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

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT COMMITTEE
MINUTES

DATE: October 6, 2008

LOCATION: Department of Consumer Affairs
Hearing Room, First Floor
1625 N. Market Blvd.
Sacramento, CA 95834

BOARD MEMBERS PRESENT: Robert Swart, PharmD, Chairperson
Stanley C. Weisser, RPh
D. Tim Dazé Esq,, Public Member
James Burgard, Public Member

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Joshua Room, Deputy Attorney General
Tina Thomas, Analyst

The meeting was called to order at 9:39 a.m.

I. Workgroup on E-Pedigree - Progress on the Implementation of Electronic Pedigrees Pursuant to the California Business and Professions Code

1. Update on provisions contained in SB 1307 (Ridley-Thomas)

The Legislative Session ended September 30, which is the date when the Governor signed SB 1307(Ridley-Thomas).

Executive Officer Virginia Herold provided a presentation on SB 1307 recently signed by Governor Schwarzennegger. She provided background on the pedigree law, including the dates of the initial law implementation and the current compliance timeline established for manufacturers, wholesalers and pharmacies. She read the statement explaining the legislative intent of SB 1307. Ms. Herold reviewed new and expanded definitions that were not provided in the prior law, including the requirement to include the “smallest package or immediate container” and the established definition of a repackager. She also explained the board’s requirements with relation to preemption of California law. She reviewed what she has been

told from the industry, as well as vendors, in terms of readiness. Ms. Herold also provided a breakdown of what the board envisions as the next steps for moving forward, which includes working with industry on standards, technology and initiatives to increase implementation, as well as engaging hospitals.

This law now staggers implementation of e-pedigree requirements away from 2011 to:

- 50 percent of a manufacturer's products by 2015
- the remaining 50 percent of the manufacturer's products by 2016
- Wholesalers and repackagers must accept and pass e-pedigrees by July 1, 2016, and
- Pharmacies and pharmacy distribution centers must accept e-pedigrees by July 1, 2017

There is preemption language that would repeal California's provisions if federal law regarding e-pedigrees is enacted, or if federal standards are enacted, they would take effect in CA.

There are provisions that define drop shipments, 3PLs, repackagers and manufacturers. Grandfathering provisions for drugs already in the supply chain are included. The board will ultimately have to develop regulations for various components, including inference.

Senator Ridley-Thomas added a letter to the Senate Journal, reflecting the agreement of those who worked on amendments to California's e-pedigree law. A copy of this letter is also included in this tab section.

Chairperson Swart thanked those in industry who have been assisting in the process and agreeing to compromise where needed.

Public Comment:

A member of the public asked if the power point will be on the board's website. It was confirmed that it would be contained within the board meeting minutes when released.

2. Presentations and Updates by GS1, Manufacturers, Wholesalers, Pharmacies and Their Associations to Implement Electronic Pedigrees

Bob Celeste (GS1):

Mr. Celeste provided a standards development and adoption update. He provided a list of the workgroup participants involved in the global standardization project, and pointed out the significant quantity of hospital and GPO participation, which was not the case prior. He discussed patient safety and explained specifically how traceability affects this area within e-pedigree and other uses of extended traceability data. He discussed standardized product identification and how it varies significantly throughout wholesalers and the difficulty that causes within e-pedigree and tracking. He gave an example of two different products that has been marked with the same number. Mr. Celeste also discussed standardized location identification, and gave an example of the various ways a single hospital is identified within the supply chain. Mr. Celeste reviewed significant events affecting pedigree adoption that have occurred recently, including a change in the area of standardized product identifiers and medical devices, a plan to eliminate of custom account numbers by 2010 and custom product numbers by 2012. He

explained two standards being developed, which are a global traceability standard for healthcare and a discovery service standard. Mr. Celeste added that the Traceability Adoption Working Group has identified five focus areas while working with NPCIS. He stated that the workgroup has done a lot of work in data alignment and pedigree events. He noted that the workgroup will meet next week and hope to place timelines with the focus areas discussed. Mr. Celeste indicated that they produced healthcare provider toolkits which are available to anyone who is interested.

Shawn Grubb (Procter & Gamble):

Mr. Grubb reviewed the current status of pedigree within Procter & Gamble. He gave a brief background on their activity in relation to preparation for compliance, and stated that they are on target for compliance and awaiting additional direction from California. He provided a visual of "unofficial sensing" and gave specifics of where eight manufacturers appear to be in terms of their readiness. He stated that the manufacturers who are prepared are taking this deadline extension as an opportunity to rethink some of their longer-term strategies and tools.

Mr. Dazé commended and thanked Procter & Gamble for their efforts in moving forward with meeting e-pedigree requirements and supporting consumer safety.

Questions from the board:

Stan Weisser asked Mr. Celeste how integrated their system is going to be with other countries in relation to compatibility.

Mr. Celeste responded that GS1 has been very active around the world. He stated that there are a number of issues with local and national standards in the use of global standards. He noted, however that they are making progress with Belgium, and that the United Kingdom and Japan will only use standards set by GS1. He indicated that some GS1 member organizations in other countries are part of the government, so they help guide the use of those standards. He also added that a lot of the countries don't know how to establish the regulations, but GS1 will provide assistance. He noted that Europe's standards are geared more around authentication.

Ron Bone (McKesson):

Mr. Bone thanked the board in preparing a path for successful e-pedigree implementation in California. He updated the board, stating that McKesson has gathered a number of manufacturers that have said they are interested in participating in the testing phase of implementation. Mr. Bone stated that the value in delaying implementation will allow industry to incorporate e-pedigree into their business (versus doing a quick-fix). McKesson is seeing more thoughtful approaches and activities being developed by partners in the industry due to the additional timeframe allowed. Mr. Bone indicated that they are working with governments overseas to agree on one system for traceability.

Chairperson Swart stated that, as manufacturers start to be involved in testing with McKesson, the board would appreciate hearing from McKesson on how the progress is going.

Mr. Weisser stated that he was glad to see large retailers such as Walmart and Target involved.

Mr. Bone referenced letters which were sent out last June by some of those large retailers indicating the upcoming changes.

Mr. Dazé asked if Mr. Bone feels that the new dates are feasible.

Mr. Bone responded that the new implementation dates are achievable, but that they will most likely see a bell-shaped curve in terms of readiness. He expanded in saying that they will have some who will flow through appropriately, others who will be ahead of progress, and others who are running behind. Mr. Bone estimated 10 percent to be running behind on their progress. He also noted that McKesson cannot ship some of their products to Florida as they have an issue with manufacturers not being compliant.

Ms. Herold asked what guidance the supply chain would like from the board now that the deadline has been extended. She noted that there will be some regulations that will need to be promulgated and questioned the timing of developing those regulations.

Mr. Bone responded that completing the work on traceability standards is the first priority, which is targeted for the early part of next year. He shared concern about putting regulations in place too early, and stated that waiting until next year for further discussion would be their preference.

Ms. Herold introduced Missy Johnson from Senate Business and Professions. Ms. Johnson was instrumental in moving SB 1307 through the legislative process.

Mr. Bone commended and thanked Ms. Johnson in working with a diverse group of individuals who have approached her throughout the process.

Marjorie Powell (PhRMA):

Ms. Powell expressed appreciation to the board, staff and Ms. Johnson for their work on SB 1307. She stated that the extension will allow industry to work together and ensure that the system will provide benefits throughout the supply chain. She added that PhRMA appreciates the urgency placed by the board and stated that it was instrumental in gaining attention to the issue by industry and the Food and Drug Administration. Ms. Powell added that PhRMA will work with the board and FDA to address ongoing issues in order to achieve successful implementation.

Chairperson Swart asked PhRMA to provide feedback in the future on the results of pilot completions conducted by PhRMA members as they are available.

Ms. Powell responded that they should have that data by early next year.

Ms. Herold thanked everyone who has traveled a considerable distance to attend the meeting. She stated the ongoing concern by the board of a lack of momentum by industry because of the date extension. She added, however, that it appears progress is still moving smoothly, based on what was shared in today's meeting.

Jim Burgard stated that he was impressed with the two major companies who presented today, specifically with the advanced progress they have made thus far.

Public Comment:

Kim Thomas (EMD Serono) stated that their company has been working on e-pedigree for some time now. She said that they will have their first product shipped to their third party distribution company in November, and that their track and trace systems will be up and running on November 24, 2008.

Ms. Herold asked if the system is in place in-house. Ms. Thomas confirmed.

II. Enforcement Committee

1. Update: CURES moving to provide online, "near real time" report to practitioners in the future

For a number of years, the board has fully supported the Controlled Substance Utilization Review and Evaluation System (CURES) to electronically track all Schedule II-IV medicine dispensed to patients. This data is submitted each week to the California Department of Justice by pharmacies and prescribers who dispense controlled substances, and contains information about the specific drug, strength and quantity dispensed by a pharmacy or practitioner, as well as the prescriber, the dispenser and the patient.

Ms. Herold referenced CURES materials provided within the board packet. She explained that the tracking system is a way to track real-time reports. Currently, the information is required to be submitted weekly and typically takes three weeks to download to the system. Ms. Herold stated that the goal is to allow practitioners and pharmacists the ability to view and determine if patients are "doctor shopping", etc. She indicated that the current project is being spear headed by Bob Pack. Mr. Pack is attempting to raise funds for the project from interested parties. Ms. Herold said that Kaiser has donated funds and will donate additional funds for a second phase. She explained that the system, once in place, would allow for an on-line inquiry of the system to identify if a patient has recently had a duplicate prescription filled at another pharmacy. The board has provided continued support, including providing $100,000 in funds via a transfer two years ago.

Steve Gray (Kaiser Permanente) thanked the board for providing the information. He stated that Kaiser is a strong supporter. He highlighted the importance of the system to hospitals, as many of those with "drug seeking behavior" often show up in acute care facilities. Dr. Gray explained that the system will assist in decreasing the volume of people in emergency rooms, allowing for the ability to help those who truly need medical care for legitimate reasons. He added that the funds amount that Mr. Pack is seeking should carry the program for a couple of years. Beyond that, they will need to look ahead for a way to continue the program. Dr. Gray reiterated that the success of the program will depend on donations.

2. Comments Submitted To The Federal Drug Enforcement Administration (DEA) On Its Proposed Rule To Allow E-Prescribing Of Controlled Substances (Docket No. DEA-218: Electronic Prescriptions For Controlled Substances)

During the July 2008 Board Meeting, the board discussed the DEA proposed regulations to allow the e-prescribing of prescriptions for controlled substances. The proposed rule would allow pharmacies to receive and dispense controlled drugs pursuant to electronically transmitted prescriptions.

Since 1994 the board has secured changes in laws to allow for electronic transmission of prescriptions, and since this time, California has been able to e-prescribe. However, because the DEA would not allow e-prescribing for controlled drugs, full implementation of e-prescribing could never be realized.

At the conclusion of the board's discussion, the board voted to prepare comments for the federal DEA in support of the proposed rule to allow e-prescribing of controlled substances.

A letter was sent on behalf of the board and confirmed that the board is encouraged that the DEA is moving forward to permit e-prescribing of controlled substances but also detailed board concerns over some of the onerous requirements contained within proposed regulations. Specifically the board's letter identifies possible obstacles to implementation that make far more stringent demands upon e-prescriptions than paper prescriptions, including e-record retention of five years and verifying the DEA permit of the practitioner every time before filling a controlled substances e-prescription. The letter encouraged the DEA to reconsider the necessity of some of the requirements.

Ms. Herold stated that although the board has submitted comments, they have not received feedback as of yet from the DEA.

3. Update On Implementation Of Drug Take-Back Programs From Patients (SB 966, Simitian, Chapter 542, Statutes Of 2007)

Last year, SB 966 (Simitian, Chapter 542, Statutes of 2007) directed the California Integrated Waste Management Board to develop the parameters for "model" drug take-back programs in pharmacies. These model programs are intended to provide consumers with the ability to dispose of unwanted prescription and over-the-counter drugs (but NOT controlled substances) without flushing them down the toilet or tossing them into the garbage "attenuated." Under SB 966, these regulations must be in place by December 2008.

State and federal law regulates prescription medicine until it is dispensed to patients. It is not regulated again unless it is collected at consolidated points, at which point it becomes medical waste, and must be handled and destroyed in specific, mandated ways.

Patients are often confounded about what to do with unwanted medicine. Californians are increasingly wanting "green" options for disposing of unwanted medicine, which current law does not allow. There is no viable process, other than to make the discarded drug products unpalatable (mixing with kitty litter or other substance, wrapping in duct tape, etc.) and then placing them in the trash. Some drugs may be flushed down the toilet, and are specifically labeled by the manufacturer to dispose of in this manner.

Pharmacies have in some cases agreed to take back unwanted drugs from patients. However, this acquisition by pharmacies is not authorized in law.

Some communities periodically offer community take-back events, or special days at landfills where the public can take back drugs.

Some drug manufacturers (and the state of Maine, where there is a pilot program underway) provide mailers that patients can use to send unwanted medicine to a predetermined location for destruction. This is the process preferred by the DEA for controlled drugs.

Since late winter, some board staff have been attending meetings with a group of individuals from the Integrated Waste Management Board, Toxics Program and Medical Waste Program and divisions within various state agencies.

The greatest problem for the board with drug take-back programs is the potential for these drugs to be diverted to the streets. There is a serious prescription drug abuse problem in the US, and the uncontrolled aggregation of prescription medicine is an attractive enticement. In some cases, drugs collected in specified bins could re-enter the prescription drug supply if pharmacies or wholesalers (or others) sell these items back into the supply chain.

Pharmacies are areas where health care is provided – it is difficult for this purpose to be combined with a recycling center, which are not necessarily areas of high sanitation.

Pharmacies have expressed concern that they may be required to absorb the costs of paying for disposal of these drugs, for sorting out controlled drugs (which potentially would require a pharmacist's time) and for assuring the safety and periodic emptying of collection bins.

Appropriate destruction of unwanted prescription medicine is a national issue, and the National Association of Boards of Pharmacy has a task force formed to develop policy for the NABP for discussion at its annual meeting in May. Ken Schell is on this task force.

Chairperson Swart shared his concern over the drug take-back program, stating that the return of non-labeled drugs provided in various container or packaging from patients could result in diversion. He added that there have been several proposals on best methods for take-back.

Ms. Herold gave background on drug take-back. She explained that in 2007, SB 966 was enacted to allow Integrated Waste Management and other agencies to develop parameters for pharmacies to be able to voluntarily take back unwanted and unused drugs. She explained the process of drugs from manufacturer to patient. Ms. Herold emphasized the demand for safe ways to return prescribed drugs, and pointed out that there is currently no operable system for consumers to do that legally. She stated that currently consumers have been discarding their drugs in the regular waste or flushing them down the toilet. Pharmacies are struggling with what they can do when patients bring their drugs back to them. She said that some have volunteered to take back the drugs, but that is against current regulations. Ms. Herold also noted that the landfill and waste management industry want them to stay out of the landfills and water. She stated that some entities are holding community events and taking back drugs with little control. SB 966 was the first step to finding a means to dispose of drugs appropriately in ways that the law does not yet allow for. She referenced model programs provided within the board packet, which are drafts developed by Waste Management. Ms. Herold indicated there are pharmacies being investigated who are buying back drugs from patients as a way to reduce the cost of acquisition of drugs, and ultimately reselling those drugs. She stated that she would like the

board members to work closely and submit comments to the draft model programs provided by the Integrated Waste Management. She added that she has some serious concerns over the safety of some of the programs suggested in the guidelines.

Public Comment:

Dr. Gray stated that Kaiser Permanente supports the concept of clean water, and recently agreed to support a "no drugs down the drain" program. However, they did not agree to take back drugs in their pharmacies. He asked what the board's position will be with regards to local ordinances being put in place that attempt to force pharmacies to allow for drug take-back.

Ms. Herold responded that the board has the ability to seek to stop any local ordinances that do not align with state law. She stated that she has been advised that a major senior housing facility has a disposal site placed in the center of a senior hall. She stressed that such an arrangement is not an acceptable form of waste disposal, and is dangerous in a variety of ways.

Jim Cropper (California Integrated Waste Management Board) stated that the procedures for collection and disposal of drug waste required within their law will be going to board at the end of November. He indicated that they would need comments submitted by the end of October, or they may be provided at their November Committee Meeting. He added that they would welcome comments in order to ensure that the procedures abide by the laws of the Board of Pharmacy.

Chairperson Swart asked if their board is addressing the possibility of diversion, as the biggest issue is with regard to the pharmacies lacking a paper trail.

Mr. Cropper responded that many of the procedures provide for security to ensure that all drugs collected are documented. He added that the Integrated Waste Management Board wants to emphasize the security of the programs.

Chairperson Swart gave the example of a person bringing a bag full of loose drugs and how cumbersome it would be for a pharmacy to document.

Mr. Cropper responded that their focus is on the tracking of drugs from pharmacy to the site for proper destruction.

Mr. Weisser referenced different types of locations for drop-off sites, as well as staffing to secure the products being deposited. He asked if the Integrated Waste Management Board envisioned a law enforcement officer in place.

Mr. Cropper responded that specific events would be held on designated dates and locations where a pharmacist and law enforcement would be present, but not at drop-off locations.

Mr. Burgard referenced an item in the proposed solutions document. He questioned staffing because the document states that the disposal and collection sites would be staffed by enforcement.

Mr. Cropper responded in terms of pharmacist involvement. He added that the board will have another draft with the previous comments provided by the Board of Pharmacy. He indicated

that the Board of Pharmacy will be able to comment in writing as well as at the Integrated Waste Management Committee Meeting.

Mr. Burgard reiterated his concern as Mr. Cropper indicated that enforcement would not be on site for an ongoing collection program, but the document states otherwise.

Mr. Cropper responded that Mr. Burgard's concerns are valid and should be provided as comments to the board.

Ms. Herold asked for the board's process based on the what the outcome is at the November Board Meeting. She asked if the regulations already have to be in place in order to move forward.

Mr. Cropper stated that the law indicates that criteria and procedures are to be developed, and does not say that they must be regulations, but rather that they "may" adopt regulations. He states that the Integrated Waste Management Board may want to add proposed changes at their next board meeting.

Ms. Herold asked what kind of enforcement authority the Integrated Waste Management has over a non-regulated model program.

Mr. Cropper responded that it is only if it is in regulations.

Ms. Herold confirmed that what Integrated Waste Management develops for pharmacies would need to be regulated by the Board of Pharmacy.

Mr. Cropper stated that the Board of Pharmacy can recommend developing regulations or comments as they feel appropriate.

Ms. Herold asked about the one-day community events and who is responsible for ensuring that the collected drugs are properly contained, secured and disposed of.

Mr. Cropper responded that the controlled drugs would be properly handled, but was unsure about the issue of non-controlled drugs.

Ms. Herold stressed concern over which agency would be responsible for regulating local community events.

Mr. Cropper responded that it might be the local health department.

Deputy Attorney General Joshua Room confirmed that would only be the case once the waste is aggregated and considered hazardous materials, but that the department of health does not regulate the intake process of collecting the drugs.

Mr. Cropper responded that they could oversee the event, but that local enforcement would be the one responsible at the time of collection.

Mr. Weisser stated his concern over staffing and their ability to take back drugs and documentation of such. He stated that such a process would be cumbersome and take more time then filling a prescription.

Chairperson Swart voiced similar concerns.

Mr. Cropper explained the process involved in collecting data. He indicated that surveys were conducted.

Chairperson Swart suggested sending a request for comments to the board members.

Ms. Herold appreciated Mr. Cropper attending and answering the board's questions. She confirmed that the most recent draft is still in process of updates and the review will be competed in time for the Integrated Waste Management Committee Meeting.

Amy Gutierrez (Los Angeles County Department of Health Services) stated that they created a multi-county task force last year to address the issues of drug take-back. The task force decided to promoted more Household Hazardous Waste (HHW) sites and provide more educational outreach to the public regarding how to dispose of the unwanted drugs. The task force discussed the issue of how to control drugs coming from the outside, and felt that it is very dangerous to bring the drugs back to the pharmacies. Ms. Gutierrez noted that she contacted several large chain drug stores regarding participation in drug take-back and there was no interest.

Mr. Weisser asked how HHW counsels patients in the disposal of drugs.

Ms. Gutierrez responded that they started the "No Drugs Down the Drain" campaign. She was unsure of the counseling process, however.

Mr. Weisser asked what suggestions are currently being given to consumers in terms of how to dispose of the drugs.

Ms. Gutierrez responded that they are referring them to the HHW website. She explained that the consumers are advised to place the drugs in the trash "attenuated" or to go to the HHW site.

Ms. Powell stated that PhRMA had major concerns with the take-back programs where they are returned to the pharmacies, specifically with regard to the "recycling" of drugs back into the chain of distribution. She clarified the concern of drugs being purchased and resold back to the pharmacies, as well as drugs being diverted to those who are looking for controlled drugs inappropriately. Ms. Powell also addressed the concern of groundwater and the effects of drugs in the environment. She stated that 90 percent of drugs get into the groundwater by human use of drugs, and only 1 percent gets there from disposal. She said that she will send a published report which demonstrates that only a minute portion of drugs which are properly disposed of into landfills is leaked into the groundwater. She stated that the Fish and Wildlife Service, the American Pharmacists Association and PhRMA are participating in a group called the "Smart Rx Disposal Program." The program encourages consumers to dispose of their drugs properly and provides steps on how to do that. She reiterated PhRMA's position on drug take-back and stated that they are not in support of drug take-back for the reasons she has provided.

Ms. Herold asked if PhRMA members (manufacturers) will provide refunds back to pharmacies if they provide pills outside of the manufacturer's container. Additionally, she asked if the contents of the container are verified, to ensure that it is the correct drug being returned in the container as indicated.

Ms. Powell responded that all of the manufacturers who responded to the request for information indicated that their return policy would only apply to unopened manufacturer's containers of product. She added that the majority of manufacturers typically don't make a decision on whether a product is waste until it gets back to manufacturer, but the manufacturer uniformly defines that product as waste if it's been opened. She noted that there is concern over some healthcare provider entities returning product that are not original manufacturer product. She added that some manufacturers are conducting tests to verify the authenticity of the drugs and its origin.

Mr. Weisser confirmed that there was a period of time when manufacturers did take back opened containers of drugs.

Ms. Powell responded that in that instance, those drugs would automatically be labeled for destruction.

Mr. Weisser asked what the procedure is currently for destruction of drugs.

Chairperson Swart responded that there is a service provided by reverse-distributors. He noted that some reverse-distributors provide credits or rebates.

Ms. Herold stated that there is now a requirement that once a pedigree goes through, drugs must go back to the original wholesaler, with the exception of drugs going straight to waste. She shared concern that there will be a cost placed on pharmacies to dispose of drugs.

Deputy Attorney General Room clarified that the restriction on whom unused drugs are returned to is current law.

Mark Hardy (EXP Pharmaceutical Services) stated that EXP is a reverse-distributor, and reviewed a number of issues for them. He stated that currently partials are returnable including, in some states, patient labeled drugs. He added that they are trying to work with the current regulations on drug take-back. Mr. Hardy stated that EXP has been advocates for mail-back programs as a way to keep drug take-back outside of pharmacies and avoid potential diversion. He noted that the DEA is looking to utilize only two reverse-distributors for the process, and they hope to continue to be involved.

Mr. Weisser asked Mr. Hardy to explain the process for drug take-back.

Mr. Hardy explained that the materials are documented, sent to their facility, and then matched with their information within the database. He explained that they are then returned to the manufacturer for credit if they are returnable, and scheduled for incineration if they are not. Mr. Hardy stated that the drugs are ultimately all incinerated, including those returned to the manufacturer.

Deputy Attorney General Room asked if there is any kind of drug recognition software that could quickly scan large quantities of drugs and identify them.

Mr. Hardy responded that there was a company that contacted them to pilot such a program. He explained that they did not see the pilot as a benefit for them because they don't receive counterfeit drugs in their facility.

Deputy Attorney General Room clarified that he was referring to the process of identifying pills by stamp, etc. and putting packets of the same together for counts, etc.

Mr. Hardy confirmed that is what the pilot program involved. He reiterated that it did not seem like a valuable use of time for them to take even 10 percent of their product and scan it within that machine. He noted that if it became a requirement or if there became a point where product being returned to them were "questionable," then they would reconsider the program.

Lynn Rolston (CPhA) stated that they oppose the drug take-back programs being placed in the pharmacy. She added that they are very sympathetic to the fact that materials left in homes cause dangers. She encouraged the Board of Pharmacy to work collaboratively and ensure that programs are not placed in pharmacies where they may be handled in inappropriate ways. Ms. Rolston added that there has been discussion of Integrated Waste Management Board getting more involved, however they claim that they can not assist unless pharmaceuticals are declared hazardous household waste.

Ms. Herold asked Ms. Gutierrez if Los Angeles County considers drugs they take back as hazardous household waste.

Ms. Gutierrez confirmed and indicated that they have not heard of any problems.

Alan Pope (Safeway) stated that every county seems to be developing a model program in relation to drug take-back, which would result in a variety of programs across the state. He encouraged the board to develop recommendations for the pharmacies in addressing requests for take-back as well as providing the board's position on the issue.

Ms. Herold indicated that the board is using their enforcement discretion and may intervene where take-back programs are being used and not legally authorized. She stated that there is a point at which the board will need to use some type of judgment on how to address the issue. She noted that for many years prior, pharmacies have taken the drugs back and only now has it become a large issue in terms of hazardous waste.

Mr. Pope stated that county health departments are actively looking at ways to dispose of the drugs, but is not sure if they are coordinating with the board in that process.

Ms. Herold suggested that Safeway submit comments to the Integrated Waste Management board.

Heidi Barsuglia (California Retailers Association) stated that they have received feedback from their members regarding waste management practices which were composed by the Integrated Waste Management Board. She added that CRA provided those comments back to Integrated Waste Management Board and will provide those to the Board of Pharmacy to share with members as appropriate.

Dr. Gray indicated that this is an area which is very complex because of the many overlapping jurisdictions. He stated that because of the varying laws from waste management, federal, county, city, state, water district, etc., it is difficult for pharmacies to know what to do. Kaiser is currently instructing pharmacies to go to the website which will direct to them to local jurisdiction. Dr. Gray stated that there are now scientific results indicating that the amount of environmental impact of unused drugs disposed of is so minute that it is not measurable in the waste. He also raised the issue of drugs, if left in the household, as a hazard because other

family members may use the drugs for their own health issues, etc. He referred back to the issue of drugs not being labeled with their purpose. He said that often patients cannot remember what a drug is for and then discards the drug as a result.

4. Role Of Reverse Distributors In Picking Up Medical Waste And Returned Drugs

Presentations to the board:

Calvin Yamada (Department of Public Health):

Mr. Yamada explained that DPH regulate medical waste, and gave background on the counties they regulate. He stated that they are not in favor of having pharmacists as waste managers. Mr. Yamada provided history on the laws in place. Specifically, he reviewed the Resource Conservation and Recovery Act (RCRA) which defines and provides the criteria of what is considered hazardous waste. He explained the laws which apply to products that do not follow under the category of hazardous waste under federal RCRA as well, including the specifics of California-only hazardous waste. Mr. Yamada explained the process of waste disposal from hospital to waste incinerator. He noted that all of their offsite treatment facilities are out-of-state and capacities of those facilities are getting low. Mr. Yamada discussed the issue at hand with disposal of home-generated drugs. He stated that DPH does not regulate pharmaceutical waste at home. When consolidated, it becomes hazardous medical waste. Mr. Yamada pointed out that the burden is on the generator to determine if something is hazardous waste, and that is not feasible in the case of drugs within homes. He reviewed law which states that household waste is not considered medical waste. Mr. Yamada reiterated that once home generated pharmaceutical waste are consolidated, they then become regulated medical waste. He stated that their concern is for those collecting drugs as things stand currently, and specifically in placing the burden on the pharmacies with that role. He also noted that household hazardous wastes are regulated by the Environmental Health and Solid Waste and, when consolidated, is treated as “poison solids.” He stated concern over diversion of those solid wastes as they are fairly accessible in that form. Mr. Yamada stressed the concern over diverters who can work through weaknesses in the law to gain access to drugs. He noted that a very small amount of citations are issued to those placing unused drugs down the drain inappropriately in the trash.

Ms. Herold stated that the CPhA suggested regulations be changed to categorize the consolidated waste as hazardous household waste (versus hazardous medical waste). She asked if it would need to go back to the legislature.

Mr. Yamada confirmed and noted that the waste will be incinerated ultimately, regardless of how it is identified. He stated, however, that incinerators are being phased out. He said that they recently met with Green Action and Healthcare Without Harm and asked the question of how to handle the disposal of drugs when the capacity of incinerators is too small. He also added that they are trying to discourage larger hospitals from comingling and condensing their unused sharps and non-incinerating products, in order to attempt to ensure the continued use of incinerators.

Ms. Herold asked what their haulers do when they receive mixed products within their collection containers that include recycled drugs, sharps in open containers, etc.

Mr. Yamada responded that they label “incinerate only” on the container. He pointed out that it is against regulations to label the outside of containers with anything stating that it is filled with pharmaceuticals.

5. Discussion of Sharps Take-Back Program by Pharmacies

A related, but separate issue to the problem of how society will dispose of unwanted drug products is the issue of disposal of used sharps.

According to estimates by the California Integrated Waste Management Board, California patients use 1 billion needles and syringes each year. This does not include lancets.

Since September 1, 2008, California law has prohibited the disposal of sharps in trash or recycling containers. Information from the Integrated Waste Management Board’s Web site was included within the board packet. Pharmacies are listed as one of the disposal locations, however, pharmacy law does not authorize pharmacies to take back sharps.

Regarding appropriate destruction, the Department of Public Health states that:

> California Health and Safety Code, Section 118286 (b)
>
> On or after September 1, 2008, home-generated sharps waste shall be transported only in a sharps container, or other containers approved by the enforcement agency, and shall only be managed at any of the following:
> (1) A household hazardous waste facility pursuant to Section 25218.13.
> (2) A “home-generated sharps consolidation point” as defined in subdivision (b) of Section 117904.
> (3) A medical waste generator’s facility pursuant to Section 118147.
> (4) A facility through the use of a medical waste mail-back container approved by the department pursuant to subdivision (b) of Section 118245.
>
> The CDPH Medical Waste Management Program is recommending the use of sharps containers approved by the U.S. Food and Drug Administration (FDA).

In July, recognizing that there was a potential problem for consumers since pharmacy law does not authorize pharmacies to take back sharps, and yet on September 1, the law would limit how patients could simply dispose of these items, board staff proposed an amendment to California Pharmacy Law to allow such a practice. Regrettably, the bill to authorize this was dropped at the end of August by Senator Simitian. The amendment was simple:

> A pharmacy may accept the return of needles and syringes from the public if contained in a Sharps container as defined by Health and Safety Code section 117750.

In the interim, since California pharmacy law does not allow pharmacies to take back sharps containers, and beginning September 1, patients cannot dispose of sharps by tossing them into the trash, this does create problems for patients.

Chairperson Swart provided his own experience when working out-of-state and participated in a sharps take-back program. He stated that they often found that patients would place sharps, which where not properly contained as required by law, on the counter after the pharmacy was closed. He explained that this resulted in janitors being stuck as they would take the bags from the counters to dispose of. He stressed his personal sense of urgency in addressing this important issue.

The Executive Officer and President Schell recommend that in the interim, the board adopt as policy that:

> California law does not authorize pharmacies to accept the return of sharps when appropriately contained in an approved sharps container. Nevertheless, the board believes that it is in the public interest that willing pharmacies do take back such items. The board reserves its enforcement discretion about whether to intervene with any pharmacy that takes back sharps containers inappropriately. However, until this matter is fully resolved, the board does not anticipate intervening in such practices. This policy may change as a result of a complaint or public safety issue.

Additionally, the issue of how and where patients return sharps and who will pay for the expense of these returns continues. This week, AB 501 was vetoed by the Governor. This bill, which the board supported, would have required manufacturers of prefilled injection devices (e.g., epi-pens) to provide information to patients about how to dispose of the items. A copy of the bill and the Governor's veto message were provided within the board packet.

Ms. Herold explained that a law went into affect September 1, 2008 which prohibits patients from discarding syringes unless placed in a proper sharps container. She emphasized the issue with the lack of guidance for patients in how to dispose of the sharps. She stated that it is not best to instruct them to return their sharps to their local pharmacy, unless there is a strong program in place to support them. She mentioned the additional issue when funding is not secured past a specific point, as is the case with San Luis Obispo County's program. She also noted the safety and contamination issue when pharmacies come in contact with sharps, and gave an example of an incident in a pilot area where a child was running through a drug store with a sharps container. She stressed that the pharmacies will need to be able to maintain some oversight on the process. The board developed the current policy in recognition that pharmacies are being confronted in multiple counties with the requirement that they take back sharps containers. For pharmacies' willing to take back properly disposed sharps, the board will allow that to occur while the board seeks an appropriate exemption in the law, in order to avoid encouraging pharmacies to do something against pharmacy law.

Dr. Gray asked for clarification that new law states that any entity that wants to be a sharps collection site needs to go through an official registration and permit process. He stated that it may not be well understood among the pharmacies, and suggest the topic be presented within the board newsletter as that would be important information to pass on. He added that there is a lot of pressure on pharmacies from physicians, hospitals, and others to become collection points.

Mr. Yamada responded that pharmacies interested in becoming a sharps collection site can go to the DPH Web site where there is an application available for each county within their

jurisdiction. He indicated that there is no fee, but that the site is subject to inspection by enforcement staff.

Deputy Attorney General Room referred to a prior comment by Mr. Yamada that there are 25 counties regulated by DPH, and asked about the status of the other counties.

Mr. Yamada responded that those counties have their own enforcement agencies.

Ms. Rolston stated that CPhA is opposed to having sharps containers collected by pharmacies. She said that, although this is seen as an important service, there are other ways to solve the issue that are more economical and safe for the public. She emphasize the request by CPhA to continue to work together and not change regulations in a manner that could cause serious harm to the public in the future.

Ms. Herold asked if CPhA objects to it as a voluntary issue.

Ms. Rolston responded that, even if it is said to be voluntary, but then there are still pressures within certain communities that will push many pharmacies to incorporate it.

Ms. Barsuglia stated that they have repeatedly raised issues within their stakeholder meetings that some pharmacies believe they can make a take-back program work, but that the business model may not work for others. She stated that there is also a concern over funding for the programs. She emphasized that CRA feels that the program needs to be voluntary.

Mr. Hardy clarified the cost previously quoted of $110 per pound for disposal. He explained that the quote was a fully encumbering cost based on overhead. He stated that the actual cost is $5 per pound for disposal of drug take-back, with $4 of that being used for postage. Mr. Hardy added that 100 percent of what comes to their reverse-distribution facility is designated for disposal; none of it is recycled for any purpose. He explained that returns only refers to product being returned back to the manufacturer and is ultimately disposed of by incineration as well. He provided an explanation of the $110 per pound cost, which is based on overhead, etc.

Ms. Powell clarified that a larger portion of $110 per pound cost was spent on getting the word out to people to advise them that they can bring drugs to the event, arranging for enforcement to attend the event, etc. She explained that the cost was not for the actual disposal.

Ms. Herold asked if there is a policy on the return mailers that would need to be provided by manufacturers.

Ms. Powell stated that they do not have a policy, but she is aware of the sharps mailers that have been approved by the postal service. She added that there is a concern as to how the container is identified, and brought up the issue and concern of placing returned drugs inside mailboxes that are accessible to anyone.

Ms. Herold discussed the issues of proper labeling and special handling in relation to personnel having contact with products.

MOTION: Recommend to the board to adopt a policy regarding the voluntary acceptance by pharmacies of used sharps for appropriate disposal.

M/S: SWART/BURGARD

Support: 4 Oppose: 0

6. E-Prescribing Forum Set for November 20, 2008

On November 20, the Board of Pharmacy will host an e-prescribing forum in conjunction with the Department of Consumer Affairs' Professionals Achieving Consumer Trust summit. Other healing arts boards whose licensees prescribe drugs have been invited. The Dental Board and Medical Board have joined as partners.

The description of the event is as follows:

The California State Board of Pharmacy will host a public forum on e-prescribing on November 20th, from 9:30 to 12:30. The forum will focus on what current California law allows with respect to e-prescribing, and will offer speakers who will describe how they are using e-prescribing today, what issues they have encountered and resolved, and the acceptance of e-prescribing by patients, pharmacies, prescribers and third-party payers. The Medical Board and Dental Board are partners of this forum, and other DCA healing arts regulatory boards have been specifically invited to attend.

7. Medication Errors Made by California Pharmacies 2007-08

At the July 2008 Board Meeting, the board held a forum on medication errors. Michael Cohen of the Institute for Safe Medication Practices, John Keats of California Patient Safety Action Coalition (CAPSAC), and Bob LeWinter of the California Department of Public Health provided presentations on activities underway to prevent pharmacies from making or repeating medication errors. Another discussion also involved the findings of the 2006 SCR 49 Medication Errors Task Force report.

At this meeting, Executive Officer Herold provided a presentation of the medication errors cited and fined by the Board of Pharmacy during 2007-08. There were 402 medication errors reported to the board during this period, and 600 medication error cases closed during the period. Of these cases 94 percent were substantiated as errors.

During the discussion at the July Board Meeting and then later during the Communication and Public Education Committee Meeting (held in conjunction with the board meeting), Ms. Herold suggested including information in the Board's Newsletter or in a separate issue on some of the medication errors investigated by the board.

Information that will be converted into a medication error supplement to the newsletter was provided within the board packet.

The Communication and Public Education Committee will discuss how it wishes to proceed with respect to educational activities to the profession and consumers about medication errors. Both

CPhA and the Institute for Safe Medication Practices have expressed interest in working with us in this area.

One area is the emerging emphasis on using TALL MAN Letters in prescriptions to prevent look-alike drug names from being confused. Several articles from the Institute for Safe Medication Practices, and one expressing the National Association of Boards of Pharmacy policy on this subject were included within the board packet.

8. Discussion: Hospital Pharmacies' Control of Drugs within a Hospital

In late spring, the board identified 94 hospital pharmacies with recalled heparin still within the facilities, two to three months following the last recall. The board has cited and fined the hospital pharmacies and pharmacists-in-charge of these pharmacies. Whereas many of these hospitals and PICs may appeal the citations and fines, the board members cannot discuss the specific parameters of any of these cases without recusing themselves from voting on the specific case in the future.

The recall system is broken and needs fixing, and staff is pursuing this with the California Department of Public Health and the FDA. A list of recommendation changes will be developed by the end of the year.

Presentations to the board:

Diane Zalba (Director Of Pharmacy - UCLA):

Dr. Zalba explained that UCLA is an integrated health system. She provided background on the number of hospitals, ambulatory surgical centers and clinics within their system and gave their locations. She stated that the Department of Pharmaceutical Services within UCLA is required to purchase and dispense drugs to all of their locations. Dr. Zalba described their secondary "hospitals" within the UCLA hospital. She provided background on UCLA's areas of expertise and concentration within the hospital system and explained which entities purchase their drug supply independently. Dr. Zalba indicated that they have five outpatient pharmacies, as well as three hospital pharmacies, with PIC's for each. She explained that they have pharmacies within every floor of their hospital, staffed with pharmacists and technicians at each. Dr. Zalba described the process of drug distribution as stock is received. She stated that they have pyxis dispensing medication stations, which account for 90 percent of the solid drugs dispensed and that the remaining drugs are dispensed by "cassette fill" for those which do not fit in the pyxis stations, etc. She indicated that 1500-2000 IV's are used daily. She also said that the total doses is 360,000 and 60,000 IV's monthly. She noted that total staff, not including pharmacist and technicians, is 150. She added that they purchase $80 million in drugs annually.

Ms. Herold asked how many pharmacists are on staff.

Dr. Zalba responded that they have 75 pharmacists and approximately 70 technicians on staff.

Ms. Herold asked if they use the tech-check tech program as authorized by 1793.8.

Dr. Zalba responded that they do not, and that the pharmacists check everything by hand.

Ms. Herold asked if she feels they have adequate control over the drugs in their facilities, or if laws help or hinder that ability.

Dr. Zalba responded that they have over 250 sites with controlled drugs that are inspected monthly. She stated that in an integrated system of this size, it is not feasible for them to have complete control.

Chairperson Swart asked if there is a protocol within the system in the event of a drug recall.

Dr. Zalba explained the process that goes into effect immediately in the case of recall.

Mr. Weisser gave the scenario of a recall and drugs being hidden by staff members. He asked if that type of scenario could ever be a possibility in their facilities.

Dr. Zalba responded that they don't have floor stock and secure their drugs within pyxis stations, and that reduces the possibility for diverting drugs significantly.

Chairperson Swart gave the scenario with physicians who might bring drugs with them when entering the hospitals.

Dr. Zalba stated that they are very stringent on not allowing physicians to do that. She also noted that patients being admitted to the hospital are also required to relinquish any drugs they bring with them until they are released.

Ms. Herold asked if they have support from administration or if she able to exercise authority independently on that policy.

Dr. Zalba stated that it is based on the Department of Public Health laws for hospitals.

Ms. Herold stated concern that pharmacy law has possibly not kept up with hospital practice and the ability for PIC's and pharmacy directors within those hospitals to exercise control and meet the demands placed on them in terms of cost control and patient care, etc. She noted that pharmacy law has not been amended at all in many years with respect to hospitals. She asked if there are any areas where pharmacy law needs to be updated to allow for optimal patient care while maintaining appropriate control over the drug supply.

Dr. Zalba responded that the greatest problem is with Department of Public Health laws rather than state pharmacy laws. She said that they don't have any issues with pharmacy law. There was discussion on the issue of "satellite" entities as well as surgical clinics where drugs are dispensed.

Chairperson Swart asked if Dr. Zalba would be willing to provide input as changes are made to update pharmacy law.

Dr. Zalba agreed.

Allen Schaad (Catholic Healthcare West):

Mr. Schaad sent out an inquiry to pharmacy directors to find out if they have any issue with pharmacy law as it stands. He indicated that he has received no response thus far. Mr. Schaad

agreed that they have issues with Department of Public Health in terms of the laws. Mr. Schaad provided background on their hospital, including their drug expenses and level of control on drug dispensing. He noted that where automation is used, such as pyxis stations, there is less possibility for diversion. He discussed the issue of decreased control as quantities of drugs and dosages increases, but stated concern over patient safety when pressure is placed in keeping more control of drugs.

Bill Yee (California Society of Health-system Pharmacists):

Dr. Yee reiterated the complexity of drug distribution systems. He stated that there is a tendency for some practitioners to divert drugs at the time of a recall. He indicated that when conducting inspections, he often finds medications tucked away, and staff then simply finds a new place to hide them. He stressed the importance of having an electronic system in place for tracking of all drugs at any point in time, and that until then there is still the possibility of finding recalled medications in facilities. Dr. Yee stated that he feels that it is a system issue, rather than a "people issue".

Deputy Attorney General Room advised that discussion regarding pending appeals before the board on pharmacists and the Heparin recalls needed to stop as the board is prohibited from listening to comments at this time.

Dr. Yee stated that systems are complex in general, and reiterated that there will always be that opportunity for diversion of drugs, including at the time of recalls.

Dr. Gray addressed former discussion relating to the storage of drugs in order to provide clarification. He stated that there are regulations that list a category of legend drugs that do not need to be stored in pharmacy. He also stated that law does not require every hospital to have a pharmacist, giving the example of hospitals with 99 beds or less.

Dr. Gray pointed out that pharmacy services law in relation to hospitals have not been revised in over 30 years, despite many requests from individual institutions, CSHP, and others to make amendments. He added that the requests have not been given priority because they are not coming from the board.

Dr. Gray also discussed "floor stock" and provided a definition as drugs that have left the pharmacy without assignment to a particular patient. He stated that, although pyxis machine are used as more secure storage cabinets, it does not necessarily mean that a hospital does not have floor stock. Dr. Gray clarified that automatic dispensing machines are different than dispensing machines used in the outpatient pharmacy environment, and provided an explanation of the difference between the two in relation to "floor stock."

He also commented on the topic of complexity of systems and control within hospitals and provided input on his experience within Kaiser. He stated that more discussion would be necessary on the level of expectations.

He stated that there have been discussions in the past on general issues of enforcement with relation to PIC liability and would like to know when the board will discuss the issue since it can not be discussed at this time.

Deputy Attorney General Room responded that discussion can occur after the appeal period of the various citations and fines which are pending as a result from the Heparin recall inspections. He clarified that nothing has been said with the meeting today that would require board members to recuse themselves from the cases. He stated the understanding by industry that the issues lie within the systems rather than the people involved. He explained that anything that might be interpreted as defense for an individual could be considered as persuasive to the board members involved in deciding on those appeals.

Dr. Gray responded that an appeal period may run for 2 – 3 years.

There was further discussion on the topic of PIC liability and the timing of the board's ability to discuss the topic in relation to the appeal period of disciplinary action from the recall.

9. Public Comment for Items Not on the Agenda

There was no public comment provided.

The meeting was adjourned at 1:20 p.m.

E-pedigree: Industry snapshot from a manufacturing perspective

Shawn Grubb
Global SAP Business Owner
Procter & Gamble Pharmaceuticals
ASUG Pharmaceutical SIG Program Chair

Procter&Gamble

- ***Three billion times a day, P&G brands touch the lives of people around the world…***
  - ~$77 billion in net sales (2007)
  - 138,000 Employees / 80 countries world wide

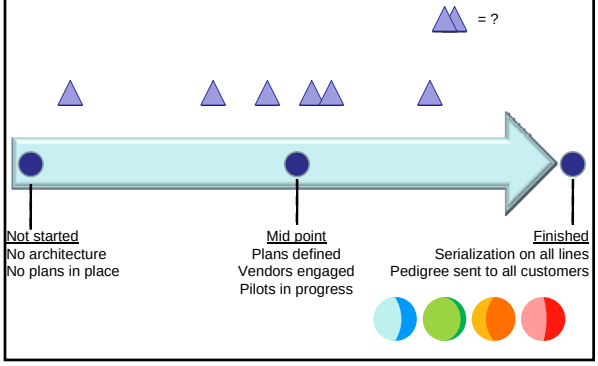
P&G Pharmaceuticals

- ***A segment of the Healthcare Global Business Unit***
  - ~2 billion in net sales (2007)
  - Three major brands: Actonel, Asacol, Enablex

Current status of Pedigree inside P&G

- US Market Primarily supplied through a CM
  - Six months ago: sprint to compliance with partners
  - One month ago: On target for compliance
  - Today: Hold for additional direction from California
    - Redefining the scope and proceeding
    - Reassessing the best tools & practices
    - Utilizing the Consumer Goods RFID & Serialization expertise
    - Time to build a strategic architecture inline with the Company

Unofficial Sensing - Span of status for 8



Pedigree Snapshot 1

- "Unofficial Pharma Manufacturing Sensing"
  - Sources
    - Taken from the ASUG Pharmaceuticals Program Chair perspective
    - 1 to 1 discussions with other Pharma companies
    - Industry round tables and water cooler discussions
  - Manufacturer 1:
    - Rethinking the approach serialization / pedigree approach
    - Intend to re-plan the pilot and move forward
  - Manufacturer 2:
    - "Still a lot of work to get to 2015"
  - Manufacturer 3:
    - "Doing what we can now"
    - Moving forward with non-serialized e-pedigree
    - One customer is currently accepting the e-pedigree

Pedigree Snapshot 2

- "Unofficial Pharma Manufacturing Sensing"
  - Manufacture 4:
    - Pilot is in place; Shifting focus to other legal guidelines (Turkey)
    - Pedigree development is waiting for further clarification
  - Manufacture 5:
    - Serialization Pilot in place (using AII, XI, 3rd party)
    - Currently sending Pedigree to one customer
  - Manufacture 6:
    - Serialization target to go live next calendar year
  - Manufacture 7:
    - Primarily virtual Pharma; building E-Pedigree plans now
- Interpretations:
  - Taking a "breather"
  - Some rethinking longer-term strategies and tools
  - Migration of focus to other legal requirements

Touching lives, improving life. P&G™

Standards Development and Adoption Update

California Board of Pharmacy – Enforcement Committee

October 6, 2008

Contents

- Building Patient Safety
- Significant Events
- Pedigree future (DPMS, EPCIS, Discovery)

Who is GS1?

GS1 is a not-for-profit organization dedicated to the design and implementation of **global standards** to improve the efficiency and visibility of **supply chains** globally and across sectors

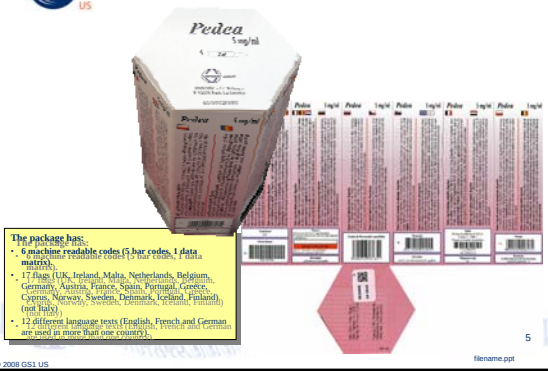
- **108** member organizations
- **35** years of experience
- **Neutral** platform for all supply chain stakeholders
- Over a **million** companies doing business across **150** countries
- Over **6 billion** transactions a day

GS1 is the most widely used supply chain standards system in the world

GS1 Around the World

108 Member Organizations
150 Countries Served

Why Global Standards?



The package has:

- 2 or more bar codes,
- **6 machine readable codes (5 bar codes, 1 data matrix),**
- 17 flags (UK, Ireland, Malta, Netherlands, Belgium, Germany, Austria, France, Spain, Portugal, Greece, Cyprus, Norway, Sweden, Denmark, Iceland, Finland) (not Italy)
- 12 different language texts (English, French and German are used in more than one country).

5

Why Global Standards?

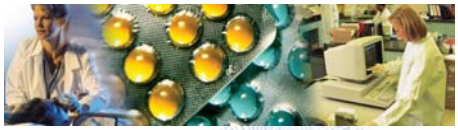
GS1 Healthcare US - Relation to GS1 Healthcare

GS1 Healthcare Role:
- Global focused
- Standards development per roadmap
- Ensuring global standards harmonization
- Communication on global standards and activities

GS1 Healthcare US Role:
- U.S. focused
- A primary customer contact for US based companies / divisions and regulators
- **Drive adoption / implementation**
- Non-voting comment to global standards development

GS1 US

- Founded in August, 1970
- 250 Employees (9 in Healthcare)
- Over 200,000 customers (16,000 in Healthcare)
- GS1 Healthcare US launched 1/1/08
- UNSPSC Administrator (2003)



GS1 Healthcare US
165 Workgroup Participants

Associations
Advamed
AHA - American Hospital Association
AHRMM - Assoc. for Healthcare Resource & Materials Mgmt.
ASHP - American Society of Health System Pharmacists
CHeS - Coalition for Healthcare eStandards
CHSCR - Center for Healthcare Supply Chain Research
GHVRHIO - Greater Hudson Valley Regional Health Information Organization
GPhA - Generic Pharmaceutical Association
HDMA - Healthcare Distribution Management Assoc.
HIDA - Health Industry Distributors Association
MITA - Medical Imaging & Technology Alliance
NACDS - National Association of Chain Drug Stores
NCPD - National Coalition of Pharmaceutical Distributors
NCPDP - National Council for Prescription Drug Programs
SMI - Strategic Marketplace Initiative

Government Agencies
Dept. of Veteran Affairs
DoD - Department of Defense
FDA - US Food and Drug Administration
US Army

GPOs
Amerinet
Consorta
Healthtrust
Medassets
Novation
Premier

Distributors
AmerisourceBergen Corporation
Cardinal Health Inc.
McKesson US Pharmaceutical
Owens & Minor
US Oncology

Hospitals
Ascension Health
BJC Healthcare
Carolina Healthcare System
Geisinger Health System
Intermountain Healthcare
Mayo Clinic
Ministry Health Care Inc.
Norton Healthcare
Novant Health
Ridgeview Medical Center
Sentara Healthcare
Sisters of Mercy (ROI)
SSM Healthcare
University Healthcare System Augusta (UHCS)
University of Kentucky Medical Center
Wellspan Health
Yale New Haven Health

Retailers
CVS Caremark
Target
Walgreens
Wal-Mart

GS1 Healthcare US
165 Workgroup Participants *(Continued)*

Manufacturers
3M
Abbott Labs
Alcon Labs
Amgen
Amphastar Pharmaceuticals
Apotex
Baxter
Becton Dickinson
Bristol-Myers Squibb
Covidien
Genzyme Corporation
GlaxoSmithKline
Honeywell Imaging and Mobility
Hospira
Johnson & Johnson
Kimberly Clark
Kinetic Concepts
Kyowa Pharmaceutical, Inc.
Medimmune Inc.
Medline
Medtronic
Merck
P&G
Pfizer
Purdue Pharma
Sage Products
Talecris Biotherapeutics
Teva Pharmaceuticals USA
Upsher-Smith Laboratories, Inc.
AAkar Technology Inc.

Solution Providers
Accenture
Acsis Inc.
Aegate Ltd
Authentix Ltd
Axway
Booz Allen Hamilton
Capgemini
Datagility
DataPros for Healthcare
Deloitte Consulting, LLP
Domino Amjet
Edge Dynamics
Elge Inc.
GHX
Globe Ranger
IBM
Infosys
Inmar/MedTurn
Lawson Software
Loftware, Inc.
Maxiom Consulting Group, Inc.
Ontuet
Product Identification & Processing Systems
RfDcel Corporation
SAP Labs, LLC
Sensitech
Sterling Commerce
Supplyscape
Systech
Tenso Solutions
Unisys North America
VCG & Associates

GS1 Healthcare US Leadership Team

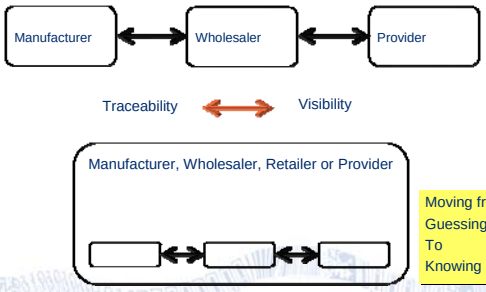
- AHRMM – Deborah L. Sprindzunas
- Amerinet – Mary Beth Lang
- Becton Dickenson – Dennis Black
- Johnson & Johnson – Michael Rose
- Mayo – Joe Dudas
- McKesson – Ron Bone
- Novation – Dennis Byer
- SMI – Dennis Orthman
- Univ. Kentucky Medical Center – Jean Sargent
- Walgreens – Steve Addante

Building Patient Safety

Building Patient Safety

Building Patient Safety

What is Traceability?



Moving from Guessing To Knowing

What is Traceability?

- Where has the item been?
- Where is it now?
- Where is it going?

Supply chain
Chemicals (OSHA)
Instruments (Crutchfield –Jacobs)

Extended Traceability Data

- What condition is it in?
- Is it fit for use?

Temperature History
Maintenance History
Certifications
Sterilization

What do you need to know for traceability / visibility

- What • Supported by the GTIN
- Where • Supported by the GLN
- When • Supported by time/date stamps
- Why • Supported by Event types (ship, receive, etc.)
- Who • Supported by GSRN (Global Service Relationship Number)

Building Patient Safety

Same Product – Different Numbers*

- Industry Distributor Numbers for 3M Product # 8630:

Nearly every hospital has a different Product ID for 3M 8630! Makes ordering, recalls, and proper identification to the patient difficult.

UnitedUMS - 001880

* Source: Department of Defense Data Synchronization Study

Same Number Different Products *

Makes Sourcing of needed products difficult and increases errors in ordering and distribution to the patient.

- **Part Number: 10313 refers to:**

Medtronic's - "**NEEDLE** CARDIOPLEGIA ADULT 16GA 5/8IN TIP 10IN"
Hantover's - "**CARTRIDGE REPLACEMENT** STUNNER YELLOW F/CALVES/HEAVY HOGS"
Chattanooga Group's - "ACCESSORY TRACTION **REPLACEMENT STRAP** XL FOR HALTER THORACIC RESTRAINT"
HF Scientific's - "**TEST KIT** WATER FREE CHLORINE DPD 25ML SAMPLE PHOTOMETRIC 1000/PK"

- **Part Number: 1050 refers to:**

3M Company's - "**DRAPE INCISE** 35 3/8X 17 5/8IN"
Tyco's - "**PAD TELFA** 3 X 4IN STER"

* Source: Premier Inc. Product Item Master

Building Patient Safety

What is the Provider Pain?

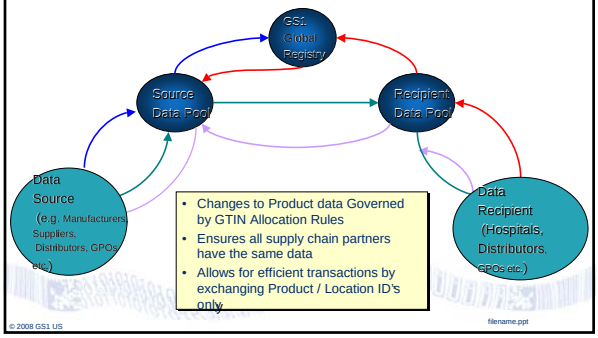
Too many identifiers for the same healthcare location -- confusion, finger pointing, inefficiency

SAINT JOHN'S QUEENS HOSPITAL 1100004570208
ST JOHN'S QUEENS HOSPITAL 100084547
SAINT **JOHNS** QUEENS HOSPITAL JAOE
SAINT JOHN'S **QUEEN** HOSPITAL 50003000431
SAINT JOHN'S **QUEEN'S** HOSPITAL CA2053
ST. JOHN'S QUEENS HOSPITAL OM 12345

Many different names different location numbers for 1 hospital

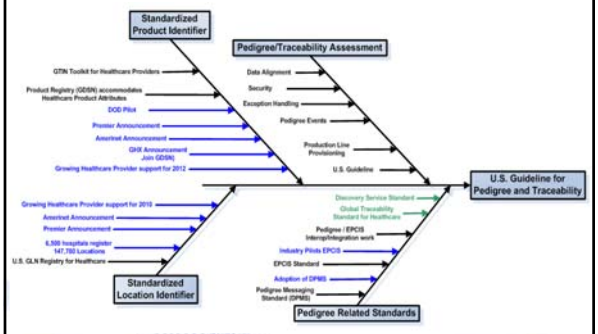
Building Patient Safety

Global Data Synchronization Network (GDSN®)



Significant Events Related to Pedigree Adoption

Significant Events affecting Adoption



2010 GLN Sunrise

"The elimination of Custom Account numbers by 2010"

- GLNs assigned by all trading partners.
- GLN hierarchy defined and maintained for all trading partners.
- GLNs used in all business transactions.
- GLN Registry used by all trading partners.
- GLNs used to identify GPO members

2012 GTIN Sunrise

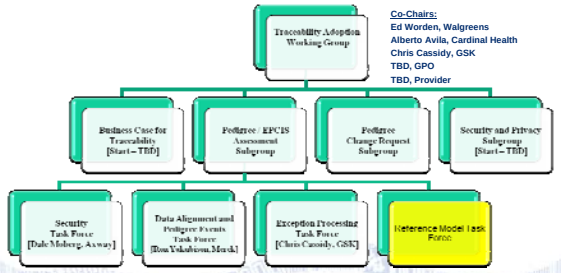
"The elimination of Custom Product numbers by 2012"

- GTINs assigned to all products.
- GTINs used in appropriate business transactions.
- GTINs marked on all packaging levels.
- GTINs scanned at point of receipt.
- GTINs scanned at point of care.
- GTINs used in product returns and recalls.
- GTINs registered in a GS1 GDSN certified data pool.

U.S. Adoption Work

GS1 Healthcare US

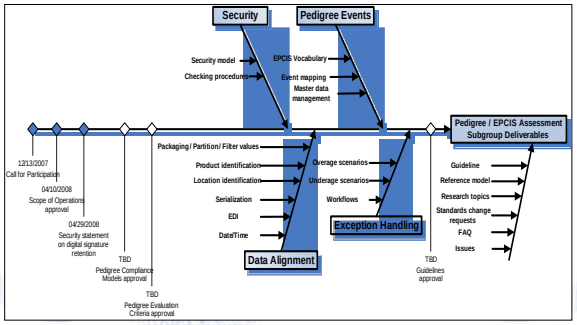
Traceability Adoption Working Group



Co-Chairs:
Ed Worden, Walgreens
Alberto Avila, Cardinal Health
Chris Cassidy, GSK
TBD, GPO
TBD, Provider

GS1 Healthcare US

Pedigree / EPCIS Assessment - Roadmap



Questions?

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California Prescription Drug Pedigree Requirement

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Pedigree Overview First Law 2004

- 1/1/2005 legislation enacted & some sections implemented
- 1/1/2007 original pedigree implementation date, board could extend to 2008

Current California Law Amended 2006

- 1/1/2009 pedigree implementation date
- CA Board of Pharmacy may delay implementation of pedigree until 1/1/11

Pedigree Definition

- Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition(s) and sale(s) by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering or dispensing the dangerous drug.

Pedigree Definition

- Pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution

Interoperable electronic system defined

- Electronic track and trace system for prescription drugs
- Uses unique identification number
- Established at point of manufacture
- Contained within standardized non-proprietary data format and architecture
- Uniformly used by manufacturers, wholesalers and pharmacies

Electronic Pedigree Requirements

- Prescription Drug Information
- Transaction and Source Information
- Ownership Information
- Certification

Historical Context

- 1988 to 2008, 20 years under the PDMA does not stem diversion or counterfeiting Publication of final regulations implementing PDMA (as amended by the Prescription Drug Amendments of 1992 (PDA)) in 1999. Pedigree regulations stayed repeatedly. Rising concern over counterfeiting leads FDA Commissioner Mark McClellan to establish Counterfeit Drug Task Force in July 2003.

Historical Context

- Beginning in 2003, states spurred to act
  Numerous contributing factors, including
  2003: Florida grand jury investigation reports
  2003: FDA Counterfeit Drug Task Force convened
  2003-2005: News reports on counterfeits and patient harm, including Washington Post series, segment of 60 Minutes, *Dangerous Doses*, events leading to "Tim Fagan's Law, and others
  Patients in CA among those potentially affected
  2003 2005: Nevada, Florida, and California

Historical Context

- In 2004, published substantive Report of FDA Counterfeit Drug Task Force
  - Restated threat from recent increase in and sophistication of counterfeits/counterfeiters.
  - Among other findings, Report concluded that adoption and common use of reliable track and trace technology based on RFID tagging of products was feasible for use by 2007.
  - Encouraged use of electronic track and trace technologies and electronic pedigrees.

Historical Context

- In 2004, California passed legislation requiring electronic pedigrees
  Original compliance date: January 1, 2007
  Basic framework of pedigree established, not changed by 2006 subsequent legislation, *including requirement of unit-level serialization.*

Historical Context

- In 2005 and 2006, follow-up Reports by FDA Counterfeit Drug Task Force
  Progress toward electronic track and trace and RFID adoption, but disappointment that industry had not voluntarily met 2007 projections for electronic track and trace, RFID implementation, mass serialization.
  We believe that members of the drug supply chain should be able to implement e-pedigrees in the very near future. We applaud those members who already are taking steps . . . and States that have championed this cause, such as California. (2006 Update)
  Recommended universal pedigree requirement (not just non-ADRs) to document all drug movements.
  Recommended lifting PDMA regulations stay 12/06.

Historical Context

- In 2006, as January 1, 2007 deadline drew near, California enacted current law (SB 1476), extended date to January 1, 2009. Primary motivation was to give more time. Still no specification of particular technology, though interoperability, track and trace, and unique identifier requirements were added – made serialization requirement more explicit. Gave Board of Pharmacy authority to extend deadline further, to January 1, 2011.

Historical Context

- In 2007-2008, always close relationship between FDA and California draws closer on pedigree
- FDA repeatedly states support for the California model, including electronic track and trace, mass serialization with unique unit identifier, end-to-end universal pedigree (all drugs, all entities).
  FDA has said FDAAA standard-setting supports, does not deter, California pedigree compliance.

Problem

- Of 4 billion US prescriptions in 2007, up to 40 million may have been filled with counterfeits, up to 10% in California; projected $75 billion worldwide by 2010.
- FDA counterfeit drug cases: number opened 2004-2007 was more than double 2000 2003, while number opened in 2003 was itself five times that opened in 2000.
  In 2007, FDA counterfeit cases resulted in 71 arrests, 50 convictions, and $26.5 million in fines and restitution.
- In April 2008 the FDA had 20 open counterfeiting cases from just one of two regional California offices.

Still Problems in Supply Chain

- Example: Board of Pharmacy in ongoing investigation with FDA involving counterfeit/adulterated drugs passed through both licensed and unlicensed hands, through at least nine states, using fraudulent paper pedigree.
- It appears Heparin incidents had fraudulent motive.

Purpose of Pedigree

- The pedigree is an important part of a series of provisions intended to address threats to the prescription drug supply from counterfeit, misbranded, adulterated or diverted drugs. The overall intent is to secure the drug distribution system and sustain and increase confidence in authenticity of prescription drugs in California

What Vendors Have Told Us

- Many of the pieces are available now, and each company must develop its strategy.
- Actual pedigree record/transmission may be the easiest (and final) piece. Hardest piece may be serialization infrastructure.
- Many industry participants are working on outdated, non-integrated, legacy systems.
- RFID prices will continue to come down.

Next Steps Forward

- Work with FDA, GS1, and industry on standards/technologies.
  - Formal and informal participation with FDA.
  - Expect to incorporate/use FDA standards.
- Continue work with other states and Congress on law.
- Seek international consensus (EU/EFPIA).
- Continue working with industry on various initiatives to increase implementation.
  - Including GS1/EPCglobal standards-setting.
- Encourage technological development.

SB 1307 (2008 legislation):

Signed by Governor Schwarzenegger
Sequenced implementation & timeline moved out

- Manufacturers (generic and brand) must pedigree:
  - 50 percent of their products by 2015,
  - the remaining 50 percent by 2016
- Wholesalers and repackagers must accept and pass pedigrees by July 2016
- Pharmacies and pharmacy warehouses must accept pedigrees by July 2017

Percentages can be based upon:

- Unit volume
- Product package (SKU) type
- Drug product family

SB 1307 (2008 legislation):

Legislative Intent (SB 1307)

California's electronic pedigree system will "provide tremendous benefits to the public and to all participants in the distribution chain. Those benefits should be made available as quickly as possible through the full cooperation of prescription drug supply chain participants. To this end all drug manufacturers and repackagers are strongly encouraged to serialize drug products and initiate electronic pedigrees as soon as possible, and all participants in the supply chain are encouraged to immediately ready themselves to receive and pass electronic pedigrees.

SB 1307 (2008 legislation):

At the same time, it is recognized that the process of implementing serialized electronic pedigrees for all prescription drugs in the entire chain of distribution is a complicated technological and logistical undertaking for manufacturers, wholesalers, repackagers, pharmacies, and other supply chain participant. The Legislature seeks to ensure continued availability of prescription drugs in California while participants implement these requirements.

SB 1307 (2008 legislation):

Exemptions:

- Radiologic drugs
- Drugs labeled "for veterinary use only
- Compressed medical gases
- Solutions:
  - IV solutions for replenishment
  - IV solutions used to maintain equilibrium of water and minerals (dialysis)
  - Solutions for irrigation or reconstitution
- Surgical kits containing a device and medical supplies, sealed by the Mfg.
- Kits containing a drug/device, biologic/device, drug/biologic/device that are physically or chemically or combined as produced as single entity
- Kits containing two or more products packaged together in a single package comprised of a drug and device or biologic and device
- Drugs received by a state or local government agency from a federal govt. agency

SB 1307 (2008 legislation):

Expanded or new definitions:

- Manufacturer includes NDA, ANDA, and BLA holders; contract Mfgs
- Smallest package or immediate container" which must be pedigreed is further defined as the smallest unit made by the mfg. for sale to the pharmacy
- Third party logistics provider: a licensed wholesaler who takes possession of, but not ownership of, drugs. Does not need to append pedigree but must maintain copies of it.
- Invoice Annotation to Pedigree: allows a customer-specific shipping number referenced to the sales invoice number in place of invoice number

SB 1307 (2008 legislation):

"Repackager" added to various sections to clarify that repackagers are:

- a manufacturer that must pedigree repackaged items
- Must reference original pedigree information on repackaged products
- Must create a unique identification number for pedigree of repackaged items

SB 1307 (2008 legislation):

Inference

- Board to establish regulations
- Allows a unique identifier to be applied to a case, pallet or other "aggregate without individually reading each serialized unit
- Specifies intent that Mfgs, Wls, Phys distribute and receive electronic pedigrees, and verify and validate pedigrees at the unit level except where efficiency and safety can be secured through inference

SB 1307 (2008 legislation):

Grandfathering

- Establishes process for Mfgs, Wls, and Phys to designate drugs already in their possession when pedigree requirements kick in
- Exempts from pedigree requirements drugs described in written lists submitted to board
- These lists are confidential
- Board may establish requirements for the lists

SB 1307 (2008 legislation):

Drop Shipment

- Provides definition: Products shipped from Mfg to Phy; Ownership/Pedigree goes from Mfg to Wls to Phy
- Regulations may be developed to establish alternative pedigree

SB 1307 (2008 legislation):

Preemption of CA law, if:

- Federal legislation or federal regulations are enacted addressing pedigree or serialization measures for dangerous drugs
  - Within 90 days board must publish notice of inoperation of pedigree requirements
  - Within 90 days board must adopt emergency regs stating inoperation of requirements
- If FDA enacts any rules or takes action inconsistent with any provision of CA law, that CA provision is inoperative
  - Within 90 days board must publish notice of inoperation
  - Within 90 days board must adopt emergency regs stating inoperation of specific requirements