF Gen2 | (SGTIN) |
| Case: | RFID UHF Gen2 | (SGTIN) |
| Pallet: | Linear Barcode | (SSCC-18) |

Mr. Celentano spoke about the guidance Purdue received from customers including McKesson, Cardinal, AmerisourceBergen, and Wal-Mart. Several graphics were displayed demonstrating UHF Gen2 item labels, in-line RFID label verification, case-read RFID portals, and RFID-tagged products. He also referred to their partners in serialization including Systech (packaging execution software), Motorola (readers, antennas, and RFID tags), Impinj (packaging line readers and antennas), Zebra (case label encoding and printing), and George Schmitt (label conversion).

In response to a question about whether Wal-Mart was an impetus to serialization, Mr. Celentano stated that Wal-Mart may have initially focused more on the consumer products. That may have been a bigger undertaking for them than the small complement of controlled substance providers engaged in a different forum.

In response to a question about fast-tracking the rest of their packaging lines, Mr. Celentano noted challenges to address including subcontractors packaging their products and the form-factor situation for various types of bottles.

Dr. Swart asked whether Purdue could mass-serialize in the next 18 months or two years.

Mr. Celentano said he would be cautiously optimistic about what they could achieve in the next two years on their remaining prescription products. He said they would struggle mightily to get products into the pipeline, even several months into 2009. He noted that building an e-pedigree platform and having it tested and interoperable with their trading partners would be a tall order.

Mr. Celentano stated that Purdue had achieved their planned objectives to establish RFID serialization for OxyContin® bottles and cases and collecting item, case, and pallet data relationships. They are now focusing on building an e-pedigree platform and evaluating a serialization path for their remaining prescription products.

Mr. Celentano emphasized that standards such as UHF Gen2 are emerging and helping to sustain forward progress, but integrating serialization for all prescription products is a significant undertaking. He asked the board to consider a delayed implementation date of January 2011 to address the remaining challenges and progress toward regulatory compliance.

Mr. Powers thanked Mr. Celentano for his presentation, and for Purdue's efforts to meet the deadlines established.

Mr. Goldenberg noted a template submission sent to the board from Activis that was a good example of detailed information regarding e-pedigree implementation readiness. The project timeline and risk profile developed by Activis showed an effort to provide much-needed information to the board.

Mr. Goldenberg also brought attention to a joint submission from CPhA, California Retailers Association, and NACDS. These organizations represent pharmacies, and they came together with a “single voice” speaking for pharmacies in California. Mr. Goldenberg thanked these organizations for coming together.

- Vince Moretti, Vice President of RFID Systems at Impinj, gave a presentation. He stated that Impinj is an RFID solution provider, and they have a complement of products to support that work. Mr. Moretti said that Impinj has been involved in a number of deployments during the last 18 months with several manufacturers.

Mr. Moretti spoke about emerging technology that will solve some of the challenges the industry is facing now. He said they have bundled a number of their products together to provide a serialization solution for manufacturers. Some of the products they make are chips, inlays that the chips go into, and specialized form factors to suit pharma and the challenges in reading through liquids, metals, and other dose forms. They also produce readers that communicate with the tags. Impinj has also introduced a set of antennas that connect to the readers and provide signals to the tags.

Mr. Moretti said that Impinj has been involved in the development of standards during the last four years, and was one of the leaders in generation of the UHF Gen2 standard. Impinj was the first to come to market with certified EPCglobal products. They also pioneered near-field, which provides a performance advantage at close range for hard-to-read items like liquids and solids. Impinj introduced those products to the pharmaceutical industry.

Mr. Moretti said that Impinj provided hardware readers, antennas, tagged chips, and expertise for Purdue during their deployment. He noted that Purdue’s deployment began at 100 bottles per minute, and now many packaging lines run two to three times faster than that. He said you do not want serialization of those products to slow down or affect the operating efficiency of those packaging lines. Bottles or labels racing by at the rate of 300 per minute requires state-of-the-art equipment and experts, which are in short supply at this time. He said that only a handful of people and equipment are currently qualified to produce reliable solutions.

Mr. Moretti said there are still a lot of details necessary to work out to get the reliability demanded from the pharmaceutical industry. A solution provided by Impinj is to get the operation off the packaging lines, which are the lifeblood of manufacturers. Impinj is able to take serialization off the packaging line by creating a “Commissioning Station.”

The Impinj Commissioning Station takes products coming off the high-speed packaging line that are placed into shipping cases, but not yet serialized. Then the case is put through the coding station, which encodes each of the items within the case at once. Then a case tag correlates with the items encoded within, creating a parent/child relationship. The commissioned case can then go into a palletizing station and be bundled into a pallet. Mr. Moretti said that this process “liberates the line.” Manufacturers can run their products as they normally do, except that RFID-enabled labels are on the items, which are later commissioned through the commissioning station to get them serialized. Instead of retrofitting all the individual lines, you can run them through as normal, then collect those shipping cases and run them through the stand alone centralized system (commissioning station).

Mr. Moretti provided graphic displays of products available from Impinj. He also provided a live demonstration of serialization on an Impinj Commissioning Station. The station included a conveyor belt and two antennas. He “wrote” a 96-bit EPC to each of the tags. He rolled a solid-dose form of a placebo product on the conveyor belt through the commissioning station. The product was provided by one of Impinj’s customers. A graphic display showed that tags for 72 items were written and showed the speed at which they were written. The tag-writing speed demonstrated during the meeting was at the rate of 800 tags per minute.

Mr. Moretti also provided a demonstration of blister packs of Dentyne gum. He rolled the case of Dentyne (two layers of the product in the box) through the commissioning station. The speed at which the tags were written was 883 tags per minute. The commissioning station used near-field antennas to give good performance, even in the presence of metals.

Mr. Moretti also provided a demonstration of liquid (placebo) products from one of Impinj’s customers. He rolled the products through the commissioning station, which detected 48 vials of liquids. The station was able to detect the products at the rate of 800 per minute. The demonstration also brought attention to one tag that “failed.”

In response to question, Mr. Moretti stated that the commission station “re-writes” all the tags each time they go through the station. Reading a tag takes less time than writing a tag, though both processes occur rather quickly. He said that Impinj has been working on this mass-serialization approach for approximately nine months to get it to a reliable stage of development. He said that this is emerging technology and Impinj is developing it with hopes of making it available for commercial deployment during the late second quarter of 2008. Impinj is working with several partners on pilot projects in the interim.

In response to a question about reliability of writing tags verses reading tags, Mr. Moretti stated that there is no inherent difference in terms of reliability between reading and writing tags. He said that Impinj is confident they can achieve reliable performance. Tags should be screened before being added to a container to remove any bad tag.

Mr. Moretti said that some converters provide tested tags with 100% “good” tags. A number of converters provide testing programs of tags.

Mr. Moretti said that deployment of a complex system could take 6-12 months, but if you stay off the packaging line, a system could be fully qualified and up and running in just 90-120 days.

Mr. Goldenberg asked if improvement in this technology would occur faster as a result of demand and competition.

Mr. Moretti responded that his “crystal ball” says this kind of technology will increase the rate of adoption and reduce other bottlenecks in the system. He noted two barriers, though; serializing reliably without disrupting packaging lines and making it scalable, and the data exchange standard (how data is exchanged and shared through trading partners). Mr. Moretti said he believes this new technology addresses the first part of the problem by serializing reliably without disrupting packaging lines. He also believes that if this technology is accepted and deployed by a number of people, then the technology will advance more quickly.

Mr. Moretti noted that their previous standard deployments consisted of an in-line approach to serialization. Their commissioning station came as a result of a research and development effort they were working on in the background, having seen the pain people were going through trying to get deployment at their facilities. The result is a solution that benefits manufacturers that have space challenges in their facilities. A separate commission station is also an advantage because it can be used by contract packagers for serialization off-line.

- Ilisa Bernstein, PharmD, JD, Director of Pharmacy Affairs, U.S. Food and Drug Administration, gave a presentation during the meeting via speakerphone. Her written remarks and PowerPoint presentation are provided as attachments to these meeting minutes. Dr. Bernstein’s presentation included the following remarks:

“We share the mutual goal of protecting patients by further enhancing the safety and security of our nation’s drug supply. Nearly four years ago, in February 2004, FDA’s Counterfeit Drug Task Force released a report outlining a framework for public and private sector actions that could further protect Americans from counterfeit drugs, including implementation of new track and trace technologies to meet and surpass goals of the Prescription Drug Marketing Act (PDMA), the Federal pedigree law. This framework called for a multi-layer approach to address the problem of counterfeit drugs and included the following measures:

- Secure the product and packaging of drugs
- Secure the movement of drugs through the supply chain
- Secure business transactions
- Ensure appropriate regulatory oversight and enforcement
- Increase penalties
- Heighten vigilance and awareness
- International cooperation

In order to implement these measures, the Task Force Report stated, among other things, that:

- Widespread use of electronic track and trace technology would help secure the integrity of the drug supply chain by providing an accurate drug “pedigree,” which is a record of the chain of custody of the product as it moves through the supply chain from manufacturer to pharmacy;
- Radio Frequency Identification (RFID) is a promising technology as a means to achieve e-pedigree; and
- Widespread adoption and use of electronic track and trace technology would be feasible by 2007.

I would like to note that it was supply chain stakeholders that told FDA during the comment period for the 2004 Task Force Report (Combating Counterfeit Drugs Report, February 2004) that widespread use of electronic track and trace would be feasible by 2007. We relied on their statements that systems would be in place and, as a result, we imposed a three-year stay on certain Federal pedigree regulations based on these assurances.

In 2006, two years after that report was issued, FDA conducted a fact-finding effort to determine how much progress had been made toward e-pedigree and electronic track and trace. As a result of this fact-finding, FDA issued an update report in June 2006 (http://www.fda.gov/oc/initiatives/counterfeit/report6_06.pdf). In summary, the agency's findings were that “although significant progress was made to set the stage for widespread use of e-pedigree in 2007, unfortunately, this goal most likely [would] not be met.” FDA did not issue a new forecast or target date for adoption of e-pedigree because we did not have enough information to do so at that time. We also stated in 2006 (Counterfeit Drug Task Force Report – 2006 Update) that we believe that “members of the drug supply chain should be able to implement e-pedigrees in the very near future.”

It was clear from this 2006 fact-finding effort that the voluntary approach that we advocated in the 2004 Task Force Report did not provide industry with enough incentives to meet FDA's timeframe for implementation of e-pedigree. The mere “risk” of the PDMA federal pedigree regulations being implemented was not enough of an incentive. Quoting from the 2006 report, we stated: “We continue to believe that RFID is the most promising technology for electronic track and trace across the drug supply chain. However, we recognize that the goals can also be achieved by using other technologies, such as two-dimensional (2D)-barcodes. Based on what we have recently heard, we are optimistic that this hybrid environment of electronic/paper and the use of RFID/bar code is achievable in the very near future.”

Also in the 2006 report, we urged manufacturers to take a risk-based approach to implement RFID and electronic track and trace by first tagging the products that are most vulnerable to counterfeiting and diversion, based on factors such as the sales price, volume sold, demand, ease of counterfeiting, and prior history of counterfeiting or diversion, among other things. We stated that if a company's products are not “at risk” of counterfeiting and diversion, then we would suggest the company choose its highest volume/highest sale drug(s) and start piloting an RFID and electronic track and trace program. The risk-based approach that we advocated was intended to be a way for companies to phase in electronic track and trace and e-pedigree, so it eventually covers all prescription drug products. We did not intend that companies use e-pedigree for only high-risk products, as some are now advocating. This was two years ago and, although there has been some progress, most companies are still in a “watch-and-wait” position.

Regarding mass serialization, FDA continues to believe that uniquely identifying product packages is a powerful tool to secure our nation's drug supply and is an essential backbone for e-pedigree and electronic track and trace, and find California's focus on this promising.

In 2004, FDA issued Compliance Policy Guide (CPG) 400.210, which describes how the agency intends to exercise its enforcement discretion regarding certain regulatory requirements that might otherwise be applicable to studies involving RFID technology for drugs; this includes RFID-triggered requirements related to reporting, current Good Manufacturing Practices (GMPs), Part 11 of FDA regulations, and registration and listing. The goal of the CPG is to facilitate performance of RFID studies and to allow industry to gain experience with the use of RFID technology and its effect on the long-term safety and integrity of the U.S. drug supply. This means that if a study is in compliance with all of the parameters in the CPG, FDA intends to exercise enforcement discretion by not initiating a regulatory action on the basis that the study fails to comply with any of the regulatory or statutory requirements of the Federal Food, Drug, and Cosmetic (FD&C) Act (and listed in the CPG) when those requirements are triggered by the use of RFID in the study--- for example, triggered by the use of RFID readers, the addition of RFID tags, or the placement of seals. This CPG is intended to facilitate the use of RFID and electronic track and trace. It is not intended to be an impediment. In November 2007, FDA extended the expiration of this CPG to December 31, 2008, at which time FDA will decide whether to amend, revoke, or further extend the CPG.

More recently, Congress gave FDA new tools to effectuate electronic track and trace and e-pedigree across the drug supply chain. Section 913 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), signed into law in September 2007, established section 505D of the FD&C Act. This section directs FDA to:

- 505D(b)(1): “prioritize and develop standards for the identification, validation, authentication, and tracking and tracing of prescription drugs.”
 - o This shall be done in consultation with manufacturers, distributors, pharmacies, other supply chain stakeholders, Department of Justice, Department of Homeland Security, Department of Commerce, and other appropriate State and Federal Agencies.
- 505D(b)(2): “develop a standard numerical identifier... to be applied to a prescription drug at the point of manufacturing and repackaging... at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug.”
 - o The standards shall be harmonized with international consensus standards to the extent practicable.
 - o The numerical identifier applied by a repackager shall be linked to the numerical identifier applied at the point of manufacturing.
 - o Develop these standards no later than March 2010.
- 505D(b)(3): The standards developed “shall address promising technologies, which may include (A) radiofrequency identification technology, (B) nanotechnology, (C) encryption technology; and other track-and-trace or authentication technologies.

Very soon, FDA will begin an information collection process to aid in our development of these standards. There are currently efforts underway that we are aware of, but there may be some that we are not aware of. We want to cast a wide net to ensure that the standards that we develop pursuant to 505D of the FD&C Act are the most practical, efficient, and effective standards in order to ensure a safe and secure drug supply chain in the U.S.

Although Congress set a March 2010 deadline for FDA's development of a standard numerical identifier, which FDA intends to meet, we cannot say at this point whether we will develop standards before this date.

The deliberate process that this Board is taking to implement the serialization and e-pedigree requirements under California law and its timeframes is impressive and has been very informative in our efforts as well. We support California's efforts in implementing these requirements.

FDA's vision of a safe and secure prescription drug supply chain is based on transparency and accountability by all persons who handle prescription drugs throughout the supply chain. We believe

California's law was enacted with a view to this same vision. Although FDA has not yet developed Part 505D standards, this should not hinder expeditious forward progress and momentum toward widespread implementation of serialization, electronic track and trace, and e-pedigree.

FDA will continue do its part in effectively enforcing the law, in conjunction with other Federal, state, and local entities, to protect Americans from criminals who attempt to undermine the public health by introducing counterfeit and diverted prescription drugs into the U.S. drug supply. At the same time, stakeholders must remain vigilant in their responsibility to provide safe and effective drug products to U.S. patients.

We stand ready to continue to work with the California Board of Pharmacy in our complementary efforts and goal to protect patients and make our nation's drug supply more safe and secure."

Ms. Herold thanked Dr. Bernstein for her comments.

Mr. Goldenberg also thanked Dr. Bernstein for her remarks. He asked her to comment on her work with stakeholders throughout this process. Mr. Goldenberg stated that the board has been faced with responses of "We cannot do it" and "It's impossible" regarding electronic pedigree readiness by 2009. He asked whether the FDA was subjected to the same type of responses from stakeholders during this process.

Dr. Bernstein responded that with respect to the information collection that the FDA did, the comments they received were, "We need more time" as opposed to "I can't do it." She continues to hear that more time is needed, though a lot of people have been working on the issue and there has been some progress. The progress seems to be slow, and some stakeholders are still watching and waiting.

Mr. Goldenberg asked whether the FDA had experience obtaining milestones or dates or activities-to-date and reporting that data back to the FDA.

Dr. Bernstein responded that in the fact-finding efforts for the 2004 report were conducted during 2003. She said a chart with different milestones was created and discussed for inclusion in the 2004 report. That led the FDA to believe that in 2007 there would be widespread use of electronic pedigree. Since that time, the only real milestones that Dr. Bernstein was aware of have been on the EPCglobal GS1 chart that shows different milestones for standards. Other than that, the FDA has not received any other timelines or milestones, despite their request for same.

Mr. Goldenberg expressed his gratitude to Dr. Bernstein and the FDA for sharing this information and their continued support to California.

Mr. Dazé asked if pharma (as an industry and PhRMA as a trade association) was part of the 2003 fact-finding when goals were set and milestones were developed.

Dr. Bernstein responded, yes.

Ms. Herold noted that there is confusion in the supply chain regarding products that have either an RFID tag or a serialized 2-D tag placed on a container. She asked whether that type of labeling change would trigger an FDA review versus an annual report review.

Dr. Bernstein responded that with respect to RFID it is described in the CPG. If a label, barcode, or RFID tag is placed on a label and it does not obscure any of the required information that must be on the label, it need only be submitted in the annual report. That is outlined in the CPG. She added that putting things on the label does trigger some CG&P regulations, so companies may have to have procedures in place pursuant to FDA's regulations in Part II.11. However, those would not have to be submitted to the FDA; they just have to have written procedures in place pursuant to their own CG&P practices.

Mr. Goldenberg asked Dr. Bernstein to comment about safety concerns, especially regarding large protein biotech drugs, and the use of a radio frequency waves on those drugs.

Dr. Bernstein responded that the FDA has undertaken some limited studies looking at how radio frequency affects certain biologics. The FDA is finishing that report, and hopes to share it with the board at their next meeting if it is available at that time.

Mr. Room asked whether the FDA anticipates that, as part of that report regarding radio frequency and biologics, the FDA intends to issue testing protocols or guidelines to manufacturers. He asked whether manufacturers could conduct testing internally that might satisfy the FDA with regard to stability of products under RFID exposure.

Dr. Bernstein responded that FDA scientists have already published the protocol they used for testing. She said it has been in literature for several months already. It is not a testing protocol; it is a protocol used by FDA scientists.

Dr. Schell asked whether consideration was given during the 2003 deliberations as to the consequences if the deadlines were not met. He emphasized that he was not suggesting punitive measures be taken.

Dr. Bernstein responded that the deadline they listed was voluntary. They did not have regulations in place that it had to be met by 2007. Because of the PDMA, they continued to put a stay on certain provisions related to the federal pedigree requirements in order for companies to use those three years to focus on electronic efforts. The FDA said that at the end of 2007 they would figure out what needed to be done. They subsequently lifted the stay on those particular pedigree regulations and let them go into effect, and the FDA was later sued based on one particular regulation. Most of those regulations are in place, but one particular regulation is the subject of a temporary injunction.

Dr. Schell reiterated his question about whether there are consequences for not complying with the regulations in force at this time.

Dr. Bernstein responded that there are provisions in the Food Drug & Cosmetic Act for violations.

RECOGNITION OF PHARMACISTS LICENSED WITH THE BOARD FOR 50 YEARS

Dr. Conroy presented the board's pin honoring Joseph Aboaf, a pharmacist who has been licensed for more than 50 years. She said it was a pleasure to congratulate Mr. Aboaf on his service in California as a pharmacist.

Dr. Aboaf stated that the reason he had made it so long was because he had missed every war. He said he was in the Army and went to Fairbanks, Alaska. It was 60 degrees below zero, but it was in peacetime. He further stated that he went to school at Vallejo Junior College and then the University of Montana. It cost only \$150 a year to go to school at that time. He will reach the age of 73 in two weeks. He feels active and healthy, and said he will never retire until he has to. He believes he is healthy because he works just three days a week. He said he worked in 47 different Costco locations over a period of 13 years, which was some sort of record. He thanked the board for honoring him.

C. Continuation of Presentations to the Board on Electronic Pedigree Implementation

- Heidi DeJong Barsuglia, California Retailers Association (CRA), and Steve Perlowski, National Association of Chain Drug Stores (NACDS), spoke before the board. Ms. Barsuglia noted that the CRA has been working collaboratively with NACDS and also with CPhA in addressing the unique pharmacy challenges regarding implementation of electronic pedigree.

Ms. Barsuglia said that CRA and NACDS represent all chain pharmacies operating in California. She referred to a letter dated January 9, 2008 submitted to the board jointly by CRA and NACDS. The letter was submitted on behalf of 30 collective chain pharmacy members and the members of the California Pharmacists Association.

Steve Perlowski, NACDS, said it has been a pleasure to work with fellow associations in California to get more of a local flavor than in Washington. He said that all of their help and insight has been invaluable as they move forward.

Mr. Perlowski thanked the board for the opportunity to present information. He said they share the board's concern for patient safety and patient access to medication. His remarks included a perspective on inference, grandfathering of existing inventory, and a request to extend the date for compliance of electronic pedigree to January 1, 2011.

Mr. Perlowski conducted a demonstration with Orriette Quandt from Longs Drugs. Dr. Quandt pulled individual packages of pharmaceuticals from a tote, and wrote (by hand) the lot numbers shown on each package.

The demonstration simulated a store-level receipt from a distributor where a tote contains a number of products from a variety of manufacturers. Mr. Perlowski stated that a typical pharmacy receives two or three totes filled with 200-300 packages in each tote per week. The demonstration showed a time-consuming method required to visually locate the lot number on each item, and then record each lot number by hand. This type of manual process is subject to human error, and diverts needed resources from patient care in the pharmacy.

Mr. Perlowski spoke about their confidence in the use of inference based on historical data and previous shipment accuracy and completeness by each manufacturer. He said that manufacturers are looking at several options for applying a serial or unique number to each drug. One proposed method is to apply a two-dimensional data matrix barcode to the package, and the other is to use one of the various RFID frequencies. Mr. Perlowski said that a limitation of the 2-D data carrier is that it requires line-of-sight in order to read the unique number.

Mary Staples, NACDS, joined Mr. Perlowski in a second demonstration. Ms. Staples pulled bottles one-at-a-time from the case, scanned the barcode on each bottle, and returned each bottle to the case. Mr. Perlowski said if they were not able to infer from shipping documents and case coding, they would be required to open every case as they receive it from the delivery truck. They would need to pull each bottle from each case, read the barcode on each bottle, and then return each bottle to each case in order to receive it into the distribution center. He emphasized the time-consuming process and resources that would be devoted to this process. He referred to a 6,000 percent increase in the number of unique products to be checked in at the time of receipt, based on receiving individual items rather than receiving cases. He said this increase in workload would require the development of a number of new processes, substantial additional head count, and the expenditure of resources. He suggested that these complex processes could increase the likelihood of theft and other security problems because each case would be opened and each prescription bottle would be touched.

Mr. Perlowski said the use of inference is an individual company's decision, but the practice should be allowed as long as received products are read and recorded before moving to the next link in the supply chain.

Mr. Perlowski spoke about grandfathering inventory that is already moving through the supply chain on January 1, 2009. He referred to research showing that doctors in California will prescribe approximately 6,000,000 prescriptions the week before January 1, 2009 and another 6,000,000 the week after January 1, 2009. In order for pharmacies to meet this anticipated demand, they will need fully-stocked shelves in order to serve the citizens of California. There are products in pharmacies today that will still be on shelves 11 months from now. Not all products sell on a regular fixed

demand pattern. A variety of factors beyond the pharmacy's control influence demand including doctors who prescribe and the formularies of pharmacy benefit managers that pay for drugs on behalf of patients.

Mr. Perlowski's remarks included a request to allow a two-year extension for compliance for inventories that exist as of the date of required compliance. That date would allow for products to be sold through the supply chain. He said it should apply to manufacturers, wholesalers, as well as retail pharmacies.

Mr. Perlowski also addressed the issue of industry readiness for implementation of electronic pedigree by January 1, 2009. He said that they have been looking at RFID technology since 2000 with the formation of the Auto-ID Center at MIT. They also worked with the FDA during 2003 on using RFID technology to deter counterfeiting of pharmaceuticals. He said they have also been involved in a number of pilot projects and research since that time.

Mr. Perlowski shared the results of a project called On Track. The study was conducted during 2006-2007 and involved five manufacturers, six serialized products, two distributors, and four pharmacy operators. The key findings of the study were part of the presentation, which are included as an attachment to these meeting minutes.

Mr. Perlowski emphasized that due to a lack of standards, multiple tag frequencies and reader protocols added significant complexity to receiving serialized product. They needed five different types of readers to read all six products included in the On Track project. He said that business processes need to drive the technology, instead of technology driving the business process.

Mr. Perlowski also spoke about other issues that pharmacies are already dealing with, including AMP. He stressed that the cost to comply with California's electronic pedigree requirement could translate into fewer pharmacies and reduced patient access to medications.

In response to a question about whether he was portraying himself as a victim instead of innovating, Mr. Perlowski said that his ability to influence manufacturers on technology choices is not significant. He stressed that they were absolutely involved in innovation and standards-development work.

Mr. Dazé asked whether NACDS was involved during the fact-finding efforts that occurred during 2003, and whether they stated at that time that they would be ready by 2007.

Mr. Perlowski responded that they were involved in the fact-finding efforts during 2003 and did not put an "end date" on it, saying the technology was not mature enough to be able to put a timeline on it.

In response to a question about an estimated cost of \$20,000 provided by Mr. Perlowski for one pharmacy to prepare for electronic pedigree, he said that that figure was "loaded" meaning it included training, hardware, and software.

Mr. Powers noted that the board supports the NACDS' concerns with AMP reimbursement for Medicaid patients. He stated that the board has taken a strong position on the issue, and sent a letter to the congressional delegation urging that there be changes. The board is concerned about the closure of any pharmacy in the state, and particularly pharmacies in rural communities.

Mr. Powers stated grandfathering and inference are not settled issues. The board is still discussing those issues and how they will be handled. He also noted that a statement was made that businesses should drive technology, instead of technology driving businesses. Mr. Powers emphasized that the health and welfare of the consumer is what drives the board. He said he believes the technology is here for implementing electronic pedigree, and the board will continue to support it as strongly as it can.

Mr. Room spoke about inference becoming less important if there is widespread RFID adoption. As an example, he referred to cases where there isn't 100 percent tag readability due to non-line-of-sight.

Mr. Room also spoke about the board's template, and asked what specific developments would occur between now and 2011.

Mr. Perlowski responded that in order for pharmacies to be compliant, they must receive compliant product. Given their economics to invest today in a particular solution, all of the training would be wasted getting their employees ready if pedigreed product was not coming down the pipeline. He said he believed one of the triggers would be to get the relationship between the manufacturer and distributor right. At that point, pharmacies will begin to work with distributors shortly thereafter. If compliance is required for everybody on day one, he did not believe there would be 100 percent compliance across 5,700 pharmacies as well as all the hospitals, clinics, and other dispensing points. He emphasized that distributors must receive tagged products so that retailers can work with the distributors in order to get that "next link" correct.

Mr. Goldenberg said if it is assumed that manufacturers and distributors will have RFID tags on the products, we still need retailers to demonstrate to the board a very specific timeline showing challenges they face, and the time needed to overcome those challenges for full implementation in retail pharmacies. The board requires that information now, not later.

Mr. Goldenberg noted that the letter submitted by CPhA, CRA, and NACDS makes good points, and he asked that their associations come together again to provide the board with information.

- Stephanie Feldman Aleong, former prosecutor in Florida whose activities were discussed in *Dangerous Doses*, testified before the board. Ms. Aleong currently serves as Assistant Professor of Law for Nova Southeastern University.

Ms. Aleong stated that her only constituency is the public. She emphasized the importance of a safe drug supply chain, and strongly encouraged the board to not delay implementation of e-pedigree.

Ms. Aleong gave her perspective, having worked on this issue since 2000. She said that promises were made in Florida prior to the 2003 Drug Protection Act. Some of the promises made were that industry was “working on it” and would have timelines, and would provide the type of evidence that California’s board is asking for. Industry eventually came back to Florida providing the state with what is now famously referred to as the “I can’t do it” memo, and nothing else.

Ms. Aleong said that California can’t wait for the drug industry to admit the threat to patients by the distribution system because of its past history and revelations that are coming to light. She also suggested that California does not have to wait to implement because there are companies poised, ready and waiting to meet the deadline. Ms. Aleong said that companies stand behind the fact that there is multiplicity of technology out there; therefore, they just can’t choose yet.

Ms. Aleong said that California cannot wait until the drug industry says it’s ready because it’s like waiting for a phone call that will never come. She noted that in the eight years she’s been involved with this issue, that phone call has not come, nor has a timeline. She noted that Purdue came closest today with the information they presented, but still concluded that they could not say when all of their product lines can be serialized. Ms. Aleong said the prescription drug industry has a history of never saying it’s ready. She referred to Ilisa Bernstein’s presentation that spoke about the Prescription Drug Marketing Act (PDMA) started in 1987, and passed in 1988. The PDMA had more than 10 stays because the industry said it wasn’t ready. The FDA accepted less than the evidence of when they would be compliant. She was relieved that California’s board was requiring the evidence needed to make a determination.

Ms. Aleong stressed that industry will not choose between the various technologies available until California’s board gives them a date. She supported California’s board in focusing on pedigree starting with manufacturers and serialization. She recalled meetings on Florida’s Drug Prescription Act of 2003, and heard industry make assurances they would be ready and the technology is there. They shook hands with the Attorney General’s Office as everyone agreed on the implementation date of July 1, 2006. Later, Florida rolled back its pedigree requirements because industry said they just couldn’t do it. They provided no timeline and no proof of efforts. The scant pilot projects that existed prior to 2006 were work products and “privileged” and neither their results were shared or any timeline given.

Ms. Aleong recalled a conversation outside the Senate Judiciary Committee when she begged Florida's Senate Judiciary Committee to not delay. A representative from the manufacturers wrapped her arm around her and said, "Sweetie, you just don't get it. The wholesalers are our consumers, not the patients."

Ms. Aleong stressed that California's board has a commitment to patient safety, and is the one entity that has the patient first in mind. She said she understands business reality, which is why she has come forward with evidence that companies can comply. First and foremost, however, if there is no evidence that a delay will protect patient health, California's board will violate its statutory mandate by delaying.

Ms. Aleong referred to recent media coverage of the problems of drug safety. While industry has not admitted there is a problem, California has tasted the sting of that problem first-hand. She referenced a Key 10 action because Medicaid funds are being robbed blind by drug diversion. California is listed as the first listed state in the Key 10 action. Merck pharmaceutical products were diverted, as were vaccines for rubella, chicken pox, measles, and mumps. California's children were the victims of that diversion. The other victims were the taxpayers because Medi-Cal was paying.

Ms. Aleong said she has heard profits will be lost to implement pedigree, but state Medicaid programs could afford to subsidize those pharmacies, had they not suffered those losses in diversion. The financial reality of imposing tougher regulations far underweighs the financial loss every state is suffering now due to diversion.

Ms. Aleong supported item-level serialization. She also noted Biogen and their plan to be ready several months prior to California's deadline of January 1, 2009. Patient safety will not be enhanced by delaying implementation of e-pedigree. Ms. Aleong stated there is no lawful reason for delay, and we should not wait for the FDA's promise of standards in 2010. She referred to the FDA as a source of delay. She is grateful that the FDA supports California's efforts, but California is leading and the FDA is following.

Ms. Aleong also spoke about inference, and that it has no place in a secure drug supply. She understands the plight of the pharmacist, having taught at a college of pharmacy, and she talks to pharmacists on a daily basis. She tries to help them understand that inference is what led to patient death and injury. In Florida, paper pedigrees were verified by inference, and looking to see if cases had visible signs of tampering. That process led to fake Epogen and injured patients. Grandfathering may be an issue for the board to consider, but she suggested a timeframe of no more than one year to move product off the shelves and help prevent disruption of supply to patients.

Ms. Aleong emphasized that a commonly used standardized data carrier will be driven by California's board, not by industry. Industry will only choose a data carrier when they are told they have to. Delay is one thing that unites industry, not a standardized data carrier. Ms. Aleong said that California's board has done far more than Florida's board or the FDA did with a commitment to the presentation of evidence.

Mr. Dazé asked about the groups that committed with a handshake that they would be ready in Florida in 2006. He asked whether those companies were represented at today's meeting.

Ms. Aleong responded that the major wholesalers present at that time included McKesson, Cardinal, and AmerisourceBergen, as well as the trade group PhRMA. She further stated that the 2006 compliance date came as a result of a negotiated process; it was not selected by the State of Florida. Negotiations took place in 2002 for the 2003 Prescription Drug Protection Act in Florida.

- Jim Dahl, National Biopharmaceutical Security Council (NBSC), gave a presentation entitled "Criminal Investigation & Patient Safety, E-PEDIGREE SOLUTIONS." Mr. Dahl stated that the NBSC is a non-profit organization composed of security professionals in the industry. He said the purpose of the NBSC is to identify global security issues, protect patient safety, increase exchange of information, and discuss best practices. On behalf of NBSC, Mr. Dahl applauded California for leadership in this area.

Mr. Dahl spoke about patient safety and his prior experience in executive level positions including the FDA Office of Criminal Investigations (OCI). He supports e-pedigree as a tool to attack drug diversion and counterfeiting. He spoke about supervising criminal investigations for hundreds of drug diversions and counterfeiting cases throughout the U.S. He said his position, as well as that of OCI and the NBSC, is that drug counterfeiting is not just an economic crime; it is a violent crime like any gun offense, narcotic drug offense, or carjacking. He said that congress chooses to treat the offense as a minor crime, with only a three-year penalty. Mr. Dahl stressed that diversion of drugs creates an infrastructure that facilitates the easy introduction of counterfeit (and other) dangerous drugs. He noted that OCI has never seen a counterfeit drug enter the otherwise legitimate supply chain without the pre-existence of a diversion scheme. He emphasized that diversion is the key to the introduction of counterfeiters.

Mr. Dahl stated that "e-pedigree" on its own, without the requirement of serialization, would greatly improve patient safety. He said paper pedigree is a good starting point to prevent reconstructing pedigree through surveillance, search warrants, subpoenas, interviews, and document analysis.

A graphic display was shown as part of Mr. Dahl's presentation demonstrating an example of an e-pedigree record. The record did not show serialization of the product represented by the pedigree, but the data fields and their inter-relationship become a complex set of data, creating a significant barrier to diversion. Mr. Dahl stated that if a counterfeiter cannot get a pedigree, then he can't introduce the counterfeit product into the market. Mr. Dahl spoke about transaction-level serialization, which he said would work to stop diversion and counterfeiting. He said the hallmark of e-pedigree is the prevention of counterfeit drugs from entering the system, which is the primary goal.

Mr. Dahl referred to Katherine Eban's book *Dangerous Doses* as a classic case in that legitimate drugs were moved out of the supply chain, manipulated illegally, then returned to the supply chain and sold. He believes that e-pedigree would have prevented those transactions from occurring. He also gave an example of the drug recall and drug counterfeiting case of Lipitor. Criminals exploited several weaknesses in federal law; the scheme included smuggling, commercial bribery, kickbacks, violations to the Food Drug & Cosmetic Act, phony documentation, and allowed plausible deniability by co-conspirators. He further stated that an attitude of "Don't ask, don't tell" was accepted by secondary people handling the product.

Mr. Dahl said it was less important to know the number on a bottle instead of verifying and authenticating the chain of custody of a drug, and that e-pedigree documents are the primary and most effective anti-diversion and anti-counterfeiting tool. He recommended that California move forward with implementation of e-pedigree in 2009, even if implementation from item-level serialization can or will be postponed. Mr. Dahl suggested that the board's inspectors may not have the hardware and software to do their job at the time the law is implemented. He questioned whether the board's field staff would have the training necessary as well. He also questioned whether patients would be able to get drugs at the time of implementation and if patients would go to pharmacies across the border to get their drugs. He also questioned whether direct mail and the Internet's anonymous characteristics would cause other problems.

NBSC's recommendations to the board were included as part of Mr. Dahl's PowerPoint presentation, which are attached to these meeting minutes.

Mr. Hough spoke about drug diversion and counterfeiting being a violent crime, and suggested that were a lot of repeat offenders. He questioned what could be done to increase the criminal sanctions against people who commit those crimes.

Mr. Dahl responded that one of the recommendations of the FDA's Counterfeit Drug Task Force Report was to have stiffer penalties for drug counterfeiting. However, he has not heard any FDA official testify in congress that they want a 10 or 20-year penalty. He suggested that the FDA alludes to increased penalties, and they support state actions, but they don't get anything done on that issue. He added that mail fraud is a 20-year felony, as is money laundering, and they usually go hand in hand.

- Jack Henderson, SICPA Product Security, stated that SICPA has been keeping an eye on California's requirements. He said that, at this time, he did not have a position and was not certain whether there could be full compliance or not. However, as a product security organization, they have noticed that secure track and trace systems have been implemented that parallel or offer similarities to California's requirements.

Mr. Henderson stated that SICPA is a world leader in product security, brand protection, and secure track and trace systems. SICPA is a research-based company dedicated to technological development. Mr. Henderson emphasized that SICPA is a product

security company first, not necessarily a technology provider. They operate with discretion as a trusted advisor to central banks, governments, and intelligence agencies. The heritage and the nature of SICPA is that what they do stays between the brand owners that they work with and the countries that they work with.

Mr. Henderson referred to track and trace they provide, meaning “secure trail,” not track and trace programs as a logistics tool. SICPA uses both secure and invisible codes for product protection. Mr. Henderson noted there are multiple stakeholders on the pedigree issue, and everyone has a different position. He found that associated costs will be reduced with standardization and everyone can start working together. Mr. Henderson spoke about case studies in California, including one involving diverted tobacco product entering the wholesale supply chain. He said the state was losing \$600 million annually as a result of that diversion. Mr. Henderson said that SICPA worked with the state putting together a SICPA-hosted, real-time data management system acting as a repository, with various data capture points throughout the supply chain. Under a state contract, SICPA monitors the usage, the audits, and investigative reports. An invisible code, rather than a 2-D barcode, was used for security. They now have 100 licensed California distributors that have implemented this program.

Mr. Henderson also spoke about a program implemented in Turkey, whose size is almost twice that of California. SICPA installed a secure automatic tracking and production control system for tobacco, alcohol, and beer. It was installed on the manufacturing packing and filling lines, putting everything in a central data-management system. The project included both direct on-pack coding and pre-coded stamps. They faced challenges in the project including 120 different tobacco packing lines, 51 alcohol filling lines, and 28 beer-filling lines (can and bottles). The project was implemented in a six-month timeframe, and required a lot of different parties to cooperate. A short video was presented demonstrating SICPA’s tracking and production system in Turkey.

Mr. Henderson concluded his presentation by stating that “California-scale” secure track and trace systems exist and are already operational. He stated that standardization reoccurs as a theme, and integrated systems offer economies of scale. He further stated that SICPA could provide an integrated multi-layered drug security system for less than five cents per product, and could be built on open standards.

In response to a question regarding the cost, Mr. Henderson stated it would cost 5 cents per-package, whether the product was a blister pack or a bottle.

- Graham Smith and Gary Noon, Aegate, gave a presentation to the board. Mr. Noon referred to Aegate’s participation in the December 5, 2007 Work Group on E-Pedigree.

Mr. Noon advised that Greece, Italy, and Belgium have completely mass-serialized their drug products. Aegate is actively working in those three countries authenticating products in pharmacies. He said the focus of their system is not a pedigree system. They looked at their objective, which was to protect patients. They used the people

most responsible in the drug channel for looking out for patients, pharmacists. Aegate gave pharmacists tools to help them prevent counterfeit drugs from reaching patients. They also built things into the system that help pharmacists, including a recall service by lot numbers, and expiry date check. Mr. Noon noted that Aegate's system captures mass-serialized codes as manufacturers put them on the individual sales packs. The codes on each pack are stored in a central database. When the pharmacist scans a product in the pharmacy, the system will (in approximately 300 milliseconds) determine whether that product is "real" or expired, or recalled.

Graphic displays in Aegate's presentation included images of a Greek pharmacy. One image demonstrated identification of an expiry date when scanning the product. Mr. Noon emphasized that there is no legislation on pharmacists in Europe to use this system. Pharmacists use the system because professional bodies in those countries see it as best practice for pharmacists. They have also done stock management systems, and these services augment the work that pharmacists do.

Mr. Noon noted they recently began implementation of their system in Italy, which has a similar population to California. Approximately 260 million tags of mass-serialized product are stored in their system. By the end of 2007, 8 million authentications had been performed, resulting in 1,325 recalled products that pharmacies may otherwise have given to patients. They also prevented 138 expired products from reaching patients, and issued 2,087 short-dated warnings. They have not identified any counterfeit products in their systems thus far. Mr. Noon stated that pharmacies have found their system very useful. The system is doable and available.

Mr. Smith stated that information they captured relating to e-pedigree requirements and the authentication model will be available in a report form presented to the board later. They considered different options, which will be detailed in their report. Aegate proposed that authentication at the point of dispense provides important patient safety. Authentication combined with case-level pedigree and inference can meet the requirements of existing legislation. Mr. Smith said Aegate sees authentication as a viable, timely, and complementary approach, and said it is readily available.

In response to questions from Mr. Goldenberg, Mr. Noon stated that serial numbers of stolen products would be quickly uploaded to their database, so that pharmacists would be aware that the products were stolen.

Judi Nurse, Supervising Inspector, noted that authentication would not address the investigative issues. Authentication would not show where a drug had been in the supply chain, so it would be a problem for enforcement. Ms. Nurse acknowledged that authentication would be one step closer to patient safety.

Mr. Noon responded that if you combine case-level pedigree and authentication, you could logistically secure the drug supply channel. You will be able to stop suspect drugs from reaching patients.

In response to questions about timeframes, costs, and multiple software vendors, Mr. Noon stated that pharmacists are charged nothing to provide this service. Data management is provided to manufacturers to protect their brands and they pay a service fee for the number of tags put on their system; it is inexpensive. He said there are 25 pharmacy systems in Europe using myriad different languages including Flemish and French. Building a system to work in a pharmacy is not a problem; their biggest challenge in Europe is that many systems in pharmacies have the older Legacy systems. More modern systems upgraded in approximately one month.

Mr. Dazé asked if the 18 manufacturers that Aegate is working with are serializing all of their products.

Mr. Noon responded yes, but authentication can be up and running more quickly than building a system for a complete pedigree.

Mr. Room spoke about some of the differences between the U.S. and European market. For example, manufacturers in Europe produce patient-pack sizes whereas U.S. markets typically do not. In the U.S. packages are often re-packaged, so it would require a level of serialization beyond what is required in Europe.

Mr. Noon concluded that authentication is not pedigree. It is an addition to pedigree, enhancing patient safety. He suggested authentication would make pedigree simpler to implement. If California's board needs to go down the pure pedigree route, there is no need for Aegate to present again. Pedigree will achieve most of what California wants it to achieve, but authentication could help drive compliance to California's requirements.

- Kathy Lynch, Esq., spoke on behalf of the California Pharmacists Association (CPhA). She said CPhA is the only voice for independent pharmacists. Ms. Lynch emphasized that CPhA members have issues with the current e-pedigree legislation regarding timing, equipment, space, budget, training personnel, and upstream partners. She stated that pharmacies do not have the resources to invest in scanners and equipment, and they do not know what they need. For example, they've been given various costs for scanners, and they may need more than one scanner (one for 2-D and another for RFID). Estimated costs to get one store up and running could be as high as \$20-30,000.

Ms. Lynch also spoke about inference, grandfathering, and the fact that pharmacies rely on their upstream partners. She asked that the board consider granting a one-year extension beyond the compliance deadline, so that pharmacies can fully prepare for enforcement of e-pedigree. Ms. Lynch referred to the previous demonstration when Dr. Quandt was identifying lot numbers from products in a tote. Ms. Lynch suggested that inference of all the products in a tote would enable a pharmacist to devote more time to taking care of their patients. They could scan the label off a tote, instead of each individual label on each item.

Mr. Powers suggested that if the individual products were RFID tagged, the process could have been completed more quickly.

Ms. Lynch emphasized that pharmacists want to comply with the law. Other issues including AMP, state budget cuts, tamper-resistant prescription pads, new labeling requirements, and Medicare Part D are important issues that pharmacies must deal with as well. She thanked the board for hearing the concerns of CPhA members.

Mr. Goldenberg acknowledged that for pharmacists to be able to read and receive pedigrees that those handling product before them have to start running. He asked that CPhA and their partners encourage manufacturers to get this done.

- Jennifer Fitzgerald and Lewis Kontnik spoke on behalf of Amgen. Ms. Fitzgerald stated that she handles state government affairs for Amgen. She thanked the board for the opportunity to speak on this issue. Ms. Fitzgerald stated that Amgen takes the issue of counterfeiting seriously, and they are working diligently to see that all Amgen products sold in California comply with the state's serialization requirements. She further stated that meeting the 2009 deadline is not possible. Ms. Fitzgerald asked that the board make a decision at this meeting to delay implementation of e-pedigree.

Some of the information provided during the Amgen presentation included remarks that the 2004 pedigree law had no opposition. Ms. Fitzgerald stated that the legislative record shows that there was no opposition to that original pedigree law. Ms. Fitzgerald stated the language of the original pedigree law required drugs to have an electronic pedigree showing each change in ownership, and referred to "number of containers" and "lot numbers." She said industry distinguishes pedigree from serialization.

Ms. Fitzgerald stated that Amgen was prepared to comply with the 2004 law, and committed more half a million dollars to that effort. In 2006, the pedigree law changed and was significantly altered. The requirements now specify an interoperable system with unique identification number (serialization added) at the smallest package level. Ms. Fitzgerald's remarks emphasized that compliance does not equal patient access to medicines. A graphic display was presented showing a timeline of Amgen's anticipated compliance in 2011. Ms. Fitzgerald stated that in order to comply with the 2009 deadline, Amgen would have to go into crisis mode. She further stated that patients in California might not have access to their lifesaving medications as a result.

Mr. Kontnik reiterated remarks made by Ms. Fitzgerald. He said that Amgen takes the issue of counterfeiting seriously. Amgen was the unwitting object of what was covered in *Dangerous Doses*. Amgen staff worked with OCI and the State of Florida in detecting the counterfeiters and putting them in jail. Mr. Kontnik said that Amgen did detailed investigation resulting in a roadmap for compliance. They developed a path showing they should be able to meet the 2011 date. Amgen's PowerPoint presentation and timeline is attached to these minutes.

Mr. Kontnik stated that if they must meet the 2009 deadline, they would have to plan for a crisis, fire-drill scenario. They prefer to put their energies into meeting their 2011 roadmap, instead of putting in non-validated systems. Mr. Kontnik suggested that the resulting manual desegregation, relabeling, scanning, and re-aggregation of products could produce shortages of medicines for patients. He gave an example of injectible products stored in freezers stored between 2-8 degrees centigrade. He said that people wearing mittens would have to put 3/8-inch stickers on packs of medicines and hoping that they don't make a mistake in the process. He suggested that the implementation date of 2009 could impair the availability of drugs for patients with cancer.

Mr. Kontnik said he believed the board would delay implementation. He said it was a waste of energy to focus on whether 2009 or 2011 would be the deadline. He concluded his presentation by stating that the board should allow them to get on with their job of technically implementing, instead of fighting over suspension of the date.

Mr. Dazé asked whether Amgen products were sold in Greece, Italy, or Belgium, and whether those products are serialized.

Mr. Kontnik responded yes, Amgen sells products in those countries, but they have different serialization aspects. For example, cases are serialized with stamps bought from the government. In other cases, he does not know how serialization is performed, but he said he would get back to the board on that issue. He also noted that Aegate has a closed system without pedigree, which is not what California's law calls for.

Mr. Goldenberg said he respected Mr. Kontnik's professional commitment to this issue, including his efforts prior to his work with Amgen. He asked if Amgen could propose to the board a consequence for companies that do not comply with the requirements. Mr. Goldenberg emphasized that no one wants to see the drug supply in California disturbed, but they also do not want efigen or Lipitor or other counterfeit drugs to result in body-count legislation.

Mr. Kontnik said he was not a senior officer in Amgen and could not make a commitment on their behalf. He could, however, say that patients in California would be put at greater risk from lack of access to live-saving drugs by sticking with the 2009 date. He asked that board to let them get on with their work instead of spending their time getting ready for another board hearing in April 2008.

Mr. Goldenberg noted that the board needs to fully understand how to break the cycle of the repeated promises to comply going back 20 years. He did not feel that the people of California would want to continue to hear that either. The board is here to enforce a law that has been passed, and veiled concerns about drug supply interference and people applying tags in freezers does not support that effort or protect patients.

Ms. Herold responded to remarks made by Ms. Fitzgerald regarding legislation in 2004. She said there was opposition to the bill, and the bill was amended to remove it. From the beginning, the board has been clear that the board intended product-level

serialization. In May 2006 the board added amendments to the legislation to provide clarification. Why someone either opposes or doesn't oppose a bill is a judgment decision during the time a bill is going through. Ms. Herold added that the board spent considerable time negotiating amendments in both July 2004 and in 2006. The record shows no opposition because the board worked to remove it.

Ms. Herold also noted the board is part of the Department of Consumer Affairs (DCA), whose mandate is consumer protection. If the board is to be educated about the law and why it cannot be implemented, that discussion has to be done in public session, not one-on-one with a board member. Consequently, board senior staff is available to meet with stakeholders. If there is something to communicate to the board, the board has established a template to put it in writing, and offers two public meetings each quarter to say it to the board members.

- Shawn Brown spoke on behalf of the Generic Pharmaceutical Association (GPhA). Mr. Brown thanked the board for the opportunity to present because GPhA and its members consider patient safety their highest priority. He said that GPhA has been active and affirmatively supportive of multiple anti-counterfeiting efforts at the state, national, and international levels. Mr. Brown said that GPhA agrees with the underlying intent of California's pedigree law. He wanted to note, however, that in Florida law and the Prescription Drug Marketing Act, pedigree didn't start with the manufacturer. When referring to the history of this issue, that distinction should be made clear to everybody.

Mr. Brown referred to the information provided to the board that conformed to the template. The information they provided was as much as they can provide at this point. They have an ongoing study and analysis they intend to present at the March 26, 2008 meeting of the Enforcement Committee. Mr. Brown noted that counterfeiters generally do not target generic medicines because there is little financial incentive. However, GPhA is committed to maintaining a secure supply chain and eliminating the threat of counterfeit medicines. Mr. Brown spoke about their members seeking practical ways to implement an interoperable serialized electronic pedigree system.

Among the activities GPhA has been involved in during 2004-2006 include selecting and implementing solutions for e-pedigree, supplying Wal-Mart with package-level serialized products for a subset of SKUs, soliciting proposals for packaging line and other hardware modifications. They have also been developing pilots with contract manufacturer distributors and large retailers, conducting studies of optimal placement of RFID tags and determining the best RFID tags available for specific applications. Mr. Brown emphasized that while the generic industry has made progress developing anti-counterfeiting measures, implementing serialized electronic pedigree for all products is a daunting challenge. He said that aside from the considerable costs involved, which may be insurmountable for some generic manufacturers, there may be practical barriers to establishing serialized electronic pedigree. Standards have been developed, but there is no interoperable system that supply chain stakeholders can agree to support. Mr. Brown suggested there is a lack of industry guidance and the technology has not

been tested and validated in large-scale operations and among trading partners. Manufacturers are reluctant to invest in an approach when uncertainties persist.

Mr. Brown stated that GPhA and its members believe that extending the deadline for implementation is a necessity. They believe it will allow the FDA to carry out its mandate to develop standards, and identify and validate effective technologies for the purpose of securing the supply chain against counterfeit drugs. He also noted that it is in the interest of protecting public health to prevent disruptions in the drug supply.

A question to Mr. Brown referred to a sentence in their letter submitted to the board dated January 9, 2008 stating, "With a full assessment of this data GPhA's members cannot guarantee compliance even by January 1, 2011."

Mr. Brown confirmed that statement, and added that there is no interoperable system in place, which is required by the statute. Until an interoperable system is agreed to among all stakeholders, there is no way to give a timeline.

Dr. Schell commented that after his review of the letters submitted to the board, as well as the verbal testimony provided, he questioned what barriers exist that prevent stakeholders from agreeing to a common solution.

Mr. Brown responded that there are potential anti-trust violations in agreeing to a particular business solution.

Mr. Goldenberg added that Mr. Room has offered his assistance to the industry to look at the anti-trust issue.

Mr. Room said no one had yet provided information to him related to industry opinions.

Mr. Brown said he received advice on anti-trust, but was not at liberty to share because GPhA wasn't the only party involved. He asked for regulatory guidance from the board.

Mr. Room advised that that GPhA and PhRMA have offered to share opinions that they have received from counsel regarding what can and cannot be discussed. He added that if his office or the board could do anything within those confines to help so that discussion would be less likely to cross boundaries, they would explore that issue. But first, they must get the parameters or obstacles as they have been identified by counsel.

Mr. Graul noted that GPhA is saying they cannot meet the 2009 deadline because there is no agreement in the industry over a common technology. He asked if no one is willing to invest until there is agreement over a common technology.

Mr. Brown responded, no. Generic manufacturers invested in pilots using different technologies, but there is no "one" universal technology solution agreed to.

Mr. Graul noted that GPhA also has not committed to a 2011 deadline. He asked what assurance they could give the board that industry would ever comply.

Mr. Brown responded that all generic manufacturers want to comply with the law, but it is an issue of practical limitation. He could not state how long it would take to integrate an interoperable system into their processing and manufacturing systems. He acknowledged that moving the deadline would not guarantee they would be compliant in 2011.

Mr. Powers referred to the FDA's stance that, without incentives, not much will happen. He suggested that moving the date out would actually slow things down.

Mr. Brown disagreed with that assessment. He added that the 2009 deadline was an incentive, but moving the date to 2011 would not change the incentive.

Mr. Goldenberg thanked Mr. Brown for his presentation, and emphasized that he has a significant position in the distribution chain.

- Marjorie Powell spoke on behalf of PhRMA. She stated that their members develop new medicines, and get them to market. Ms. Powell asked the board to note that manufacturers were not part of negotiations in Florida, as pedigree did not start with manufacturers. She stated that PhRMA cannot make commitments for its member companies to comply with any given date. Therefore, that type of discussion would not have occurred with legislators in Florida. She also wanted to clarify that in meetings with FDA during 2003, written comments from PhRMA were provided to the FDA citing a number of technical issues involved in developing an electronic track and trace system. Those issues included technological, legal, regulatory, and financial issues, and PhRMA believed it would take a minimum of five years to work through those issues before industry could consider an electronic track and trace system.

Ms. Powell emphasized that it is not PhRMA's policy to make commitments for their member companies, in part, due to anti-trust laws. She noted a conversation with the liaison counsel to the board, Mr. Room, about whether there was anything the board could do to provide a safe harbor for member companies to get together and agree on a particular technology. She said she received a letter from a national law firm regarding the subject of federal anti-trust laws. She said the letter advised that they could find no basis by which the board could provide manufacturers with protection from anti-trust litigation by the Department of Justice, state Attorneys General, or by state and county prosecutors, or individual companies. Ms. Powell stressed that, as a trade association, PhRMA has an obligation to make sure their members do not get together and select a technology in any given area. They are working on a wide variety of things including standards development and pilot projects with companies in the supply, and regulations.

Ms. Powell noted that her doctor asked her to lower her blood pressure. Despite that request, she did not lower her blood pressure by her subsequent appointment. She

likened that to things that just cannot be pushed any faster than they can move. Ms. Powell acknowledged that California's deadline has pushed development of the technologies and provided a variety of options to manufacturers. She noted that technology is emerging, and she urged a delayed implementation date beyond 2009.

Mr. Dazé asked a question relating to PhRMA's comments to the FDA in 2003. He added that it appears that companies are no further along in January 2008 than they were in January 2004. He asked how pushing the date to 2011 would guarantee that the citizenry of the State of California would be more protected than they are now.

Ms. Powell responded that the comments were that it would take a minimum of five years to resolve the technological, regulatory, legal, and financial issues involved in developing an electronic track and trace system. She did not agree with the comment that industry was in the same position today as it was in 2004. She referred to testimony of companies that have serialized products, and other parts of the distribution chain that are part of pilots looking at how to communicate that information. She also referred to vendors who are developing data systems to manage the transfer of information, demonstrating that we are infinitely further along than in 2004.

Mr. Dazé noted that presentations to the board contained many limiters such as "maybe" and "if" and "possibly" regarding compliance. Those limiters concern the board because the board's obligation is to ensure that when patients give a prescription to a pharmacist, the product they get back is what the doctor ordered and that which is indicated on the label. He emphasized that he had not heard anything that would justify a delay in implementation beyond 2009.

Dr. Swart asked what percentage of PhRMA's members would have serialized products, particularly high-risk products, in the pipeline by 2009.

Ms. Powell did not know whether each company would have a high-risk product serialized and in the pipeline by the current deadline, though a phased-in approach may be workable. It would allow companies to put their resources into those products that are at most risk for counterfeit.

Dr. Conroy noted that a phased-in approach would be problematic at the wholesale level because they would have to have controlled substance lines, pedigree lines, and non-pedigree lines. Problems would also occur in pharmacies because people would have to be trained on which items to check the pedigree on.

Ms. Herold added that a drug manufacturer attending this meeting has an agreement to sell its product directly to pharmacies because there is a counterfeit risk. That manufacturer provided Ms. Herold with a letter indicating their product had been found in a pharmacy that they did not have an agreement to sell to. Sole distribution agreements do not always prevent drug products from going sideways. The board will investigate that pharmacy to determine how they came to have a drug product that it should not have.

- Edward Rickert spoke on behalf of Sagent Pharmaceuticals. He referred to a letter submitted to the board on January 9, 2008, but he did not see it in the materials for this meeting. Mr. Rickert noted that Sagent's product line includes generic pre-filled injectible syringes. The company has not been in the marketplace very long, though they are taking the pedigree issue seriously. Sagent has been working to comply with Florida's pedigree and other states that have passed various legislation. Mr. Rickert spoke about various problems Sagent is facing trying to get into compliance with California's requirements by 2009. Sagent is concerned about the lack of standards and being an early adopter, and the effect that might if they make the wrong choice.

Sagent worked with 2-D barcoding technology, and has been working with consultants and attorneys to help them figure out what they need to do. Mr. Rickert thanked the board for posting FAQs, which addressed some questions they had. Now they have better direction about saleable units verses individual syringes. Mr. Rickert noted the biggest challenge they have is contract manufacturers. As a small generic company, they have a number of networks of contract manufacturers. They have products that are nearing approval by FDA, and will likely be approved during 2008. Their discussions with contract manufacturers are causing concern for Sagent because those manufacturers are either not willing to comply with the 2009 deadline, or will not be able to comply. Manufacturers are giving estimates running from 38-64 weeks to install, integrate, validate, and execute shipping studies on 2-D technology.

Mr. Rickert said Sagent has asked the board to make a decision to extend the deadline. Short of that, they ask the board to give serious consideration to grandfathering of products that are already in the pipeline as of January 1, 2009. They also supported the idea of a phased-in approach. Mr. Rickert also noted that generic products are less likely to be counterfeited than the higher-priced high-ticket products out there.

Mr. Dazé asked whether Sagent would be ready given a deadline delayed to 2011.

Mr. Rickert said that, as outside counsel for the company, he could not make that guarantee for Sagent. He also noted that some of their contract manufacturers were outside the U.S., including one contract manufacturer in India.

- Liz Gallenagh spoke on behalf of the Healthcare Distribution Management Association (HDMA). Ms. Gallenagh serves as HDMA's Senior Director for State Government Affairs. She shared the board's concerns about what appears to be a lack of response from industry, but the board should consider the percentage of industry that is represented in the 42 responses sent. HDMA represents approximately 40 full-service distributors, representing about 95 percent of the market. More than 80 percent of all prescription drug products go through HDMA's member distributor. Individual letters were not sent to the board on this issue. Instead, they stood collectively behind the comments in HDMA's written submission.

Ms. Gallenagh stated that Florida and California are very different. She noted that the original 2006 date for Florida was not necessarily a choice; it was a negotiated date. She added that the law in Florida is lot-level based. There is no serialized product or track and trace. Ms. Gallenagh referred to increased licensure and enforcement efforts in over half of the states in the U.S. since the time of Florida's legislation. She believes those efforts have gone a long way to prevent counterfeiters from being able to infiltrate the legitimate supply chains. There have been substantial changes in the marketplace and business practices that the board should consider when looking at safety of the supply chain today. For example, direct purchase works, and is not a "sham pedigree" as was called earlier. It is enforced by the Florida's Department of Health, and by manufacturers that require their customers to adhere to it. It is also enforced by the distributors who choose to do business with those manufacturers.

Ms. Gallenagh concluded that California's law is right in terms of track and trace. HDMA maintains that pedigree should start at the manufacturer and should be based on serialized unit-level product. However, based on the information provided by technology providers and supply chain partners, they do not believe the entire supply chain will be ready by January 1, 2009.

Mr. Graul asked for HDMA's position on a phased-in approach.

Ms. Gallenagh responded that it depends on what is meant by phased-in. If it means ultimately getting to a fully operational track and trace system for all products, then it is something they would consider. If it were based on only a few drugs, we would end up with segregation of product in warehouses and multiple systems. It could result in a hodge-podge that would be an optimal solution in facilities of their size and volume.

Mr. Weisser asked a question regarding a statement in HDMA's letter about technology.

Ms. Gallenagh responded that different opinions and stages of readiness were presented during meeting. She cautioned that different systems are ready today, like lot-level serialization, but those solutions do not meet California's standard.

Mr. Goldenberg asked everyone to look to their manufacturing partners and encourage them to help everyone in the drug supply chain to comply with the law.

- Eileen Gould spoke on behalf of Endo Pharmaceuticals. Ms. Gould noted that one of the reasons they did not submit a written statement to the board was because they consider some of their timelines proprietary. Their timelines have dates on them, and they would like to be able to submit that information to the board, but asked if parts of it can be considered confidential. Endo Pharmaceuticals does not want all of their information to be made public and to their competitors.

Spencer Walker advised that trade secrets are regarded as confidential. Information not considered to be a trade secret would not be regarded as confidential.

D. Discussion and Action Regarding Implementation of Electronic Pedigree Requirements for Prescription Medicine in California

There was discussion about the upcoming Enforcement Committee Meeting scheduled for March 26, 2008. The issue of e-pedigree will likely be discussed during that meeting.

Ms. Herold clarified that all board members may attend that committee meeting; however, the five members of the Enforcement Committee will conduct the meeting. Additional board members could sit in the audience. She suggested that given that that a quorum of the board is seven members, that the board may want to schedule the March meeting as a board meeting to allow full board participation.

President Powers stated he will consider whether an additional full board meeting will be conducted, prior to the next quarterly board meeting scheduled for April 2008.

E. Summary of the Meeting of December 5, 2007

The minutes of the Work Group on Implementation of E-Pedigree held December 5, 2007 was included in the meeting materials. Copies of the PowerPoint presentations given at that meeting were included as attachments to the meeting minutes.

F. Second Quarterly Report on Enforcement Committee Goals for 2007/08

The Second Quarterly Report on Enforcement Committee Goals for 2007/08 was included in the meeting materials.

III. LICENSING COMMITTEE REPORT AND ACTION

A. Report and Action on Items Discussed at the Licensing Committee Meeting of December 11, 2007

Licensing Committee Chairperson Ruth Conroy noted that all items noted in the Licensing Committee Report were for information only. There were no action items to consider.

- Update of Emergency Preparedness for California Pharmacy

Dr. Conroy noted that disaster or emergency preparedness continues to be an important initiative of the Schwarzenegger Administration. The meeting materials

included details about presentations given at the last Licensing Committee Meeting regarding California's state of readiness for emergencies and disasters.

Dr. Conroy stated that she was encouraged by the interesting and informative discussion following the presentations made during the Licensing Committee Meeting. The state of California's readiness to respond to disasters and emergencies was detailed in materials and presentations from the following agencies:

- Emergency Medical Services Authority (EMSA), Jeffrey Rubin, Chief, Disaster Medical Services Division – on the subject of California Medical Volunteers (materials only, no presentation)
- Los Angeles County Department of Public Health – Dr. Glen Tao, PharmD, Strategic National Stockpile (SNS) Coordinator – on the subject of SNS and roles of pharmacists
- Orange County Health Care Agency, Mark Chew, PharmD – on the subject of preparedness plans in Orange County and the need for volunteer pharmacists
- California Department of Public Health (CDPH), Thomas N. Ahrens, PharmD, Chief of CDPH Emergency Pharmaceutical Services – on the subject of how CDPH and the board could work together to recruit pharmacist volunteers
- CPhA, Cathi Lord and Carl Britto – on the subject of CPhA's Disaster Preparedness Committee and a draft brochure entitled *Emergency Preparedness for Pharmacists*

Mr. Goldenberg stated that on February 2, 2008 he would give an outreach program relating to emergency preparedness. He asked that Board Member Graul join him and share some of his experiences during the recent wildfires. Mr. Graul agreed.

Mr. Graul also commented about surviving the recent wildfires, and having his store closed for almost a week. Without a database during that time, he had to communicate with a lot of pharmacists around the state to help take care of patients. They provided emergency supplies of medication to his patients. He could not communicate the transfer-type information such as last day filled, and in some cases, they were trying to figure out what medications they should be on. Mr. Graul said some of the information provided by patients was, "I'm on a white tablet that's a beta blocker." It was necessary to narrow down what medications that patients should be taking based on limited information provided. He noted that he could be reached by cell phone to validate legitimate patients with legitimate needs, but still experienced hesitation on the part of pharmacists not knowing their limitations and powers. On more than one occasion, Mr. Graul stated he was on the Board of Pharmacy in order to convince them it was O.K. Mr. Graul suggested an outreach effort to licensees consisting of a synopsis of what the powers are for pharmacists operating under an emergency situation. The synopsis should emphasize that taking care of patients is their first obligation, and they may be able to things they normally can't do under normal circumstances.

Ms. Herold noted that board has a fact sheet stating authority granted to pharmacists under Section 4062, which allows pharmacists to refill a prescription if you can't get hold of a prescriber and it is in the patient's interest. The board also has a disaster response

policy providing broad coverage. Ms. Herold suggested that the separate stand-alone policy be provided at the Kaiser presentation. It was also printed in the newsletter. Ms. Herold also referred to an item provided by a community fair vendor that includes a list of medications stored in an empty vial in the refrigerator. The medications themselves would not be in the vial, but a list of the medications would be stored in the vial instead.

Mr. Goldenberg added that many fire departments look for those vials. He recalled a decal to be posted alerting fire departments that the vial was present. He recalls that during the 1970s and 1980s this was more common, and it was helpful to see what drugs were listed, particularly if you were being transported to a healthcare institution.

Dr. Conroy added that the program is called "Vial of Life" and schools of pharmacy have Vial of Life programs. If you live in a community that does not have a school of pharmacy, information about the program may not reach you.

Mr. Goldenberg suggested the Vial of Life be subject matter for an article in *The Script*.

- Competency Committee Report

Dr. Conroy noted that the Licensing Committee was advised that the Competency Committee continues to work on exam development. Ms. Herold reported that the most recent quality assurance review ended on November 9, 2007 and that the Competency Committee is in good shape with respect to an item bank for the CPJE, providing the exam timely, and completing quality assurance reviews.

- Other Items Discussed

The committee was advised that the Office of Administrative Law approved the rulemaking to increase the board's fee schedule. The committee was advised on the status of the implementation plan to implement the new fees.

The committee discussed actions taken by licensees during the recent California wildfires and received copies of various articles on the topic.

The committee received a copy of the new Accreditation Standards for Continuing Pharmacy Education that will take effect on January 1, 2009. These standards are a result of a two-year revision process completed by the Accreditation Council for Pharmacy Education (ACPE). The new ACPE standards were provided in the meeting materials as well.

B. Meeting Summary of the December 11, 2007 Meeting

Minutes of the Licensing Committee Meeting were provided in the meeting materials.

C. Licensing Statistics

Statistics reflecting the Licensing Unit's processing activities for the first quarter of the fiscal year were provided in the meeting materials for information only.

D. Second Quarterly Report on Licensing Committee Goals for 2007/08

The Second Quarterly Report on Licensing Committee Goals for 2007/08 was provided in the meeting materials.

E. Public Comment

Kathy Lynch asked a question about the handouts relating to the board's disaster response policy provided by the board. She asked whether there is a Web site address that pharmacists can present questions to. Given the recent wildfires in Southern California, it would provide a level of comfort to pharmacists knowing they can send those questions to the board.

Ms. Herold clarified that the board will try to answer questions, however, answering questions of licensees becomes a staff workload issue. Questions asked that will serve a broad base of licensees would be more likely to get answered than one-on-one questions about working in a particular pharmacy with a particular situation. If a question is too specific, the board probably cannot answer the question. Ms. Herold noted that there are 35,000 pharmacists in California, but only 24 pharmacists working for the board. The ratio is problematic for individual questions.

Mr. Graul suggested a portion of the board's Web site could be developed for FAQs.

Ms. Lynch offered to provide a list of the questions that were forwarded to CPhA during the recent wildfire events. She will send those items to Ms. Herold.

Mr. Goldenberg suggested people join the board's subscriber list as well.

Dr. Schell noted that many questions are posed in the form of, "Will I get in trouble if..." The questions must be broad-based, instead of specific questions about professional judgment due to the many factors involved in making decisions.

IV. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE REPORT AND ACTION

A. Report and Action on Items Discussed at the Communication and Public Education Committee Meeting of January 8, 2008

Chairperson Schell summarized the items discussed during the Communication and Public Education Committee Meeting. Minutes of that meeting were provided in the packet.

- Consumer Fact Sheet Series

Dr. Schell noted that the board was engaged by a major university's school of pharmacy to integrate pharmacy students into public outreach activities. The intent was to offer students the opportunity to work with the board on meaningful projects promoting consumer education, while the board would benefit from the production of these materials. The project was initiated at UCSF, at its specific request. The UCSF Center for Consumer Self Care worked directly with its students to develop fact sheets, which were reviewed by faculty members and by the board. The board and the center distributed these fact sheets at community health fairs and has them available online.

Nine fact sheets were developed under this program with UCSF, but that process slowed down as UCSF had other commitments. It became clear they would require compensation to continue to produce these documents. Since then, the board opened up the program to other schools of pharmacy. Representatives of other California pharmacy schools were very interested in this project for their students, when contacted by committee members or staff.

The board directed staff to proceed with the committee's recommendations to develop a template for future fact sheets, and work with schools of pharmacy to initiate this intern project. The template will include the general format for the fact sheets, and require an annotated copy with footnotes citing the origin of information. The board will confirm, edit and otherwise review this information, and format into a standardized fact sheet. The board also liked the committee's recommendation to host an annual competition to acknowledge the interns who have produced the published fact sheets and select the very best fact sheets for a specific award. The committee refined the letter to school deans to encourage student involvement and suggested changes to the template. The committee also suggested that the board highlight priorities for the fact sheets. Priority topics for the fact sheets were determined at the July 2007 Board Meeting as:

- Counterfeit medicine
- Immunizations
- Direct to consumer drug marketing
- Buying drugs off the Internet (revision to existing brochure)
- cold medication for young children under the age of two
- pediatrics and over-the-counter products

Dr. Schell referred to an additional list of potential topics for the fact sheets in the packet. He suggested that other ideas about topics for the fact sheet series be sent to board staff for integration into the list of topics. A new format for the fact sheets will be designed as well to make it user-friendly and important are highlighted.

- Update Report on The Script

Dr. Schell noted that the next issue of *The Script* is at the Office of State Printing for publication. The focus of this issue will be on new laws, questions and answers about pharmacy practice asked of the board, and new regulation requirements. The next newsletter is planned for July 1, 2008. The committee suggested that medication errors and prevention steps be the core of some articles, as information from ISMP on recurrent errors has been a feature in the last few newsletters. The committee would also like input from the board and the public on topics for inclusion in the newsletter.

- Development of New Brochures

Dr. Schell noted that the board offers brochures for the public. Three brochures have been recently revised:

- Healthy Californians Through Quality Pharmacists Care
- Do You Have A Concern Or Complaint About A Pharmacy or Pharmacist?
- Drug Discount Program for Medicare Recipients

Each brochure now has a similar appearance with respect to the board's logo and state seal. Examples of these three brochures were provided in the meeting materials. During the January 8, 2008 meeting, the committee discussed whether the complaint brochure generated negative responses about the profession of pharmacy. The board wants to hear about issues that patients have with pharmacies, but also wants to hear if there may be good things to bring forward. Positive information could be brought forth as best practices and included in *The Script*. As a result of the discussion, board staff changed the title from "Do You Have a Complaint?" to "Do You Have a Concern or Complaint About a Pharmacy or Pharmacist? We Want to Hear From You." Dr. Schell did not believe that the changes were enough, but supported the more neutral title.

Dr. Schell also referred to a brochure that is being updated regarding buying drugs from foreign countries or on the Internet. The goal is to have a draft of the updated brochure completed by the next committee meeting.

Dr. Schell also referred to informational materials for pharmacist applicants. There is a wealth of information on the board's Web site regarding instructions for the pharmacist exam, but some applicants do not read this information or perhaps do not retain it or reference it throughout the application process. Staff will develop specialized fact sheets for specific applicants (foreign graduates, pharmacists licensed in other states) to make it easier for them to submit applications. Staff is also developing a checklist applicants can use to track their applications through the process. Additionally, an article published in CSHP's Journal written by the board will be converted into an information sheet.

- New Notice to Consumers Poster

Dr. Schell noted that there has been an incredible amount of feedback on this particular issue. In November 2007, the Office of Administrative Law approved amendments to 16 CCR section 1707.2(g), creating additional requirements for a Notice to Consumers poster that present information about a patient's right to obtain lawfully prescribed medicine from a pharmacy. The required notice must be posted in a pharmacy, or alternatively, printed on the back of customer receipts. The board prints these posters so they have a consistent look from pharmacy to pharmacy.

Dr. Schell said there was robust discussion on this issue at the committee meeting. While the notice now contains a number of important provisions, it contains so many provisions that comprehension may be compromised. The board's challenge is to make the poster(s) interesting and attractive. Display of this information in a pharmacy is an important means for public education. The committee reviewed three posters developed by two different artists on converting this wording into a readable, interesting and yet informative format. The committee did not come to consensus on which poster was the best, but did get good information to go back to staff.

Executive Officer Herold will work with graphic artists at the State Printing Plant and with the two other artists to secure an appropriate design. After the design is finalized, the posters will be printed and mailed to all California pharmacies. The board should have this completed by July 2008.

- Establishment of Public Hearing Schedule to Implement SB 472 (Corbett, Chapter 470, Statutes of 2007) Standardized, Patient-Centered Labels by 2011

Dr. Schell stated that last fall, Governor Schwarzenegger signed SB 472 that directs the board to develop a patient-centered, standardized prescription container label for all medicine dispensed to California patients after January 1, 2011. The board drafted the amendments ultimately enacted as SB 472, requiring the board to hold public meetings statewide, separate from normally scheduled hearings, to seek information from the public. The Medication Label Subcommittee has been formed as a subcommittee of the Communication and Public Education Committee to work on the labeling requirements. At the October 2007 Board Meeting, President Powers appointed these individuals to the subcommittee: Ken Schell, Chair, Bill Powers, Ruth Conroy, Rob Swart, and Susan Ravnar. The timeline for rolling this out would be to conduct hearings statewide in 2008. Six hearings would be held. It is hoped that by 2009 regulations will be developed and adopt the requirements by the end of that year. By 2010 pharmacies will begin implementation, and the requirements would become effective by 2011. Dr. Schell emphasized that the subcommittee is hoping to everything in place so that pharmacies have an entire year to roll out implementation.

Since the Communication and Public Education Committee, Ms. Herold has asked the California Pharmacists Association, California Retailers Association, and the California Society of Health-System Pharmacists to provide samples of diverse containers and labels in use in California pharmacies. The subcommittee and public can use those samples to see the diversity of prescription containers that must be labeled. Ms. Herold also requested copies of all auxiliary labels that are currently used on containers.

- **New Board Web Site**

Dr. Schell noted that the Governor's Office directed all state agencies to have a state-standardized Web site by November 1, 2007. The board met this deadline. Board staffers Kim de Long and Victor Perez worked on this project. Currently, staff is modifying the Web site to add a web page devoted to locating information on electronic pedigree requirements in California, and consolidate this into one place. A copy of the board's Web page and that of the Department of Consumer Affairs were provided.

- **Miscellaneous Consumer Issues in the Media**

Dr. Schell advised that several articles of consumer interest were reviewed by the committee, and were provided in the meeting materials.

- **Update on Public Outreach Activities**

Dr. Schell noted that from mid-September through December 2007, the board provided two presentations to professional associations, four presentations at major conferences, three presentations at meetings involving public policy discussions, and staffed a booth at four public information fairs. A detailed list of the board's public outreach activities during September to December was provided in the meeting materials.

B. Meeting Summary of the January 8, 2008 Meeting

Minutes of the Communication and Public Education Committee Meeting held on January 8, 2008 were provided in the meeting materials.

C. Second Quarterly Report on Committee Goals for 2007/08

Dr. Schell noted that the Second Quarterly Report on Committee Goals for 2007/08 was provided in the meeting materials.

Public Comments

Steve Gray spoke on behalf of Kaiser Permanente. Regarding the Notice to Consumers posters, he asked if the board would consider whether mandated posters could be displayed electronically. He emphasized that many mandated signs must be posted in a pharmacy. Dr. Gray asked the board to consider allowing posters shown on a flat screen. The information would roll through on a flat screen, which is attention getting. He said Kaiser already uses this electronic method to provide health information to patients in the waiting room.

Ms. Herold responded that it would require regulation change, but she supported the idea.

Dr. Schell added that the committee has had discussions about other ways to provide the information, other than on a standard poster. He thanked Dr. Gray for the idea.

V. NEW BUSINESS/AGENDA ITEMS FOR FUTURE MEETINGS

Dr. Swart suggested that there be a discussion regarding the possibility of an additional full board meeting, prior to the April 2008 meeting.

Mr. Powers said he had the authority to schedule an additional full board meeting or Enforcement Committee Meeting. He will consider those options.

Mr. Powers adjourned the regular portion of the full board meeting, so that the Enforcement Committee could conduct its meeting. (See separate minutes for Enforcement Committee Meeting.)

Thursday, January 24, 2008

VI. Closed Session

The board convened in closed session at 7:00 a.m. pursuant to Government Code section 11126(c)(1) to discuss and evaluate administration of the pharmacist licensure examination. Also, the board moved into closed session pursuant to Government Code section 11126(c)(3) to deliberate on disciplinary matters.

VII. Legislation and Regulation Committee Report and Action

President Powers noted that the board conducted an extended closed session, which ran longer than expected. He called the public portion of the meeting to order at 10:41 a.m.

Part 1: Regulation Report and Action

A. REGULATION HEARING - Proposal to Repeal 16 CCR § 1716.1 and 1716.2, and Amend §§ 1751 – 1751.8, and Adopt §§ 1735-1735.8

Ms. Herold asked that attendees requesting to speak during the regulatory hearing regarding pharmacies that compound use the sign-up sheet provided. She also asked Ms. Sodergren to give an overview of the regulatory hearing process, for the benefit of new board members and members of the public in attendance.

Ms. Sodergren advised that a process exists to promulgate changes in regulations. That process initiates with a 45-day public comment period. This hearing came as a result of the 45-day comment period for proposed regulatory changes regarding compounding. Ms. Sodergren noted that various written comments were received on the proposed changes regarding compounding, including comments provided to board staff as recently as January 18, 2008. Recent comments, as well as responses to those comments, were provided as supplemental material to the board packet.

Ms. Sodergren stated that the point of this regulatory hearing was for people to provide comments on the proposed regulation. There will be opening remarks, then time will be provided for comments. She noted that the draft language included noticed and recently proposed modifications to the compounding regulations. Ms. Sodergren advised that additional testimony would be provided for board consideration during this hearing. At the conclusion of the hearing, the board may vote to withdraw the regulation proposal, or consider revising the language. Any changes to the language would result in either an additional 15-day comment period or a new 45-day comment period, depending on the scope of the changes.

Current pharmacy law provides authority for pharmacists to compound drug products as well as compound sterile injectable products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that perform general compounding.

In 2004 the board formed a Work Group on Compounding comprised of board members, board staff and industry representatives. The Work Group recognized that current pharmacy regulations addressing compounding governed the physical circumstances, procedures, and record keeping requirements for general compounding, but did not address quality, strength, or purity. The Work Group recommended changes to the regulations. Since 2006, the board continued to refine the language based on subsequent comments from interested parties during board and committee meetings, as well as changes recommended by counsel.

At the October 2007 Board Meeting, the board voted to move the language as presented and initiate the 45-day comment period as required by the Administrative Procedures Act. This regulation was noticed on November 16, 2007. The 45-day comment period was

scheduled to end on December 31, 2007, but the board received a request for a hearing on the matter. This request extended the comment period through the regulation hearing.

Mr. Powers initiated the regulation hearing by advising that this hearing was being conducted to consider a proposal to repeal 16 CCR Section 1716.1 and 1716.2, amend Sections 1751-1751.8, and adopt Sections 1735-1735.8, as outlined in the public notice. He noted that the proceedings were being recorded, and he asked that people giving comments identify themselves so that the board would have a clear record. He advised that this was not a forum for debate. Written testimony could be summarized verbally, but questions should be rephrased as comments.

Ms. Herold noted that the board participated in a series of discussions with the Department of Health Services (now the Department of Public Health) regarding what constitutes compounding and what constitutes manufacturing. The discussions started with the intent to define compounding as opposed to manufacturing. Two outcomes resulted from those discussions: 1) a legislative proposal, and 2) a series of regulations that established minimum requirements for those pharmacies that compound. The regulations have gone through a number of iterations.

Mr. Powers said a number of people requested time to testify on the issue. A summary of their verbal testimony is shown below.

- Kathy Lynch and John Cronin, California Pharmacists Association (CPhA)

Ms. Lynch stated that CPhA requested a hearing for this regulation. She said that CPhA heard comments from their pharmacists, and subsequently submitted three rounds of comments to the board on the issue.

Mr. Cronin stated that he is a pharmacist attorney, owns two pharmacies, and served as general counsel for CPhA for 13 years. He assisted CPhA in drafting their comments to the board, and emphasized their concerns with the definition the board has used for compounding. He said they made a number of suggestions that were rejected by the board. He referred to a court case (Thomas v. Western States Medical Center). He did not suggest the board replace the definition. Instead, he suggested supplementing the language to clarify the broad idea of compounding, and to make other sections more specific.

Mr. Cronin referred to "occasional" compounding. He spoke about mixing two or three products together and shaking it up, and that pharmacists should be able to document that on a prescription. He said that that type of compounding should not have a requirement to have a full policy documenting the procedure. Mr. Cronin also spoke about the regulation having a significant economic impact on the State of California.

Mr. Spencer advised that comments should be confined to this regulation package. He emphasized that testimony must be limited to these proposed regulations.

Mr. Cronin stated that having a separate self-assessment form for a compounding pharmacy would affect pharmacies. He suggested that only one self-assessment form for all pharmacies should be required. He also commented on policies and procedures, and asked for written guidance from the board regarding pharmacies that compound often and those that do not compound at all. In response to a question, Mr. Cronin said he was referring to Sections 1735.5 through 1735.8.

Ms. Herold asked a question related to CPhA's suggested wording that compounding is a process by which a pharmacist "or a doctor..." She asked whether adding "or a doctor" would include any physicians who are compounding.

Mr. Cronin noted that that could be a result. He said he was quoting the court, and that it was not his language; they were quoting the FDA.

Mr. Room clarified that other components of the definition are already in regulations (i.e., altering, combining, performed by a pharmacist, and not typically done on commercially available products). He asked what CPhA was asking to be included.

Mr. Cronin said their suggested language would provide a clear single statement of what compounding is, instead of a litany of things stating what compounding is and what it is not. Also, including language about physician is something he has raised in the past, but the board decided not to include it in the language.

Mr. Room advised that some elements of this language could not be done by regulation. For example, the board has no ability to regulate the practice of physicians, and such a requirement could not be enacted in a regulation.

Mr. Graul asked about including a general statement prior to the Section 1735 definition, and whether it would be subject to a new 45-day comment period.

Ms. Herold advised that amendments could be done within a 15-day comment period, unless the language was changed to include expanded requirements or regulation over expanded groups. In that case, another 45-day comment period would be necessary.

In response to a question from Mr. Graul, Mr. Room noted that the board is the policymaker. As liaison counsel to the board, he cannot support or oppose a suggestion to include a statement prior to the Section 1735 definition. He noted that Mr. Cronin was referring to federal cases and federal law. He also noted that inserting a general statement, which is redundant and overlaps current language, could cause confusion. It would require more significant modification than just adding language to the current regulation.

Dr. Schell spoke about compounding and whether these changes would expand into other areas and similar activities. He provided an example of nurses in pediatric hospitals that do compounding.

Board Counsel Spencer Walker stated that such requirements couldn't be done by regulation. It would require a statutory change.

Mr. Room noted the context in which this regulation arose. Both federal and state laws define compounding as a type of manufacturing. What this regulation does is modify the pharmacy code word "compounding" when it refers to a pharmacy where compounding takes place. Our definition of compounding is specific as to what can take place in a pharmacy. We are also stating that it can only be done under the supervision of a pharmacist. Mr. Room advised that other professions are authorized, or not authorized as the case may be, to compound under their own practice acts.

- Larry Shaw and Phillip Swanger, California Society of Health-System Pharmacists (CSHP)

Mr. Shaw stated that he serves as Chair of Governmental Affairs for CSHP. He referred to written comments CSHP submitted to the board in November and December 2007 regarding acute care settings and recordkeeping requirements. Mr. Shaw spoke about intermediate use and stat medications and recordkeeping components in Section 1735.3. He noted that the objective of stat medication is to get medication to the patient as quickly as possible, and any extra recording requirements would be an impediment to getting medication to the patient. He suggested that immediate-use medication have an exemption, as long as it was a "low-risk" medication.

Mr. Room asked if these comments replaced CSHP's prior comments.

Mr. Shaw responded, yes.

Mr. Swanger added that the recordkeeping requirements were primarily used for recalled drugs that needed to be taken off the shelf. There is no benefit in recordkeeping requirements during administration of immediate-use medication.

Dr. Ravnan asked for examples of specific products they were referring to.

Mr. Shaw gave examples of cardiopulmonary drugs and other medications administered in a critical care situation.

Dr. Schell asked for clarification about what substances the exemption would cover and where it would occur.

Ms. Sodergren advised that when the CSHP comments were received, staff sought clarification regarding circumstances where a drug must be compounded immediately. Based on a physician's order, they would need to compound immediately; recording the manufacturer, lot number, and equipment would delay administration of that product. Given that it is a one-time quick administration of the medication, there would be no benefits to recording this information for a recall because the medication would have already been administered to the patient. They discussed the issue further, resulting in this proposed language submitted before the board, instead of the wording provided in the board packet.

Dr. Ratcliff noted that he participated in the discussion regarding administration of a one-time dose. He clarified that the circumstances did not include a code blue. The exemption requested was for one dose. Dr. Ratcliff gave an example of a patient needing a dopamine drip in a one-time stat dose. He clarified that they were asking for an exemption from Section 1735.6.

Dr. Schell noted that you would not want to wait longer than necessary to administer an immediate stat dose. However, the recordkeeping requirements could be performed after the dose was administered.

There was a discussion about recording information after the fact, and whether so much could occur during an emergency that it would be hard to reconstruct what happened after the fact.

Mr. Room gave an example of discovering contamination in a compounded product, and having reason to believe the contamination came as a result of using a certain piece of equipment. In that case, you could retrace your steps for investigative purposes and identify the source of contamination. He suggested it might be appropriate to modify the suggested language to reflect that recordkeeping be performed within 24 hours of a one-time administration.

- Jerra Banwarth, owner of a compounding prescription specialist pharmacy in Northern CA

Ms. Banwarth noted that her pharmacy also holds a sterile compounding license. She stated that she is on the board of compounding pharmacists with CPhA. Ms. Banwarth referred to Section 1735.1 and language that says "absence of harmful contaminants, including filth, putrid, or decomposed substances." Ms. Banwarth recommended that the language be replaced with "absence of proven harmful levels of contaminants." She gave an example of chlorine put in water. In high amounts, chlorine may cause harmful effects on the body, but is used to prevent dysentery. Ms. Banwarth said she understood the intent of the language, but needed to understand how it would be interpreted.

Mr. Room said Ms. Sodergren incorporated proposed comments, including harmful “levels” of contaminants. He believed it was an unnecessary change because the word harmful implies harmful levels. In an administrative case, a harmful level would have to be proven. However, to provide peace of mind to those concerned, the language will not undermine the enforcement ability of the statute to say “harmful levels.” Harmful “proven” levels would not be appropriate, but “harmful levels” is an appropriate compromise.

In answer to a question, Ms. Banwarth stated that we drink tap water. She was trying to give an example of what people incorporate into their bodies on a daily basis.

Mr. Room noted that there can be harmful ingredients like carcinogens, but not in sufficient quantities to cause harm.

Ms. Banwarth suggested insertion of “active” in front of the word “ingredients” in Section 1751.2(b). She referred to concentrations of active ingredients in a product.

Ms. Sodergren advised that that would constitute a change to existing requirements.

Mr. Room clarified that Section 1751.2(b) currently states, “Name and concentrations of ingredients contained in the sterile injectable product.” The material change suggested was addition of the word “active.”

In response to a question from Mr. Goldenberg, Ms. Banwarth stated they are seeking addition of the word because of confusion about what is in the medication. She said many things go on during a crisis, and it is difficult to get nurses and health care providers to understand relevant strengths of the ingredients.

Mr. Graul asked how they label the compounding product now.

Ms. Banwarth stated that her pharmacy was inspected and she was advised to label by active ingredient, concentration, and vehicle in which it was being administered (i.e., sterile water). The proposed language would also require that she add other things including ingredients used to adjust the pH, which can vary from lot to lot.

Dan Wills, from Grandpa’s Pharmacy, said he believed existing law meant “active” ingredients only. He recalled being inspected five times to that standard of practice.

A person from the audience stated that just because the board has used that standard during 2007 or 2008, that doesn’t necessary mean they will continue to use that standard in 2010, 2011, and 2012. He recalled different state inspections, with varying interpretations of the statute, and inconsistencies among board inspectors.

Mr. Goldenberg spoke about consumers and their rights to know whether they are exposing themselves to ingredients left off a label. He acknowledged challenges of

space on labels. He also spoke about adverse events in hospitals. Mr. Goldenberg emphasized that the board is trying to balance rights of consumers and the pharmacists' challenge to limited space on a label.

Ms. Banwarth said they consult with patients to determine if there is an allergy to a certain medication, but some clients are sensitive to everything. Writing down every ingredient in a particular product is not practical, and is arduous at best.

Ms. Herold indicated that staff would review the prior rulemaking for sterile injectible products. She stated that it is her recollection that the lack of the word "active" before ingredients was deliberate, in order to include all ingredients in a product. Ms. Herold said she wants to ensure that the language does not stray from what was originally intended.

- Joe Grasela, University Compounding Pharmacy, San Diego

Dr. Grasela stated that labels on manufactured drugs do not show every ingredient in those drugs. Minute amounts of ingredients are included in medications, and there is insufficient room on the label to list every ingredient. He emphasized the importance of listing only "active" ingredients.

Mr. Goldenberg noted that information is provided with manufactured products, which is integral. He spoke about standardized labels, including those on food packages. Mr. Goldenberg stressed that consumer protection is most important.

Dr. Grasela suggested that out-of-state pharmacies be held to these requirements. He noted that 50 percent of compounded drugs in California come from out-of-state.

Dr. Ravnar commented that she is concerned about physicians and pharmacy technicians who are compounding.

- Dan Wills, Grandpa's Compounding Pharmacy, Placerville

Mr. Wills acknowledged the board's efforts in labeling requirements and ensuring consumer rights. He spoke about "harmful levels" of ingredients in a product. He also spoke about "active" ingredients, sterile compounding, replacing the word "product" to "preparation," and replacing "expiration" with "beyond use date." Mr. Wills referred to his written statement to the board included in the board packet.

In response to a question from Mr. Wills, Mr. Room noted that a sentence in Section 1751.7(a) contained both strike-through font and underlined font. The double-underlining was intended to indicate language that was added back in.

Mr. Wills also referred to Section 1751.7(c) and (d) and “batch-produced” sterile injectable drug products and his interpretation and definition of the phrase.

Mr. Graul spoke about using more than one unit (i.e., more than one vial, more than one injectable syringe), and asked whether an individual lot number is assigned to it.

Mr. Wills stated that if the product is made one time, it is given one lot number.

- Steve Gray, Kaiser Permanente

Dr. Gray spoke about the definition of a “batch.” He noted that “batch” is not just a quantity or number; it has implications as to testing and when those products can be administered to patients. For example, products must be quarantined and tested; it would not be unusual to make 200 or more piggybacks from one batch. Testing for sterility and contamination could take days or weeks. He also spoke about using “batch or anticipated administration” when you anticipate a lag in time between the time the product is made and when it is administered. Dr. Gray stated that even simple testing is not instantaneous. Problems in enforcement could occur if there is confusion about what constitutes batch compounding.

Ms. Sodergren noted that the term “batch-produced” is current law.

In response to questions from Dr. Conroy and Mr. Goldenberg, Ms. Herold stated that pharmacy technicians work in a pharmacy, whereas pharmacists can work for physicians not in a pharmacy. A pharmacist who compounds a product incorrectly, in a pharmacy or working for a physician, is subject to discipline by the board.

Mr. Room spoke about the legislative history of changes to Section 1751.7.

- Bill Blair, Director of Compounding Services, McGuff Compounding Services

Mr. Blair referred to his written comments to the board that were included the meeting materials. He spoke about the definition of “potency.”

Ms. Herold said she believed the initial language originated with a USP connection, and it was rewritten to include plus or minus 10 percent of the label amount.

Mr. Powers suggested that board staff review the language and incorporate the applicable recommendations, then bring the matter back to the next board meeting.

Mr. Graul thanked the pharmacists who provided responses to the board. He is proud of compounding pharmacists who are paying attention to these important issues.

