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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:** June 24, 2008

**LOCATION:** Radisson Hotel
500 Leisure Lane
Sacramento, CA 95815

**BOARD MEMBERS PRESENT:**
Ken Schell, PharmD, President
D. Timothy Dazé, Esq., Public Member, Vice President
Stanley Goldenberg, RPh
Robert Swart, PharmD
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
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Janice Dang, Supervising Inspector
Kristy Schieldge, DCA Staff Counsel
Tina Thomas, Staff Analyst

President Schell noted that the majority of the meeting would be on the topic of E-Pedigree. Discussion, however, may be delayed due to a legislative hearing regarding related SB 1307 at the state capitol. Board member Bill Powers, as well as others, are attending the hearing and the results could be relevant to the discussion of the board meeting.

President Schell called the meeting to order at 10:00 a.m.

## ***I. General Announcements***

Introductions of the board members and staff were provided.

President Schell discussed the Professionals Achieving Consumer Trust Summit sponsored by DCA, scheduled for November 17 – 21, 2008. DCA Director Carrie Lopez is coordinating the summit, which will provide all of the DCA boards and bureaus the opportunity to hold concurrent public meetings. President Schell indicated that this forum is designed to allow DCA agencies to observe how other boards and bureaus conduct their meetings, as well as provide training sessions for board members. He noted that the Board of Pharmacy will schedule a public discussion of SB 472, which is the standardization of prescription labeling initiative. He indicated that the concept of e-prescribing might also offer an opportunity for coordinated topics among the healing arts boards.

Sarah Boire (Department of Consumer Affairs) provided an update on the schedule of the Summit. She stated that DCA is in the process of drafting the final agenda. Ms. Boire referred the board members to the DCA Web site in July for further details of the meeting, including hotel location and related board meetings which may be of interest. She indicated that a notice would be sent out to Virginia Herold. She clarified the nature of the various seminars, as well as which seminars are open to the public versus those specifically intended for board members, advisory committee members and executive officers. Ms. Boire encouraged board members to review the schedule of speakers and seminars and advised them to contact her by mid July in order to register for those seminars they would like to attend.

## ***II. Presentation by Supervising Inspector Robert Ratcliff, PharmD: "Walking Through a Pharmacy Inspection"***

Supervising Inspector Ratcliff provided an overview of the board's inspection process. This was a CE presentation that Dr. Ratcliff made to professional associations upon request.

Supervising Inspector Ratcliff provided a breakdown of the licensee population. He provided a brief explanation of the information that can be found on the Board of Pharmacy Web site relating to inspections as well as how to navigate through the Web site to locate the information. He also provided an explanation of the purpose of pharmacy inspections as well as which types of entities and licensees board staff inspects.

Supervising Inspector Ratcliff reviewed how often inspections are completed. He noted that licensed sterile compounding clinics (LSC) are announced and inspected annually. He also indicated that inspections can be triggered by a complaint and that pharmacies and pharmacists on probation are subject to quarterly inspections as part of their monitoring.

Supervising Inspector Ratcliff discussed how to "survive" an inspection. He reviewed the tools the board provides to allow pharmacists to feel prepared for an inspection (i.e. self-assessment form). Supervising Inspector Ratcliff explained what occurs when the inspector arrives for a site inspection. He noted that they will attempt to be unobtrusive and observe for consultations and other appropriate protocol.

Supervising Inspector Ratcliff listed the items that are reviewed and conducted when the inspector first meets with the pharmacist-in-charge (PIC). Specifically, the inspector will request a list of who works at the premises and review appropriate recordkeeping documents. The inspector will complete a general inspection as well. At the conclusion, the

inspector will complete an Inspection Report that documents their findings. The inspector will complete an exit interview.

Supervising Inspector Ratcliff stressed the licensee comments section, which allows an opportunity for the licensee to provide comments.

Supervising Inspector Ratcliff stressed the importance of the PIC providing comments in response to the inspection as it is requested on the inspection report.

Supervising Inspector Ratcliff discussed what occurs if there is a problem during the inspection. He noted that all pharmacies are entitled to due process in the form of an appeal for any corrective action or discipline. Supervising Inspector Ratcliff highlighted that there is no need for an immediate alarmed reaction. He stated that discipline is not decided on at the time of the inspection and provided the standard range of a citation fine amount. Supervising Inspector Ratcliff indicated that corrections and written notification of non-compliance would be given if appropriate. He explained that a PIC is given the opportunity to reply to the findings and provide either a plan for correction or state disagreement with the stated violations. Supervising Inspector Ratcliff suggested that pharmacists could ask the inspector to show them the relevant sections of pharmacy law (in the Pharmacy Law book) where the violation occurs. He also said that if a PIC doesn't agree with a violation, they can contact him directly. He provided his e-mail address and phone number.

Supervising Inspector Ratcliff reviewed the top ten corrections most commonly found during a site inspection.

Supervising Inspector Ratcliff recommended that pharmacies maintain an inspection notebook. The notebook should include documents from past inspection reports, completed self-assessment forms, DEA inventory, quality assurance, etc.

***Questions to the presenter:***

Bob Graul asked whether inspectors request to view the DEA 222's. He also asked what they look for in pharmacies on the Controlled Substance Ordering System (CSOS).

Supervising Inspector Ratcliff responded that CSOS pharmacies have 222's, which are filled out. The inspector will then be checking to ensure that the electronic receipt has been done.

## ***III. Workgroup on E-Pedigree***

### ***A. Presentations to the Board on Electronic Pedigree Implementation***

***Bob Celeste (GS1):***

Mr. Celeste provided an update on GS1's development for e-pedigree standardization. Mr. Celeste reviewed the support role GS1 provides, which includes ensuring global standards harmonization and communication on global standards and activities. GS1's role within the

United States (U.S.) specifically includes providing primary customer contact for U.S. based companies, divisions and regulators, and driving adoption and implementation. The company's role also includes providing U.S. requirements to global standards development.

Mr. Celeste reviewed the reason for standardization, which involves the current lack of consistency with regard to machine readable codes used by drug manufacturers.

Mr. Celeste described the timeline and progress to date on standards traceability adoption activities, with specific focus on the Pedigree/EPCIS status. He explained that related tasks involve looking at the pedigree messaging standard existing today along with EPCIS, which forms the basis of track and trace, and how to make the two interoperable within the supply chain. He reviewed the specific areas of focus which GS1's Traceability Adoption Workgroup has placed in terms of creating such interoperability. Those areas of focus are security, pedigree events, data alignment and exception processing.

Mr. Celeste explained that they have moved forward with their progress to the point of having more significant "second level" discussions on specific analysis, action items, and barriers needing to be addressed.

***Marjorie Powell (PhRMA):***

Ms. Powell explained their role in the e-pedigree standardization, which involved an economic study of the cost and benefits of serializing products. She noted that both technologies, 2-D Bar Codes and RFID, were included in the study. She also stated that the study was conducted in relation to the effect on manufacturers only, and not others within the supply chain. Economists involved were instructed to look at the unit of sale level at the point of packaging. Ms. Powell noted that, for the purpose of the study, the assumption made by manufacturers and vendors was that the benefits would begin to accrue after full implementation of the process within the subsequent year.

Ms. Powell discussed the issue of guidelines needed by the Food and Drug Administration (FDA) on required qualifications of the manufacturer's systems in ensuring read accuracy. She also noted the sources of data utilized in conducting the study. Statistics on packaging speed and average recall and product returns per year were provided as well.

Ms. Powell provided a breakdown of the minimum implementation costs, which indicated a cost of $1.3 million in capital costs and $1.08 million in labor costs per packaging line. She noted that the human cost totals do not include the costs related to ongoing communication needs within the supply chain. She provided additional cost totals relating to licenses for serialization, equipment modifications, labelers and readers. Ms. Powell pointed out the various issues of high labor costs related to implementation. One of those issues includes the need for a large number of employees with specific training and skill sets to implement and qualify the packaging line, as well as the delay in other lines when those specific employees are needed elsewhere.

Ms. Powell pointed out the variances in cost by manufacturer and packaging line, including the cost for those manufacturers whom will need to buy new equipment. There are also scheduling issues related to the delay in making changes in a line when high demand

products are being processed. She stated that there is a need for guidance from the FDA on the use of RFID for some classes of products.

Ms. Powell discussed the additional costs to account for in working with other distribution chain partners, including the resolution of issues that arise when exchanging information and the costs to resolve misread serial numbers. Additionally, Ms. Powell stated there will be slower distribution throughout the supply chain as partners read and verify serial numbers.

Ms. Powell reviewed the ongoing costs once the lines are implemented in full, which will range from $130,000 to $1.5 million. The cost varies significantly based on what type of technology companies choose to use. Costs will be much lower where 2-D bar codes are utilized, rather than RFID tags.

Ms. Powell discussed the results provided by the economists in regards to whether the benefits outweigh the costs. Although there are numerous benefits, many of them cannot be quantified. She reviewed some of those benefits, which included the increased ability to identify counterfeit products and diverted products as well as faster and potentially more complete recalls. Additional benefits which can be quantified include the existence of an automated process for returns and expiration management, federal research and development tax credits for some manufacturers, management of discounts for diverted products, increased visibility for invalid returns and faster accounting for recalled products.

Ms. Powell provided a brief summary of the potential risks associated with implementation, including the issue of uncertainty of future changes in law and regulatory requirements.

Ms. Powell ended the presentation by providing the information of the consulting firm who conducted the economic research. The report is available upon request.

***Questions to the presenter:***

Mr. Dazé noted that the cost findings presented today are substantially higher than what has been shared by others in past presentations and board meetings. He asked if she knew the reason for the large discrepancy.

Ms. Powell responded by indicating that the costs provided in this study are broader and more complete, whereas prior presentations may only include the costs a vendor requires to implement their system. The costs provided in the presentation include all labor costs, costs of down time, etc.

Mr. Dazé shared his concern over the accuracy of the actual costs, and suggested that the consulting firm should contact some of the firms who have already implemented RFID within some of their lines.

Ms. Powell stated that the economics spoke with a number of different vendors to determine what they would charge, and also spoke with manufacturers to determine what their other internal costs would be as well.

Mr. Dazé restated that the numbers provided in the presentation are of great concern.

Ms. Powell responded that the numbers are in fact very large, but there are large variances in the costs as well depending on the line.

Stan Goldenberg asked if there has been any discussion on the upside relating to the sales of legitimate drugs as the decrease in counterfeit drugs occurs.

Ms. Powell stated that the manufacturers have not indicated an increase in sales, but rather a decrease in the cost of investigation and enforcement with counterfeiting and potentially recalled drugs. She added that they cannot determine what those costs will actually be until they have full serialization implementation, state/federal legislation is clarified, and know how the parties in the distribution chain will interact.

President Schell noted the lack of dollar figures related to the benefits of serialization, and asked if the economists were able to identify approximate figures.

Ms. Powell responded that there was nothing the economists could quantify.

President Schell asked if there is a dollar figure on the actual cost of counterfeiting as an industry.

Ms. Powell responded that she does not believe there is such a dollar figure, but will go back to the economists and verify. She noted the issue of confidentiality with counterfeit investigations and how that hinders the ability to collect such data.

***Ron Lanton (HD Smith):***

Mr. Lanton gave a brief overview of the company and their role within the supply chain. Mr. Lanton noted that HD Smith has taken a leadership role in several industry initiatives to safeguard the drug supply chain, including being the first to pilot a radio-frequency identification process program that allows them to track and trace product movement throughout the supply chain. HD Smith also assumed the lead on the development of an e-pedigree system and was the first to process an electronics narcotics system that would evaluate the type of products ordered as well as quantities.

Mr. Lanton gave the company's perspective on e-pedigree and the decisions so far to delay implementation. Mr. Lanton reviewed the progress so far on serialization efforts, and pointed out the lack of federal legislation and guidance to address the issue of counterfeiting. He stated that this lack of leadership by the government has affected everyone within the supply chain, and described how the "national dysfunctional domino affect" could create harmful repercussions within the pharmaceutical chains. Mr. Lanton stated that HD Smith publicly joined stakeholders in supporting HR 5839 – Safeguarding America's Pharmaceuticals Act of 2008, sponsored by Bouliere and Mattheson. HD Smith feels that HR 5839 has a more comprehensive philosophy over the initiatives being placed at the state level, including providing the industry with greater direction on issues such as direct and standardized pedigrees, serialization and returns. Mr. Lanton raised the issue of lack of standards on 2-D bar codes versus RFID. He pointed out that manufacturers are hesitant to commit to a standard for fear of investing in a system that may not be the chosen

standard. He stated that the supply chain and government need to agree on one standard so that progress can move forward with more certainty.

Mr. Lanton stated that it is now time for Congress to take the lead once again and provide clarity and obtainable benchmarks to the industry.

***Questions to presenter:***

Mr. Graul asked what the status is of HR 5839.

Mr. Lanton responded that it is still in the committee and has not moved since introduction.

President Schell agreed that it is time to come together and agree on one particular standard. President Schell asked how Mr. Lanton feels things are different today than in 1987 when pedigree first started.

Mr. Lanton responded that we are much smarter now than we were then. He pointed out various pilot programs conducted and how that has allowed the industry to learn and speak more knowledgably on what does and does not work. Mr. Lanton stated that the main issue here is that we will continue to have endless discussions until we make a decision on a standard.

President Schell responded that we wouldn't be in this position if action had been taken back then, and now the state was put in a position to do something in order to protect the California consumers. President Schell stated that if HD Smith or anyone has ideas that haven't been discussed which would solve the issues at hand, the Board of Pharmacy is very interested in hearing them.

Mr. Lanton stated that they spoke to board members last January regarding some of their pilot programs and would be happy to share those with the board.

President Schell responded that they would most definitely appreciate the information.

Mr. Dazé asked if HD Smith is using RFID internally. Mr. Lanton confirmed. Mr. Dazé asked if there was a reason they chose RFID versus bar code for their company.

Mr. Lanton responded that the company is very innovative, and predicted it was where the industry would ultimately end up.

Mr. Dazé asked if they have provided the costs and benefits, which HD Smith has incurred with the RFID implementation at their company to the proponents of the federal legislation.

Mr. Lanton stated that they have not testified formally, but have had informal conversations with the authors and have shared with them what has and has not worked for them.

Mr. Dazé expressed his appreciation for their actions.

Stan Weisser asked if they have any pilot programs in place currently with their customers.

Mr. Lanton responded that when he spoke to his Operations department last week they were looking for pharmacies to work with on pilot programs. He is unsure if they have made any progress on that as of yet.

Hank Hough express concern on the impact of inflation on costs. He noted the increase on gas and importation of oil, and felt that it should be factored into the forecasts as it will impact the economy significantly simply by the nature of how quickly it is affecting our society as a whole.

***Aaron Graham (Purdue Pharma):***

Mr. Graham explained his prior role with the Food and Drug Administration as investigator of the diversion of pharmaceutical drugs from institutional pharmacies through secondary wholesalers and into the public. He explained the concern when he was in that role in 1994, which involved the concern over whether paper pedigree (PDMA) was still effective in its purpose in safeguarding the public from counterfeit drugs. He referenced one investigation, which resulted in the arrest of over 150 people, $30 million in fines and the closure of Binley-Western.

Mr. Graham discussed the current status of the nation's drug supply. He discussed the dilemma of not knowing which drugs to make as the priority in serialization. He also pointed out that counterfeiters follow legislative activity in order to be one step ahead and they will simply counterfeit drugs that are not on that priority list. Mr. Graham displayed examples of various drugs, both counterfeit and non-counterfeit, which illustrated the difficulties in differentiating between the two. He discussed the case of Mark Kolowich, one of the most prolific counterfeiters in the history of America, and the insignificant conviction placed on him considering the heinous crime involved. His conviction was for money laundering rather than counterfeiting. Mr. Graham shared a portion of a video where Horowitch was interviewed, explaining his choice to counterfeit certain drugs because of the ease in duplicating them. Mr. Graham pointed out the cost difference of 18 cents per pill for creating the counterfeit drug versus 12 dollars per legitimate pill. The video interview included asking Horowitch about the ability for a terrorist to transport counterfeit drugs with deadly ingredients into the United States in the same manner as he did. Horowitch responded that it would be fairly easy, and the drugs would reach consumers within a matter of days. The ability for terrorists to sell drugs from their own countries via the Internet was also discussed as being very simple to do. Mr. Graham added that Horowitch has already completed his sentence and is no longer in prison.

Mr. Graham shared the issue of internet drugs. He described a "sting" operation he was involved in where he arranged purchases with persons selling counterfeit drugs over the internet, and then met with them to make the deal. He shared the video footage from a hidden camera when meeting with some of those sellers, which included pharmacy owners from Tijuana. He discovered the system these sellers had in place in getting the counterfeit drugs from their original origin to Tijuana.

Mr. Graham gave another example of a counterfeit ring and how the process of creating and routing the drugs occurred. When the counterfeiters were ultimately caught, they were only fined $30,000.

Mr. Graham shared an excerpt from a Dateline highlighting a counterfeit of the drug Procrit and the results of patients receiving this counterfeit product. He shared the issue of how minute the differences can be on the packaging of a counterfeit drug versus a legitimate one.

Mr. Graham discussed the issue of diversion, answering the question of how a counterfeit drug gets into a legitimate local pharmacy from a counterfeit production in China. He provided a flowchart of the process of drug distribution starting at the manufacturer. He explained how "grey marketeers" (grey market wholesalers) would solicit the manufacturers to purchase their drugs for a significant discount. He stated that the wholesale license document that is typically required for such a purchase is easily created by "doctoring" a legitimate wholesale license. He explained the process of becoming an Authorized Distributor of Record (ADR) and how that allows the seller to buy directly from the retailer without a pedigree and bypass the wholesaler, institutional pharmacy, etc.

Mr. Graham shared the concern with large shipments of drugs making their way into the United States in various ways, including the large containment units shipped overseas where drugs are hidden inside other products.

Mr. Graham gave another example of a counterfeit case where drugs were being manufactured in the United States, but then shipped through China (where they were hidden inside toys and stuffed animals) and then back into the U.S. He emphasized that it is difficult in this scenario to determine where an e-pedigree would begin.

Mr. Graham shared examples of various attempts that have been made to hinder counterfeiting, such as holograms, color-coding, etc. All of them have been either unsuccessful or require unrealistic training of the pharmaceutical industry or the consumer. He pointed out how e-pedigree, when placed early in the production process, can be utilized to ensure that counterfeit drugs are not allowed the opportunity to enter into the distribution chain.

***Questions to the presenter:***

Mr. Dazé asked if Mr. Graham has had the opportunity to provide the same presentation at the federal level in Washington D.C.

Mr. Graham responded that he had not.

Mr. Dazé encouraged him to do so.

Stan Goldenberg agreed with Mr. Dazé's comments and added that bringing the presentation down to such a personal level provided an extremely powerful presentation.

***Bill Von Rohr (DDN Pharmaceutical Logistics):***

Mr. Von Rohr explained that DDN is a third-party pharmaceutical distributor. He provided a brief history and background on the company. He indicated that some of their customers

have begun the process in becoming compliant for the e-pedigree implementation. This preparation includes participating in pilot programs. He explained that the customers are now at the point of needing to address more specific issues that must be decided before the process can move forward. Mr. Von Rohr referred to them as "operational reality" questions and indicated that guidance is needed from the board in response to them. These questions are related to items such as pedigree records in relation to possession change, grandfathering provisions for returns without serial numbers, operational realities to an authentication certification failure (human error) demanding return on received product, manufacturing e-pedigree certification in a 3PL environment, and inference.

Mr. Von Rohr indicated that DDN's customers would like to be proactive by developing a "process definitions" document for their direct "small-end" customers. This document would be created to assist with operational planning and issues that might occur. There are additional relevant questions for the board surrounding this. Those questions include whether pharmacies can retrieve the pedigree from their suppliers as well as return products by way of e-mail, web link, etc., and whether the authentification and certification can be performed on the supplier's pedigree system. These questions are being raised due to the possibility of some pharmacies being unable to invest in a pedigree system of their own.

Mr. Von Rohr referenced SB 1307, but noted that the definition provided by the board was not used. He felt that the definition provided by the board on labeling was strong and provided clear guidance and that there may now be more questions from manufacturers and distributors again around whether serialization will be needed at the unit level.

Mr. Von Rohr reiterated the need for a Q&A document and hopes that it will be provided in the near future. He noted a process-flow diagram provided to the board to represent how DDN plans to operate within the pedigree environment.

***Josh Bolin (National Association of Boards of Pharmacy):***

Mr. Bolin stated that NABP recently learned about some potential amendments to SB 1307 that would utilize NABP's Verified-Accredited Wholesale Distributors (VAWD) accreditation program to authenticate a distribution channel. This would essentially exempt accredited wholesaler distributors from the pedigree requirement under current California law, and would replace what California presently has "on the books" with regard to track and trace e-pedigree system. Mr. Bolin stated that NABP was not involved with those amendments. He stated that they were not consulted with the development of the language in those amendments. Mr. Bolin explained the process involved in NABP's accreditation program for wholesale drug distributors. He stated that currently there are no states utilizing the accreditation as a prerequisite to pedigree exemption as the amendments in SB 1307 would purport to do. He stated that NABP believes that a regulatory structure for wholesale drug distribution should contain three independent tiers that work together to regulate wholesale drug distributors. Those tiers would include establishing strong criminal penalties, increasing the licensing requirements and establishing a pedigree system that may contain two phases. The two phases would be normal distribution channels as well as a track and trace system.

Mr. Bolin provided a brief history on NABP's stance on e-pedigree. He emphasized that the normal distribution channel method was never intended to be a final pedigree solution, but rather a temporary "band-aid" while allowing wholesalers the time needed to comply with a full electronic track and trace system. He pointed out that NABP is disappointed to see those same industry members who agreed to the normal distribution channel as an interim step now working to attempt to make it permanent, and stated that they might never had agreed to the temporary solution if they had known that industry would then try to make it a permanent pedigree solution.

Mr. Bolin stated that NABP can no longer support a proposal that, with the amendments currently suggested, as it is "taking a step back" in removing a track and trace pedigree structure, which is needed to protect the distribution channel across the country.

***Questions to the presenter:***

Mr. Goldenberg asked for clarification on the approval and inspection process of a wholesaler becoming approved as a VAWD by NABP.

Mr. Bolin explained that the process involves an inspection once every three years as well as a renewal process annually. The renewal process includes verification of updated policies and procedures, as well as checking the validity and good standing of the license.

Mr. Graul indicated that the board has heard of some states coming up with their own pedigree standards, which could create a problem for the industry. He asked if there has been any progress in Washington towards a federal solution.

Mr. Bolin responded by referencing the request from FDA on comments for setting standards. He noted that it is just legislation at this point and nothing is finalized. He also stated that FDA's collection of the comments for those standards is the most significant progress to date and the results of those should be forthcoming.

Mr. Dazé asked if NABP has had the opportunity to address their concerns to the author of SB 1307.

Mr. Bolin responded that he only recently read the proposed amendments and has not had the opportunity to address them at this time.

***B. Discussion and Action Regarding SB 1307 (Ridley-Thomas):***

***Greg Hurner (State and Consumer Services Agency):***

Mr. Hurner stated that Agency has been looking at the issue and its direction over the last several months. The Governor's office has attempted to evaluate the priorities in terms of investment and costs as well as where the consumer will receive the most benefit. He stated that he was struck by the presentations and how it is most definitely a federal issue and should be appropriately dealt with at that level. Mr. Hurner pointed out the governor's aggressive actions in health care and consumer protection, and stated that Agency believes California costs would be better imposed in the areas of e-prescribing and health care

access. He stated that it is not feasible to have a secure chain unless you have a national model. Mr. Hurner said that the board needs to look at the costs being imposed in the system and what that does in terms of people being able to afford health care as well as being able to acquire what they need to maintain their quality of life. He stated Agency that looked at existing law and devised an accredited distribution chain, which included a VAWD accreditation as well as one where the board would adopt a standard with accreditation requirements. Mr. Hurner stated that they feel that this is a reasonable next step of protection until the federal government acts to have a uniform e-pedigree proposal across the country. He clarified that Agency is thus not asking for the delay. They feel that the risks by the supply chain are not as great as the benefits that can be provided to the consumers in the other areas mentioned earlier. It is understood that there are some issues with regard to lot numbers and language and they will be flexible in working with stakeholders to address those issues. He also added the concern over VAWD accreditation and its lack of value and reiterated the potential for a less expensive option for accreditation with the board.

***Questions for the presenter:***

Mr. Goldenberg shared his understanding of the issues the state is facing in terms of budgetary restraints. He pointed out that the industry is facing that same issue with regard to a changing economy that is difficult to survive in. He shared his concern over the possibility of pharmacies that are struggling to manage their expenses that will become more likely to obtain their supply from whatever source necessary in order to reduce their costs. He expanded on how this change can affect the board as well in trying to enforce the industry and protect the public.

Mr. Graul stated that the e-prescribing issue is very important to him as a practicing pharmacist. He feels that it is a tremendous consumer protection issue and is glad to hear that the topic is being considered. He agrees that e-pedigree is a federal issue. He asked how the board could proceed to get the issue addressed properly at the federal level and provide impetus for that solution which everyone ultimately wants.

Mr. Hurner responded by stating that they are very engaged in the issue and are engaged at the federal level as well. He stated that they would attempt to help guide the direction of the federal government in what they think is reasonable. He added that they would depend on the board's expertise to provide input and feedback so that Agency can move forward in partnership.

Mr. Hurner commented on the concern brought up in earlier presentations regarding penalties being inappropriate and noted that part of the proposed amendments to SB 1307 involved enhancing the board's penalty authority. He added that it is a question of identifying appropriate tools to deter and identify counterfeit activity. Mr. Hurner stated that they consulted with staff on what the penalties would be and feel that those suggested are appropriate.

President Schell responded that the board appreciates that opportunity, but added that they may need to consider some methodology of how to make the tools most effective.

The board was advised that SB 1307 passed out of the Business and Professions Committee. Ms. Herold explained that this means the bill cleared the policy committee in the second house and will now go to the fiscal committee in the second house. After that it will have to go to the Senate for concurrence. She added that the bill has been amended several times and included a summary of those amendments.

Robert Swart asked if we need to have more involvement at this point.

Ms. Herold indicated that a number of people who are in attendance at today's board meeting have been sitting in on those meetings. She added that that decision was made at the April board meeting already.

MOTION: President Schell to draft a letter to the author of SB 1307 indicating the baord's willingness to work with administration.

M/S: GRAUL/SWART

SUPPORT: 10 OPPOSE: 0

## ***C. Discussion and Action Regarding the Board's Heparin Recall Inspections 2008***

President Schell stated that the board inspected all 533 licensed hospital pharmacies in California between late April and early June 2008. The board identified 94 hospitals where recalled Heparin or Digitek was found in nonquarantined areas. He noted that in 29 of these hospitals, the board identified the recalled heparin in patient care areas, and that the primary goal of these inspections was to ensure patients did not receive recalled products. President Schell stated that sanctions for failure to adhere to the recall would be pursued in the coming months.

President Schell indicated that the board also mailed letters to the board's licensed surgical clinics about the Heparin recalls, and called the administrator in each location. He added that, in the case of Digitek, the board sent letters to the state's 6,000 community pharmacies to ensure these facilities initiated action to remove the product from the pharmacies and recall it from patients as the recall notice directed.

President Schell shared with the board an incident he was advised of by a hospital pharmacy. The pharmacy had cleared out all of the recalled Heparin and sent it back to the manufacturer, but the shipment was resent back to them again by the wholesaler manufacturer. He pointed out that this issue as well as others has caused concern by pharmacies over being held accountable for areas where they do not have control.

President Schell noted that the board has been working with the California Department of Public Health and the FDA on these inspections and activities, and that the board will provide its findings in the January 2009 *Script* newsletter. He also added that future regulations and statutory changes might be needed to ensure future recalls have better adherence rates.

President Schell pointed out that, had serialization requirements been in effect at the time of these recalls, pharmacies would have been able to identify what specific Heparin or Digitek products had been delivered to the pharmacy, and by using decommissioning data for dispensed product, could have identified how many remaining products where located in the hospital.

Mr. Goldenberg asked for confirmation that cite and fines are pending for pharmacies where recalled Heparin was found on the shelves at the time of recall inspections.

Ms. Herold responded that the board staff has a number of disciplinary sanctions at their disposal and are in the process of writing the investigation reports. She provided background on the specifics of the recall and its severity, which is why the staff decided to take serious measures to ensure the recalled drugs were removed. She stated that there where94 entities identified recalls with Heparin. Ms. Herold also stated that there were a number of hospitals found to be dispensing the recalled Heparin even after the board inspectors had inspected the facility and advised the hospital to remove the drug. She stressed the concern over non-compliance by some hospitals and pharmacies, and emphasized that consequences for failure to adhere to the recall will most definitely occur.

Mr. Goldenberg concurred with the chosen disciplinary actions of the enforcement staff and feels that the cite and fine action should send a clear message and bring awareness to the industry.

Ms. Herold noted that the recall notices themselves are not very clear. She added that when the pharmacies and hospitals receive numerous notices from various sources, they may sometimes choose to ignore them because they assume they are duplicates. Ms. Herold stated that the board staff is considering the required participation in the board's Subscriber Alert system as a better means to distribute recall notification.

Dr. Swart shared his concern that pharmacists will assume that new drugs being shipped after the recall are safe and unaffected by the recall.

Ms. Herold responded that there were three that were documented.

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

This portion was presented earlier in the Board Meeting.

President Schell asked if there are any requests from the audience to have the presentation provided once more by Supervising Inspector Bob Ratcliff. There were none.

## ***IV. Committee Membership Roster***

President Schell provided the membership roster to the board and allowed time for review. He listed the committees and their members.

President Schell explained that, during the June 23rd Licensing Committee meeting, the committee was advised that a task force was being created to evaluate pharmacy technicians and their requirements for licensure. President Schell requested that Stan Weisser be the board representative of this task force.

## ***V. Public Comment for Items Not On the Agenda/Items for Future Meetings***

No public comments were provided.

The meeting was adjourned at 2:15 p.m.