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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: March 25, 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
Kristy Schieldge, DCA Staff Counsel
Tina Thomas, Staff Analyst

Call to Order

The board meeting was called to order at 9:15a.m. by President Powers.

President Powers made a number of announcements and recognitions:

President Powers honored 50-year Pharmacist, Barry Solomon. Mr. Solomon was presented with a 50-year lapel pin by the Board of Pharmacy.

President Powers introduced Rich Mazzoni, a former board member and former president of the board.

President Powers introduced Lori Rice, a previous executive director of the board.

President Powers introduced the Board of Pharmacy's new staff counsel, Kristy Schieldge and provided a brief background on Ms. Schieldge's prior experience

President Powers and Ms. Herold requested that any representatives who would like to speak on E-Pedigree readiness, to sign-up on the form outside of the room.

President Powers acknowledged Spencer Walker, who has been promoted to special counsel for the director of DCA. President Powers thanked Mr. Walker for his service to the Board of Pharmacy over the past two years.

Presentation to the Board from Food and Drug Administration
Ilisa Bernstein, Director of Pharmacy Affairs (via telephone).

Dr. Bernstein began by reiterating FDA's support for California's efforts to provide safety to the drug supply chain.

She provided an update on new developments relating to identification, validation, authentication and track & trace of prescription drugs. Dr. Bernstein discussed the details of recently enacted federal legislation which includes standards development; specifically the use of a standards numerical identifier, and standards developed to address pharmacy technologies. There are two notices published in the Federal Register requesting comments and information related to the new section 505D provision.

Two separate dockets were initiated (standards and technology information).

The first notice focuses on standards development. The FDA prefers that these standards be a result of existing private and public sector collaborative processes. The FDA has published a series of questions to focus the responses. The FDA will use those responses to determine the standards development and how aggressively it may move forward. The FDA may consider adopting such standards through a guidance process as quickly as possible.

Examples of types of information the FDA is seeking:

> The standard numerical identifier – should it contain recognizable characteristics (i.e., NDC codes) or random? How can the supply chain determine that the numbers are unique and not duplicated?
>
> Should a Lot/batch number be included?
>
> Standards:

Do standards currently exist? To what extent do these standards reflect stakeholder consensus? Should the current standards that exist be adopted by FDA? If not, can changes be made to make the standards acceptable?

Are the standards developed in other countries? Who is developing them? Is there a timeline? What are the elements of those standards? What is the feasibility, cost, etc.?

Should certain standards be implemented before others, or concurrently?

The second notice is regarding technology development. In order to address the recent technological advances as outlined in new provisions of the act, the FDA is seeking information from technology vendors via this federal register notice.

Examples of type of information FDA is seeking:

What are the RFID technology advances specifically?
What are the costs?

Comments for both of the above notices are due May 19, 2008. Notices and a full list of questions in the notice, as well as instructions on how to submit comments can be found at www.fda.gov/counterfeit.

Dr. Bernstein reiterated that this should not deter the expeditious progress in California toward widespread implementation, serialization, e-pedigree, and track and trace in the drug supply chain.

Mr. Goldenberg and President Powers thanked Dr. Bernstein for presentation. The board looks forward to sharing California's information with FDA as they move through this process.

Presentations to the Board on Readiness to Implement E-Pedigree

Ron Bone – McKesson Corporation:

McKesson requested a delay in the e-pedigree deadline. Mr. Bone stated that he feels the health and safety of the public will best be served by this delay.

Based on a recent survey conducted by McKesson, only 100 of 650 suppliers believe they could comply by 2009. Extending the deadline will provide the suppliers, as well as the wholesalers and manufacturers the time they need to be properly prepared for e-pedigree. McKesson feels that the hospitals and pharmacies should also be given additional time to comply with the e-pedigree law as well.

Questions to the presenter:

Mr. Dazé asked how a two-year delay will be a safety feature for the consumers. Mr. Dazé expressed deep concern for additional delay and allowing counterfeiting to enter our drug supply for two more years.

Mr. Bone responded that steps have been taken in the supply chain to reduce opportunity for counterfeiting (i.e., committing to buying only from manufacturer, thus cutting down the number of companies in the chain of distribution).

Mr. Bone stated that there has been a great deal of momentum from manufacturers in running tests through their facility in getting ready. He said that the issue is that ALL drugs would need to be ready by 2009. Many are moving forward, but at the case level only. McKesson stressed that they don't want to be the "gate" that stops pharmaceuticals moving through to the patients because their manufacturer partners do not have e-pedigree in place.

Mr. Bone noted that McKesson speaks on this topic more than any other topic as an industry, which places a large amount of attention on this issue, thereby creating more difficulty for counterfeiters to enter the system.

Mr. Goldenberg asked for clarification on how the insurance of manufacturing of drugs works. He questioned whether insurance companies are stakeholders in this issue as well and whether we should be inviting them to provide input.

Mr. Dazé provided previous experience as general counsel for airlines. He explained that if something went wrong, insurance companies handled the issues (versus the airlines). Mr. Dazé suspects pharmaceutical and manufacturing companies have business loss insurance and do same. He gave the example of the recalled Heparin, and stated that they may have insurance to cover the costs of any lawsuits which may have resulted.

Dr. Schell thanked McKesson for the presentation and has been impressed by the efforts of McKesson so far. He asked if, based on their survey, McKesson was able to determine if the manufacturers will be ready by a deadline of 2011, if it is extended.

Mr. Bone responded that there is signifant energy on this topic right now in the pharmaceutical industry. He said the message is clearly being delivered. McKesson is making themselves available for people coming to them for assistance. They are only getting a "sliver" of interactions that are going on within the industry. Mr. Bone noted it certainly has the attention of all.

Dr. Schell stated his concern over the risk of not having a good system in place. He shared his concern over whether it will ever be done if it's not going to be done in 2009.

Mr. Hough indicated that he had done an informal tally of e-pedigree mailings regarding the implementation deadline. His tally reflected that 33 want to delay and 4 can implement to some degree. Mr. Hough noted that the theme in the mailings is that we cannot accept deterioration of patients' safety during implementation, which is a very important note. Mr. Hough elaborated on Mr. Dazé's comments, which are that if the board decides to delay, there should be some kind of sanctions regarding continuous delays.

Lara Simmons – Medline Industries, Inc. (PowerPoint presentation attached):

Ms. Simmons stated that Medline is the nation's largest wholesale hospital supplier.

Ms. Simmons discussed the surgical convenience kits (which include drugs) provided to their customers (hospitals). All items needed for surgical procedures are inclusive in the kits. The kits are hospital/surgeon specific, and have exactly what a doctor needs. Medline contracts with the drug supplier, and the kits include over-the-counter and prescription drugs. The drugs are placed within the kit and the kit is then sterilized with drugs inside of kit. The drugs are typically low-risk (for counterfeiting) and low-cost drugs that are not found on the streets.

Ms. Simmons stated that the challenges MedLine faces in implementing e-pedigree are that any given kit may have 1) multiple drugs, 2) drugs from multiple manufacturers, 3) a sterile kit packaged within another larger kit and/or 4) drugs from different lot numbers. From manufacturing perspective, the ability to identify on the insert of a kit exactly what lot number of drugs within the kit is a fully manual process, thus allowing for human error. Additionally, there is no way to verify the accuracy of the information without opening the kit (which then causes kit to lose sterility). Ms. Simmons stated that another challenge is contract manufacturing, which makes pedigrees complex. She gave examples of two drugs in one kit and the complexity of pedigrees due to the routing process. Multiple lot numbers of multiple drugs within multiple kits causes more complexity and a larger challenge with verification. Additional challenges include the lack of clear guidance for repackagers working with surgical kits. Suppliers like Medline also have the challenge of not being able to put a system in until they know what the manufacturers will do.

From Ms. Simmons' perspective, they cannot meet a 2009 deadline.

Ms. Simmons provided some workable options: Placing an E-Pedigree in the kit itself, two-step pedigrees (serialization of the kit itself), exemption kits that contain low-risk drugs, or not putting drugs in the kit at all. The latter is not best option.

Ms. Simmons provided additional challenges, which include naming the legal manufacturer (information often withheld), intra-company transfers, proprietary information, lag time on receiving pedigree post-delivery, employees concern over liability, and cost (which is passed down to the consumer).

Questions to the presenter

Dr. Swart asked what Medline would do if drugs are recalled.

Ms. Simmons responded that all kits would be recalled (entire kit).

Mr. Goldenberg shared that there will be a presenter here later on from the Engineering Dept. at UCLA which outsources its talents to the industry to solve problems such as this. Mr. Goldenberg encouraged the speaker and everyone else to stay for the duration of the meeting to hear what they have to say. Mr. Goldenberg noted that there are solutions out there to these problems.

Ms. Herold stated that a future Enforcement meeting will be addressing various packaging issues for drugs and how to address that for e-pedigree and the industry as a whole. She

encouraged MedLine to provide questions proposed to the board for discussion at that meeting.

Shawn Brown – Generic Pharmaceutical Association (PowerPoint presentation attached):

Mr. Brown explained that this is a follow-up to the presentation at the December board meeting, and is in response to board's questions. It includes results from a survey of their members to show what they have done to prepare to comply.

GPhA is a member of a coalition of a trade association, and are working with FDA to develop standards. They will be having a workshop with FDA within the next month in that regard.

Mr. Brown shared statistics, including employee hours and out-of-pocket expenses required to prepare and implement and comply with e-pedigree law. Mr. Brown noted that one particular manufacturer indicated they have spent over12,000 hours and $5 million in order to comply. He reiterated the challenge of capacity of the tags, and whether they would have enough tags for all pharmaceutical companies. Vendors are indicating that it could be up to 6 months before the tags are ready.

Mr. Brown presented steps and preparation activities taken to date by manufacturers to implement serialization. He also provided a general timeline of major events conducted within the industry.

Mr. Brown provided an estimated cost breakdown, including start-up costs ($500 million) and packaging line serialization equipment upgrade costs ($503+ million). Mr. Brown discussed additional costs, including serialization operating costs. The estimated operating cost was placed at $350 million. Mr. Brown noted that these estimates represent approximately one-third of the dosage forms; they do not include the other two-thirds of dosage forms.

Questions for the presenter

Mr. Dazé stated that the numbers presented are high, and he understands that the cost will ultimately affect patient cost. He shared his concern over whether anything will change if we delay to 2011. Mr. Dazé pointed out that the cost will still be there (and be higher due to inflation), and the industry could come back to the board and state that they can't implement due to higher costs.

Mr. Brown responded that he has heard (but does not have facts to support) that the costs will go down. Mr. Brown feels there is a lot more momentum now towards taking extra security measures. The message has been conveyed.

Mr. Dazé brought up the Baxter recall example. Mr. Dazé suggested that, had serialization been in place, the factory may have only needed to recall a fraction of the drugs. Mr. Dazé stated his concern over a slow down of the process with another implementation delay.

Mr. Brown responded that he's not sure having serialization would have stopped the medicine from reaching the consumers, but it would have facilitated the recall procedures.

Mr. Brown stressed that GPhA shares Mr. Dazé's concern. They are looking into options of measures they can take as an industry.

Ms. Herold asked what total sales are estimated to be if they go with RFID (in conjunction with figures of costs provided).

Mr. Brown responded that he believes they have the information. He will send it to Ms. Herold.

Ms. Herold pointed out that, when we look at sales as well, the cost may not be quite so big in perspective.

President Powers asked for clarification as to whether GPhA is asking for a delay.

Mr. Brown responded that they are.

Julianna Reed – Hospira Inc.:

Ms. Reed stated that Hospira manufactures products that are purchased by and administered to patients in acute care hospitals.

Ms. Reed stated that Hospira will need to convert over 50 manufacturing lines at over 50 plants around the world to comply with e-pedigree law requirements. Hospira requests that the Board of Pharmacy work with them to identify the safest and lowest cost approach to e-pedigree implementation.

Ms. Reed discussed Hospira's concerns with implementation, which involved timing and technologies that can be used for track and trace.

Hospira states that they will not be using RFID technology because of insufficient data to indicate RFID safety with regard to liquid and/or metal-containing drug and IV devices. Hospira will use 2D bar codes as it has been successful in the past. Hospira asks that the Board of Pharmacy remain flexible in allowing manufacturers to determine the safest technology for their product

Another concern by Hospira involves the development of standards. Hospira will need to meet the requirements of several different states and countries, and each change adds cost to system. They request that the Board of Pharmacy continue to work with global stakeholders, to develop pedigree standards that would work for California as well as other countries.

Additionally, Hospira is concerned with the cost in e-pedigree for low risk drugs. Low risk drugs are costly and difficult to manufacture, however they are not attractive to counterfeiters, and there have been no records of counterfeit incidence for over 70 years. Hospira asks that the board consider a risk-based application to the pedigree requirements.

Questions for the presenter

Mr. Dazé asked if they are stating that all 50 of their lines would be on-line for 2011. He asked if they are committing to being ready, and that they are not going to come back to the Board of Pharmacy six months prior to 2011 and ask for another extension.

Ms. Reed responded stated that they are trying to meet that, however they can't predict what might happen.

Mr. Dazé reiterated his concern that another request for delay may occur if the board grants the extension.

Ms. Reed responded that she can only speak for Hospira. She restated that Hospira is shooting to be on-line for 2011. Ms. Reed commented that they're doing this for other states and countries.

Scott Turner – Sciele Pharmaceutical (PowerPoint presentation attached):

Mr. Turner explained that he was presenting today to summarize the letter submitted to request for a delay. He confirmed that Sciele will meet the 2009 deadline, however they need an extension for full compliance, which includes serialization to the unit level. Sciele feels that, although they are requesting the extension until 2011, they will be compliant prior to the deadline. Mr. Turner stressed that they do not feel this delay will put the public at additional risk.

Mr. Turner provided a background of Sciele.

Mr. Turner explained the reasons for the additional time needed:

> The relocation of their distribution center, which will be completed by the first quarter of 2009.
>
> Sciele's product line is manufactured and packaged by third parties, and will require supplier alignment on how to implement. The current deadline will not provide sufficient time for that.
>
> The IT teams need time to realign and focus on implementation product security (versus transaction security). Transaction security is scheduled to be in place by summer of 2008. Product security is targeted for 3rd quarter of 2010.

Mr. Turner reviewed Sciele's specific barriers, as explained within their written request for additional time. He also restated their targeted dates of compliance, as well as the request for extension. Sciele supports the mandate to be compliant in order to protect the public.

Questions for the presenter

Mr. Burgard asked if Sciele will be prepared and on-line if delayed to 2011.

Mr. Turner responded that they will. He stressed that Sciele's objective is not to slow this process down, but rather to continue to stay focused and not put it on back-burner.

Liz Gallenagh – HDMA:

Ms. Gallenagh explained that she was presenting today to reiterate their points made in extension letter submitted to the board, and to reemphasize the comments made today by their members of HDMA who previously presented.

Ms. Gallenagh stated that California's model offers the best framework for e-pedigree, and that it will preserve the integrity of the entire supply chain. HDMA is, however, concerned that the supply chain won't be able to implement by the 2009 deadline.

Ms. Gallenagh stated that HDMA understands more today about what technology can and cannot do, and what is required for companies to move forward towards track and trace systems. She stated that suppliers are working more closely together to address challenges and technology prior to implementation. She reiterated that HDMA does not intend to stop progress that is already started, and are requesting the extension so that the supply chain has adequate time to "get it right."

Questions for the presenter

Mr. Dazé asked if they are feeling any "pushback" from their members, indicating that they will NOT be ready by 2011.

Ms. Gallenagh responded that HDMA has not received such specific feedback. In general, they are indicating will be ready. Because of their position in the center of the supply chain, it places them in a unique position. She stressed that the entire supply chain needs to work in tandem for this to come to fruition. She has no doubt they are doing that.

Mr. Dazé shared his concern that the board will have the same request for another extension in two years.

Ms. Gallenagh responded that, in speaking for the distributors that HDMA represent, they have invested a large amount of money in time and labor to develop the systems to do this. She wouldn't anticipate that they would abandon that investment, or that they would choose to find a better way to do it rather than what California law suggests.

Mr. Hough stated that it appeared additional costs are questionable. He questioned whether they have looked at the big picture in looking at the full cost of this.

Ms. Gallenagh responded that their distributors are the most efficient in world. Ms. Gallenagh stated that she would trust they will preserve efficiencies in the supply chain as much as possible.

Mr. Weisser noted that in the presentation, Ms. Gallenagh referred to the manufacturers only. He asked what kind of programs they are developing for the end users (i.e., pharmacies, hospitals)?

Ms. Gallenagh responded that they are working on trying to find the best solutions. She referred to Mr. Bone for additional response.

Mr. Bone (McKesson) explained that there is a two phase process. He stated that the wholesalers play a significant role in adopting a process for the non-major chains, and the community and hospital pharmacies look to the wholesalers to help them. It will take more time between McKesson and the retail community. Mr. Bone noted that the process will be quicker and go more smoothly for the larger retail entities, while the smaller entities will be challenging. McKesson shares the board's concern.

Mr. Weisser commented that wholesalers have been very supportive in the past with regard to the community pharmacy and new technology. He asked if they feel that they can only speak for McKesson in terms of being committed to the end of the supply chain. Mr. Weisser noted that without the wholesaler engagement, there will be no continuity to the community.

Mr. Bone responded that McKesson is customer based, and understands that this is one of challenges which need to be addressed. He stated that they would rather work with the manufacturers first, and then address the retail side. Mr. Bone requested the board's consideration in allowing them to work on first connections, and then work on the second connections.

Dr. Swart commented that he has no doubt that the process will come quickly for McKesson in working with the manufacturers and wholesalers, and that the second part will come quickly as well. He commended McKesson for entering into this the right way. Mr. Weisser agreed.

President Powers allowed opportunity for any additional presentations or comments. No additional comments were offered.

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

President Powers commented that the board takes it public protection very seriously. President Powers reiterated that the board wants to see the e-pedigree law in place as soon as possible.

President Powers read a statement pertaining to the increasing threat of public safety due to counterfeited, misbranded, adulterated and diverted drugs, and the subsequent need for a flawless e-pedigree system. The statement addressed the board's possible decision to allow the requested extension in the current e-pedigree deadline, as well as the reasons to allow for such an extension based on the feedback given to date from the pharmaceutical industry.

Mr. Graul thanked the stakeholders who made presentations. Mr. Graul made a motion to extend the date of the implementation of e-pedigree requirements.

Mr. Dazé clarified that President Power's statement not yet been approved nor discussed.

Mr. Room added the statement President Powers read with a proposed decision of the board was written as if the board has already made that decision (which it had not). The

statement of decision was read prior to the motion to extend. The board would now need to have that discussion on whether or not to extend the deadline.

Ms. Room added that at the request of the president of board, staff prepared the statement which was presented by President Powers. This statement articulated the reasons why the board may choose to delay the implementation if the board chooses to do so. It is entirely appropriate to have a written decision that states those reasons in the event that such decision would ultimately be made (based on the direction of the motion). This is one proposed decision that Mr. Room prepared at President Powers' request.

Mr. Graul made his decision based on that written proposed "decision," and the board would need to vote down Mr. Graul's motion first in order to do something subsequent. He recommended limiting the discussion at this point to Mr. Graul's motion.

Mr. Graul stated that this was his own motion.

Ms. Herold strongly encouraged the board to consider that there is no benefit to pushing the industry through the 2009 "gate." Ms. Herold stated her support of the 2011 extension. She also clarified that elements of President Power's statement came from letters and comments provided by the industry, and was created in order to be able to provide a releasable public statement in the event that the extension was in fact granted. She noted that the board had not seen the statement which President Powers read.

Ms. Zinder requested to hear the motion again. Mr. Graul reread the motion.

Copies of President Powers' statement were distributed to the board members.

Mr. Weisser asked if the motion for extension is being proposed for the entire supply chain. Mr. Graul stated that the only decision that can be made at this time based on the law is to delay or not delay the implementation. Subsequent legislation would be the only way to address modifying who participates in that delay. Mr. Room stated that the board can express interest in additional legislation, but it is not within the power of the board to do at this point.

Mr. Goldenberg stressed to the board members that he and President Powers have put an enormous amount of energy and passion in to this issue, and that he hopes the supply chain of partners are listening carefully as he talks with the rest of the board. He stated that if the motion passes, he has concern over the industry's focus and attention to the matter, which will be evident in the turnout of audience in subsequent board meetings. Mr. Goldenberg pointed out that changes may need to happen if this occurs. Mr. Goldenberg also shared his personal viewpoint that, although a delay may be decided as the best decision at this time, any continuous delay or drop in focus on this issue would not be in the public's best interest.

Mr. Hough referred to comment he had made earlier regarding sanctions in the form of milestones that must be met during implementation.

Mr. Room responded and referred to upcoming discussions on SB 1307 (Ridley-Thomas). He pointed out that such suggestions from board members will be crucial in determining the form and details of additional legislation relating to the implementation process.

President Powers stressed that the board takes the implementation of the law very seriously and will continue to focus on this issue, even if there will be a delay.

> MOTION: For the reasons given in the proposed written decision of the board, which if this motion carries shall issue as the official decision of this board, those reasons including that the threat to our drug supply is real and growing, that the California model for pedigree is widely recognized as the best approach to securing the prescription drug supply, that the industry has committed to implementing that model but faces technical, infrastructure, and resource obstacles rendering the majority unable to implement by January 1, 2009, that the industry has promised compliance will be achieved by January 1, 2011, that the additional two years will allow necessary time for fuller development and implementation of technology solutions, and that insistence on full compliance by January 1, 2009 may lead to disruptions in supply or pricing of life-saving drugs, I move that the board exercise its authority under Business and Professions Code section 4163.5, to delay implementation of the electronic pedigree requirements stated in Business and Professions Code section 4034 and 4163, until January 1, 2011.
>
> M/S: GRAUL/DAZÉ
>
> SUPPORT: 12 OPPOSE: 0

Mr. Room addressed an issue relating to two separate deadlines within the law.

The first is the general pedigree deadline. The second deadline is relating to sterile injectable drugs (B & P Code 4034 (g) that has a 2010 deadline.

There is a separate authorization within that section for the board to extend the date as well to January 1, 2011. Mr. Room suggested that the board address this deadline to have a separate vote whether to extend this date to 2011.

> MOTION: Extend the e-pedigree implementation deadline for injectable drugs administered to patients until January 1, 2011.
>
> M/S: WEISSER/SCHELL
>
> SUPPORT: 12 OPPOSE: 0

A discussion on the motion ensued. Mr. Weisser noted that we did have a presentation from Hospira earlier in the meeting where the issue of injectable drugs was addressed, and a request for delay for that category of drugs was made. Mr. Room noted that there are other manufacturers that have made the same request which would fall in this category as well.

Presentations of Technology Firms for E-Pedigree

Bob Celeste - GS1 Healthcare/EPC Global (PowerPoint presentation attached):

Mr. Celeste reviewed the history of the company over past two years, including the progress they have made in developing standards and technology for e-pedigree. He pointed out that they are now focused on improvements of those standards versus deciding on the standards themselves.

Mr. Celeste presented the state of standards, including their role in the US and global standards. Mr. Celeste emphasized the importance of focusing on global standards rather than just US standards, and that the effort is being placed in reducing all to one standard bar code.

A timeline was presented of the standards in place and work in progress. Mr. Celeste pointed out the key points of the traceability standards.

Standards adoption was discussed.

A detailed timeline was presented, reflecting the stages from assessment through adoption of the standards.

Mr. Celeste reviewed the pedigree/EPCIS assessment and advised that a business case of traceability will be conducted later in 2008.

Mr. Celeste explained the pedigree messaging standard and the EPCIS standard, as well as their various aspects and uses thus far.

Mr. Room asked if it is fair to say the pedigree messaging standard has all data formats included, whereas the EPCIS at this point is mostly a framework and an information exchange standard and that the pieces that are yet to be supplied are the actual data content and format requirements of that standard. Mr. Celeste responded that that is a fair way to look at it. Mr. Celeste noted that they have received many well thought-out proposals that describe a way of doing this and are going through that analysis. They are also finding that security is an issue, and that not every exception event is really an exception event, and could in fact be counterfeit event. He stated that they are looking at the exception process closely.

Mr. Celeste reviewed the items still needing to be addressed or that require follow-up. He noted that weekly conference calls are being conducted to address some of these areas.

Questions for the presenter

Mr. Room asked if GS1 will have a large role to play at the Federal level. He asked if have they have a vision of how that process will go forward. Mr. Room asked what role they see themselves playing in the process.

Mr. Celeste's responded that they will provide comments to the FDA which includes the basic standards of product and location identification. Mr. Celeste stated that those areas are fairly settled. He indicated that the FDA does recognize the difficulties of the national

numbering system versus a global one, and is also working with other countries on that issue.

President Powers invited questions or comments from the board and public. None were provided.

Catalent Pharma Solutions/Secure Symbology (PowerPoint presentation attached):

Akan Oton – Catalent

Mr. Akan Oton presented to explain Catalent's role, as well as Secure Symbology's specific solutions for e-pedigree.

Mr. Oton gave a background on Catalent, as well as the contract packaging services group. He stated that they provide all the tools that a manufacturer packaging organization would need.

Hans Hultgren – Secure Symbology,Inc.

Mr. Hultgren (Secugave a background of the company. He noted that they are a leader in track and trace technologies and uses both 2D Bar code as well as RFID from the item level through to the case and pallet. Mr. Hultgren also pointed out additional features that make their services attractive to track and trace implementation for e-pedigree.

Mr. Oton provided some history of Catalent and noted that they signed an agreement to provide serialization for Biogen-Idec in 2008. Catalent is confident they will be operational in serializing their products some time later this year.

Mr. Oton shared lessons learned over the past three years, including the theory that RFID and serialized bar codes should be used interchangeably. He noted that serialized bar codes should be the initial process, with RFID being added as the process goes forward. Mr. Oton also indicated that inference is needed between units of sale and the cases/pallets the products go into.

Mr. Oton stated that some manufacturers are seeking solutions for internal capability, while others are planning to establish an outsource relationship to establish serialization and e-pedigree. Catalent is working with various manufacturers, and is seeking to provide a short-term bridge or be a long-term provider for each of them.

Mr. Oton shared the capabilities and systems needed to enable e-pedigree.

Questions for the presenter

President Powers asked if they are indicating that this is a financial decision, rather than a technology issue.

Mr. Oton responded that there is a learning curve of what's out there in terms of technology. As the manufacturers understand what's out there, they then ask the questions of how to

integrate internally, as well as manage the complexity of doing that. At this point, it becomes an investment and resource decision for the manufacturer.

Mr. Room asked how contract manufacturing lines are set-up. He asked if lines are typically set up by form factor (i.e., by certain size or line), or designed specifically for each manufacturer.
Mr. Oton responded by explaining two types of customers

> Dedicated customer, which is where the same product is run every day. In this case, there's a discussion around changes in that manufacturing line.
>
> Campaign customer, which involves running multiple products on that line. It is a line-by-line (versus product-by-product) design, but they would also need to make changes to packaging to reduce their investment.

Mr. Room noted that there is ultimately an attempt of the industry to move to a more widespread adoption of RFID. He asked if they have a sense of timeframe in which the dominance of RFID would come to pass.

Mr. Oton responded that he would be speculating if he gave a timeframe.

Mr. Weisser asked what percentage of items would actually be read if using 2D barcode, depending on inference.

Mr. Oton responded inference helps the suppliers from having to open up a case, and the barcode on that case is linked to all individual saleable units inside that case. Inference allows for ease of distribution and shipment and adds efficiency. However, it increases the amount of procedures and protocols involved, and there is a need to make sure that the right parent-child relationships are in place.

Mr. Room brought up the need for the types of data the board is looking for in deciding whether inference is the appropriate way to go with 2D bar codes until RFID or other technology comes more prevalent.

Mr. Oton responded that he feels this should be answered directly by a distributor, and is not something he could address.

Mr. Oton discussed the challenges faced with packaging operations relating to equipment as well as other new aggregation challenges.

Hans Hultgren – Secure Symbology, Inc.

Mr. Hultgren provided a presentation on data integration and the "serialization vault".

Mr. Hultgren shared the challenges with data, including massive data volumes, integration of many systems, auditability and visibility. He explained their data management solution, known as the data serialization vault, and how it can be provided to each manufacturer, as well as at all levels within the supply chain. He provided an overview of the data serialization vault and some of its more specific features and advantages.

Questions for the presenter

Dr. Schell asked if they have ever rolled out this type of system to a company before.

Mr. Hultgren responded that regarding the serialization vault, the data behind it (data vault architecture) is used specifically for large active data warehousing deployment. There are many examples of companies using this successfully. With regard to serialization, this is a brand new solution

Dr. Schell asked what some of the challenges are that they foresee.

Mr. Hultgren responded that the statistics have been consistent over 20+ years, which reflect that approximately 65-70% of products in the IT realm end up as failures. Mr. Hultgren commented that, although he would like to see that percentage a lot lower, it really hasn't changed much. He pointed out that the primary reasons for that involve adding multiple parties, communication, the learning curve delay and other issues. Mr. Hultgren also mentioned the very probable challenge of running into future "technical snags", specifically the larger issues that can delay the process for a month or more.

Mr. Goldenberg referred to Catalent's statistic of globally packaging over 80 million doses per day. Mr. Oton clarified that the statistic refers to tablets. Mr. Goldenberg asked how many packaging units are within the potential market for the US, with each unit having a tag on it. This was asked so that the board can develop an understanding of, as implementation occurs, how many people will jump into that market.

Mr. Oton responded by referencing IMS (an information "house" that tracks scripts sold in US). He suggested taking 12% of that number to represent California's volume.

Mr. Goldenberg stated that that is not the number of containers that a manufacturer produces that requires a labeling to indicate that it's a subscription item. Mr. Goldenberg requested a follow-up on his question with an approximate number. Mr. Oton agreed to follow-up.

Mr. Graul asked for clarification on the 2D barcode process and packages/units. He asked if, at the breakdown at the pharmacy level, whether data is still aggregated at that point.

Mr. Oton responded that ideally it will, with appropriate implementation, but the pharmacy is also linked into the warehouse management system in the interim. Mr. Oton also stated that it is not necessary on pharmacy level, because they have received final units. Mr. Oton stated that the key issue is how pallets and cases are broken down in middle of chain.

Rajit Gadh (Director) - UCLA Winmec (video presentation)

Professor Gadh presented a discussion on the e-pedigree mandate in California, as well as what UCLA lab is doing in the area of e-pedigree by using their software program, know as Win-RFID.

Professor Gadh reviewed the upcoming deadline for e-pedigree implementation, as well as the current counterfeit issue. Professor Gadh stated that they strongly feel that the RFID approach is a better option than barcode because RFID has many more advantages, including cost, ease in visibility and durability.

Professor Gadh stated that they want to work in partnership with the state of California and the pharmaceutical industry in using RFID for e-pedigree.

Professor Gadh explained the UCLA WinRFID E-pedigree program. Professor Gadh described UCLA's labs and their products in various production and pilot stages at this point.

Professor Gadh acknowledged and expressed gratitude to the consortium of partnerships with companies and organizations of which they have been working with over the last seven years in their lab.

Professor Gadh discussed the connectivity layer of the program, the pilot conducted within the lab, and its advantages. He also reviewed the hardware and energy costs involved.

Professor Gadh stated that UCLA Winmec is prepared to collaborate on their RFID software program to help the industry work toward the mandates. They invited the manufacturers, distributors, IT companies, etc. to contact them and would like to showcase their available solutions, as well as work with them to design solutions to address their more specific needs.

Professor Gadh pointed out that in many instances the same hardware can be shared and used for different projects, and the application cost is then significantly less versus building the hardware on an individual basis. He also pointed out that the lab can be used in developing the hardware, thus bringing the cost down as well.

Professor Gadh detailed the benefits to the pharmaceutical companies of RFID, including fewer lawsuits, increased customer confidence, a better management of inventory, and reduced shrinkage.

Dr. Peter Chu - UCLA Winmec (onsite)

Dr. Chu listed their training and workshops, and invited the board and audience to attend their next conference in October.

Dr. Chu stated that the key feature of WinRFID is that it allows the manufacturers to carefully choose what is the appropriate technology in different environments and different applications.

Dr. Chu shared some different examples of projects they have done with the WinRFID applications, which included the specimen tracks used in a pilot project in the UC hospital system. They have also conducted personnel and asset tracking, as well as supply chain demonstrations for customers. They have done a number of projects with the hospital system to address specific tracking needs.

Questions for the presenter

Mr. Weisser referred to a prior presentation from a manufacturer, with intent to use 2D bar code program due to concern over radiation effects of biologicals in glass and metal products. He asked Dr. Chu to speak to that concern.

Dr. Chu responded that radiofrequency does have some effect on liquids and metals, but they can choose the best spot for the tag that has least interference with liquid and metal. They feel they can work around that issue and provide proper technology to correct that.

Mr. Room clarified the question. He asked if UCLA has the capacity to engage in any testing on the biological effects of radiation on glass and metal projects

Dr. Chu responded that they have not done any such studies yet, but that they could.

Mr. Goldenberg noted that he attended one of their seminars. He shared information that was passed along at the seminar, which is that the Department of Defense will not do business with a distributor unless RFID tags are on everything they buy, including the possibility of every bullet. Mr. Goldenberg pointed out that he sees programs such as this one offered by UCLA as a possible solution to those companies who presented today who stated that they were too small to take on the initial implementation and were relying on other larger companies to begin the process. Mr. Goldenberg felt that the presentation should be helpful to those in audience, as well as the board.

John Chorley - Oracle

Mr. Chorley stated that Oracle is very interested in supplying solutions to the industry and to help the consumer feel comfortable with the products they receive.

Mr. Chorley provided Oracle's background, including their presence in many industries. Oracle explained their role within the supply chain system, in developing solutions for the manufacturing and distribution process, and how this integrates with the rest of the business systems. Mr. Chorley explained that their goal is to provide solutions that are integrated, yet modular.

Mr. Chorley also discussed the challenges surrounding implementation technology, including uncertainty around standards, and the likelihood of validation by the FDA. Mr. Chorley also talked about the issue of inference, with the need to be able to read one tag on a box and infer what is inside that unit. He stated that they have a lot of experience with that technology, involving imbedding contents inside other contents and using labels to infer what's inside.

Mr. Chorley shared Oracle's overall statement of direction. He stressed that they are committed to developing and delivering a solution. Mr. Chorley gave a timeline of delivering a solution within the end of their next financial year (May 2009).

Mr. Chorley talked about the pedigree extension as it is tracked down through the supply chain and the issue of document forwarding versus global repositories. Mr. Chorley stressed that Oracle's main focus is on wholesalers and manufacturers at this time, and will not be

involved with the pharmacy operations. Mr. Chorley stated that Oracle is experienced and focused on the manufacturing pedigree piece of e-pedigree, as well as pedigree management and EPCIS. Mr. Chorley presented additional illustrations of Oracle's design ideas. He stated that they will also support customers with other open integrations to and from business systems, regardless of whether they use Oracle's business applications.

Mr. Chorley shared Oracle's timeline regarding business requirements and design process, including working with focus groups. Oracle will initially work with their current customers, followed by delivering the complete program into market, and will be in alignment with the mandated deadline of California's e-pedigree law.

Mr. Chorley introduced members from his design team who were prepared to answer any questions from the board.

Questions for the presenter

Dr. Schell stated that it seemed like a partial solution, and left off the solution to most important interface, that being the patient. He asked why they are leaving them off.

Mr. Chorley responded with clarification. He pointed out that pharmacies have business systems within their dispensing process. Oracle will provide "hooks" that can be used within those business systems that will inquire and validate the pedigree. He feels that this results in a closed business process. Oracle is not going to deliver a complete solution for pharmacy processing, but will work in conjunction with their internal business system which they have in place.

Discussion on Senate Bills 1307 and 1270

Ms. Herold introduced the discussion of Senate Bill 1307 and provided a summary of the bill. Ms. Herold explained that the proposed amendment clarifies that the serialization number must appear as part of the e-pedigree. Ms. Herold requested that the board take a position on this issue.

During discussion of the bill, Ms. Schieldge suggested that the board consider authorizing the board's president and executive officer the ability to negotiate future amendments before the bill is passed.

MOTION: To support SB 1307.

M/S: WEISSER/GRAUL

SUPPORT: 12 OPPOSE: 0

Ms. Herold reviewed Senate Bill1270. Ms. Herold indicated that the bill is currently in spot bill form, and strikes all the dates with respect to California's e-pedigree requirements. Ms. Herold advised that the board should not take a position on a spot bill until they better know

what the bill will do. Ms. Herold stated that she has seen proposed amendments, but until the amendments are added into the bill we should not move forward. Ms. Herold stated that the sponsor of the bill is a coalition of pharmaceutical manufacturers, wholesalers and retailers who have conducted a series of meetings that she has not been invited to.

Ms. Herold explained the definition of a spot bill. She stated that there are legislative deadlines by which bills have to be introduced and have to pass particular committees. The spot bill shows, in general, where a bill is going to amend the law, but allows time beyond the deadlines to work out the provisions.

Ms. Zinder confirmed that there is a legislative committee meeting on April 11th, and whether this bill would be amended then.

Ms. Herold said the committee will review the bill, however there is a hearing before then and the action of the committee is not binding on the board. She noted the next board meeting is April 23rd, which is close to the deadline for the house of origin.

Mr. Room commented that board Members or the Executive Officer may expect to be called to that hearing to testify.

> MOTION: To authorize the president and executive officer to negotiate future amendments to legislation as needed.
>
> M/S: DAZÉ/SWART
>
> SUPPORT: 12 OPPOSE: 0

President Powers asked the audience if there are any comments or questions for the board.

There was a question from the audience on clarification of the next board meeting.

Ms. Herold provided the date and location for the next board meeting, which is April 23 (Radisson Hotel - Sacramento) and 24th (Department of Consumer Affairs – Sacramento).

Ms. Herold stated that an agenda has not yet been published. She gave a brief summary of what to expect at that meeting, which will include a lengthy session on legislation, possible presentations based on e-pedigree, as well as discussions on public education and licensing issues. Ms. Herold said that any items relating to E-Pedigree will most likely be placed on the agenda of the first day of the meeting.

Tony Ross addressed the board. He stated that he works with companies that will be involved in meeting the e-pedigree law requirements. Mr. Ross suggested that the board attempt to clarify all the gray areas (i.e., inference, grandfathering), questions and barriers that are potentially slowing down the process for the industry as a whole in completing the various stages of implementing.

The meeting was adjourned at 3:45p.m.