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

Enforcement Committee and Workgroup on E-Pedigree

Meeting Summary of the December 12, 2006 Meeting

Radisson Hotel Sacramento
500 Leisure Lane
Sacramento, CA 95815

Present: Bill Powers, Board President and Chair
Ruth Conroy, PharmD, Board Member
Stan Goldenberg, RPh, Board Member
Rob Swart, PharmD, Board Member

Staff: Virginia Herold, Interim Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Karen Cates, Acting Assistant Executive Officer
Anne Sodergren, Legislative Coordinator
Joshua Room, Deputy Attorney General
Spencer Walker, Staff Counsel

Call to Order:

Chairperson Powers called the meeting to order at 9:33 a.m.

Letter to the DEA Supporting the Ability of Prescribers to Issue Multiple Prescriptions for Schedule II Controlled Drugs at One Time

Chairperson Powers referred the committee to a copy of the board's letter to the DEA supporting a proposed shift in DEA policy to allow prescribers to write multiple prescriptions (up to a 90-day supply) for Schedule II controlled substances during a single office visit. For example, this revision in DEA policy would allow prescribers to provide patients with three 30-day prescriptions at once, writing "do not fill until" a specified date on the additional prescriptions eliminating the need for patients to return to visit the prescriber simply to obtain a new prescription.

Proposal to Develop a Ethics Course For Pharmacists, Modeled After the Experiences of the Medical Board of California in Establishing an Ethics Course for Physicians

Lorie Rice, Associate Dean, External Relations, UCSF School of Pharmacy, and former public member of the Medical Board of California, provided a presentation on her experiences in developing an ethics course for physicians who had been disciplined by that board. This course was developed following the Medical Board's determination that existing ethics courses available for physicians were inadequate for the frequent ethical violations that come before the board for discipline.

Existing ethics courses, when found, focus on the theory behind ethics, similar to what one learns in traffic school. The Medical Board thought that such courses lacked the opportunity for the individual to think about the ethical violation and its impact on the individual, the patient and society. Of 770 physicians disciplined by the Medical Board, 75 percent were ethics violations in part.

Ms. Rice stated that there are two major types of violations: (1) quality of care issues, e.g., where a prescription order has been misinterpreted, dispensed incorrectly, or a patient has been inappropriately consulted, and (2) personal conduct issues, e.g., diversion for self use, sexual misconduct, adulteration of drugs.

If the board were to develop a course, there are some issues the board would need to address:

(1) Who would be part of the task force to develop the components?
(2) What type of cases would be referred?
(3) What criteria would be needed to assess rehabilitation, redemption and contrition? Is there a willingness to change on the part of the licensee?
(4) How to build skills involving empathy, to ensure there is an opportunity to focus about the impact of the licensee's action on society and how it impacted patients?
(5) Follow up for each licensee is needed in 6 –12 months

The Medical Board course is set up for a maximum of 12 individuals, and she indicated it would seem feasible to have physicians and pharmacists in the same class. According to the Medical Board regulations, the class must be at least 22 hours.

The timeline for the Medical Board to develop its course was:

- 2002: Formation of the Task Force
- 2003: Public Comment periods
- 2004: Regulation Hearing
- 2005: Regulation became effective

Ms. Rice referred to the Medical Board's regulation which was provided in the meeting materials. She stated that as the former executive officer of the Board of Pharmacy,

she has some knowledge about pharmacy violations and would be willing to assist the board in developing the course if the board decides to develop a course.

Chairperson Powers invited Ms. Rice to attend the January 2007 Board Meeting to determine the board's interest in proceeding with this project at this time.

Presentation by the FDA on the Implementation of the Prescription Drug Marketing Act Provisions Involving Pedigrees

Ilisa Bernstein, Director of Pharmacy Affairs, Office of the Commissioner, US Food and Drug Administration, joined the meeting via telephone from Washington, DC. Ms. Bernstein stated that very recently a US district court judge in the eastern district of New York issued a written order granting a preliminary injunction preventing the FDA from implementing the paper pedigree requirements which had been set to go into effect in December 2006, exempting authorized distributors. She stated that because the FDA is involved in litigation regarding the PDMA pedigree requirements, there is nothing that she could state at this time until the FDA releases a policy statement.

However, she complimented the efforts and leadership role that California has taken in moving forward an electronic pedigree system to further secure the drug supply.

Workgroup on E-Pedigree

Progress of the EPCglobal Workgroup

1. Presentation by EPCglobal:

Robert Celeste, EPCglobal, and Ron Bone, McKesson Corporation, provided a PowerPoint presentation on the development of standards for electronic pedigrees (**Attachment 1** contains this presentation).

EPCglobal is currently at the final stages of review for intellectual property rights. This is the final stage of review before the standards will be finalized. Completion of this review is expected in early January 2007.

EPCglobal reported the following progress:

- Pedigree management use cases: objective: define all supply chain use cases, processes and information needs for use in creating pedigree messaging standards.
  Status: complete
- Pedigree messaging standards: objective: define a standard format for the pedigree messaging standard that meets all federal and state requirements.
  Status: all standards work completed, prototype event was successful, technical review passed, intellectual property review underway
- Item level tagging: objective: define requirements for tagging pharmaceuticals at the item level; this includes requirements for

manufacturing lines, distribution environments, transportation and retail environments.
Status: requirements complete. A high frequency technical work was formed to define the standard. High frequency and ultra high frequency pilots are underway to provide uniform air interface protocol at the item level. The high frequency standard is expected to completed in the 3rd quarter of 2007

- Serialization: objective: define requirements to be encoded on the electronic tag.
  Status: requirements completed. Two identifiers were identified for use (global trade item number (GTIN) and serialized shipping container number (SSCC)). All remaining issues will be addressed by the newly formed serialization group.
- Decommissioning: objective: define requirements for decommissioning tags as they leave the supply chain.
  Status: work to begin in January 2007, timeline is 6 months
- Track and trace: objective: define supply chain use cases, processes and information needs for sharing EPC-related data for forward and reverse logistics.
  Status: forward and reverse logistics processes and data exchanges completed, additional use cases to be addressed for 3rd party logistics and repackagers, product recall, data sharing strategy and guidelines are being developed.

Mr. Bone stated that the features of the pedigree standard will support: item level serialization, electronic signatures, RFID using non-line of sight identification of pallets, cases or items, and inference.

EPCglobal's next steps will be to work through scenarios with the Board of Pharmacy, host a workshop for regulators from states with electronic pedigrees, and work with the formed industry adoption workgroup on serialization and time tagging issues. There will also be a regional summit for hospital issues on February 20.

Some of the issues that will be addressed by EPCglobal in the coming weeks will also involve use of NDC numbers involving controlled substances, which may be an issue when controlled substances are being transported.

The generic manufacturers are also interested in joining some of the pilot studies.

Board Member Goldenberg thanked the Mr. Bone and Mr. Celeste for the presentation, and acknowledged and commended those who have worked so hard to get to current status that was highlighted in EPCglobal's report. He also reaffirmed the board's position that 2009 is the implementation date for implementation of electronic pedigree requirements in California.

2. Presentations by Manufacturers, Wholesalers and Pharmacies on Implementation of Electronic Pedigrees:

(a) AmerisourceBergen Corporation:
Shay Reid, Vice President, Integrated Solutions, AmerisourceBergen (ABC), provided a PowerPoint presentation describing a pilot project initiated using electronic pedigrees with IBM (**Attachment 2** contains this presentation) that would track all drug products from manufacturers, through wholesalers and repackagers to pharmacies. Mr. Reid stated that ABC initiated this project in the belief that it has an opportunity to either be a leader or follower with respect to electronic tracking of drug products.

Mr. Reid walked through various scenarios involving a document-based pedigree that would be passed from one owner to the next as a drug product moves through the distribution channel. He noted that problems include massive redundant data repositories, especially for those near the end of the distribution channel. There is little other use that a company will gain from such repositories, except for compliance with requirements.

He then highlighted the "track and trace" model that is being tested by ABC and IBM. This system passes only a minimal amount of data as the product moves through the distribution channel, but that at any point, full data describing all items and all ownership can be quickly accessed and obtained by legitimate users. The system can also be accessed to obtain real time receiving and shipping information and for better management of inventory.

The ABC pilot will use ultra high frequency, 2-D bar codes and new high frequency tags on the drug products tested.

Mr. Shay indicated that inference will be one component evaluated as products are shipped from manufacturer to wholesaler. He also indicated that inference will be evaluated on mixed totes of products from wholesalers to pharmacies. Board staff indicated that these practices will be carefully reviewed for compliance with California requirements as the data is collected during the pilot.

Progress reports will be made to the board at future Workgroup on E-Pedigree meetings.

(b) Cardinal Health
Julie Kuhn, Cardinal Health, presented information on a RIFD pilot run on ultra high frequency tagging of drug products from manufacturers through the supply chain (**Attachment 3**).

The results of this study indicate that it is feasible for these tags to be added to product containers and be read throughout the system – under this pilot, they were read 95 to 97 percent of the time. Cardinal Health believes after some adjustment, readings near 100 percent can be accomplished, without disruption to the distribution channel.

Two different types of containers were tested, a round container and a square container. Tagging at various places (container, pallet, etc.) was also tested.

The results indicate:

- RFID tags can be successfully inlaid under existing FDA-approved pharmaceutical label stock.
- Packaging lines can be run at validated speeds while encoding and verifying RFID tag application.
- A single frequency (UHF) has the potential to work in critical points from pharmaceutical packaging to pharmacy receipt.
- No tag failures were encountered in any stage of the pilot.
- Item-level reads are not possible when cases are stacked on a pallet
- Unit read rates within mixed totes exceed 99 percent, but are not at 100 percent.
- 100 percent read rates at the case level on pallets are potentially obtainable
- Case read rates on a moving conveyor at shipping and receiving had read rates exceeding 99 percent.

The conclusion of the study was that RFID technology is feasible for tracking and tracing item level drugs in the pharmaceutical chain provided that higher levels of collaboration are initiated among stakeholders to identify opportunities in the supply chain to improve efficiencies and reduce costs.

Ms. Kuhn indicated that there has been more collaboration within the last six months among industry partners than in the last 18 months. She also commented that generation 2 UHF tags are superior in quality to the Gen 1 tags.

3. Presentation on Technology for Electronic Tagging of Items

Bertrand Teplixky, Secure Packaging Systems, provided a demonstration of a form of electronic tagging that would be positioned in the cap of a medicine container. Mr. Teplixky indicated that such tags could be beneficial for high cost biologicals and are in use in Europe. They are also capable of being developed with Braille markers and with color-coded caps.

During discussion mention was made about testing of biological products for stability following 48 hours of exposure to high frequency fields without any change in the medication inside the containers.

4. Comments by the California Retailers Association

Heidi Barsuglia, Director, Government Affairs, California Retailers Association, provided comments from the chain store pharmacies in California. She discussed comments provided in a letter dated December 1, 2006.

The CRA's members are concerned that the 2009 date for implementation of electronic pedigrees in California will be impossible for the state's chain-store pharmacies because they are at the end of the distribution channel, and the technology put in place by manufacturers and wholesalers will need to be readable, adopted and installed in pharmacies before pharmacies can comply with the requirements.

Ms. Barsuglia indicated that pharmacies need to initiate testing to ensure these systems are operable, can protect patient privacy and will not delay the dispensing of medication to patients. She indicated that this process may take at least two years.

Moreover, pharmacies are concerned that they will need to develop methods for storing and accessing electronic pedigrees, and these databases will be huge databases at the store level to manage and maintain. There are also concerns about whether there will be adequate staff available to install these systems and provide training to pharmacy staff about how to use them. These latter tasks cannot be initiated or planned for until the manufacturers and wholesalers fully implement and integrate the systems for electronic pedigrees that will be passed to the pharmacies.

She concluded that the pharmacies will need time beyond 2009 to be able to implement the standards.

2007 Meeting Dates

The committee announced the following Enforcement Committee and E-Pedigree Workgroup Meetings for 2007:

- March 21
- June 20
- September 20
- December 5

At the current time all these meetings are planned to be held in Sacramento.

Adjournment

There be no additional business, Chairperson Powers adjourned the meeting at 12:30 p.m.