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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

ENFORCEMENT COMMITTEE MEETING
Summary of Agenda Items Discussed – Not an Official Meeting

December 7, 2005
Holiday Inn Capitol Plaza
300 J Street
Sacramento, CA 958914

Present: William Powers, Chair, Board Member
Stan Goldenberg, R.Ph., Board President and Member

Staff: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Joan Coyne, Supervising Inspector
Board of Pharmacy Inspectors
Joshua Room, Liaison Counsel, Deputy Attorney General
LaVonne Powell, Staff Counsel

Call to Order

Chair William Powers stated that committee members Marian Balay and David Fong were unable to attend due to previous commitments. Because the Enforcement Committee did not have a quorum, it would be operating as a subcommittee. All agenda items will be placed on the agenda for the February board meeting for discussion and action.

Implementation of the Electronic Pedigree Requirement for Prescription Drugs Effective January 1, 2007 – Questions and Answers on Implementation (SB 1307 -Chapter 857, Statutes of 2004)

Chair William Powers stated that in 2004, the Board of Pharmacy sponsored SB 1307 (Figueroa), which was signed by Governor Schwarzenegger and became law on January 1, 2005. The bill made various changes to the wholesaler requirements and distribution of dangerous drugs. Most of the changes strengthened and clarified the requirements for the distribution of dangerous drugs and dangerous devices in California.

The Enforcement Committee is monitoring the implementation of this legislation especially the implementation of the pedigree requirement. The bill requires an electronic pedigree by January 1, 2007 and gives the board the authority to extend the compliance date for wholesalers to January 1, 2008. The Legislature may extend the compliance date for pharmacies to January 1, 2009. The

purpose of the pedigree is to maintain the integrity of the pharmaceutical supply chain in the United States.

The industry anticipates that Radio Frequency Identification technology (RFID) will be the method used to track a drug's pedigree. The manufacturer would tag the drug with a small chip and antenna. When the tag is in close proximity of a reader, it would receive a low-powered radio signal and interact with a reader exchanging identification data and other information. Once the reader receives data, it would be sent to a computer for processing.

During the last year, the board and enforcement committee has had presentations from various companies displaying their electronic pedigree solutions. The first presentation was by T3Ci, an application software company that provides drug counterfeit, diversion detection and electronic drug pedigree for the pharmaceutical market. They demonstrated their technology solution for the electronic pedigree. The next presentations were by SupplyScape and Acerity Corporation. SupplyScape presented its electronic pedigree software program that enables a safe and secure pharmaceutical supply chain that complies with federal and state regulations to prevent counterfeit drugs. Acerity Corporation presented its security software program, which is an electronic authentication process. This system employs a cryptography techniques in conjunction with RFID forming a multiplayer secure process, which provides numerous advantages and allows versatile applications.

At the September Enforcement Committee meeting, Lew Kontnik, Director of Brand Protection/Business Continuity for Amgen presented to the committee the challenges that Amgen has encountered in developing an electronic pedigree for its manufactured products. He stated that Amgen, a billion dollar company that is headquartered in California, is the leading human therapeutics company in the biotechnology industry. He demonstrated the challenges that their company is facing in the implementation of RFID technology to track the electronic pedigree of its liquid products. Primarily he showed how the placement of the radio frequency tag on the products have resulted with inconsistent and inaccurate readings by the scanner unless the scanner is in close proximity of the tagged item, which is not conducive to tracking large quantities of distributed product. He also stated that whatever mechanism is used to generate the electronic pedigree, it must be incompliance with good manufacturing practices (GMPs), which is regulated by the federal Food and Drug Administration (FDA).

Upon conclusion of his presentation, Mr. Kontnik presented his company's position that it will be extremely difficult to meet the January 1, 2007 deadline to implement an electronic pedigree for its manufactured drug products.

The board also has been participating in the Uniform Drug Pedigree meetings. This is a group of participants that represents manufacturers, wholesalers, and regulators. The purpose of these meetings is to provide a cooperative effort to develop uniform standards and regulations regarding electronic pedigrees. As result of the board's participation with this group and others, a list of questions and answers were developed on the implementation of California's pedigree requirement. The questions and answers were provided in advance of this Enforcement Committee meeting.

Committee Chair Powers invited comments regarding the questions and answers. Clarification was sought regarding the definition of "change of ownership." The law requires that each time a change of ownership occur, the pedigree information must be documented. Some felt that there was an inconsistency with the definition because it included "third party logistics transactions." This means when a manufacturer sends a prescription drug to a "third party logistics" carrier to store and transport the prescription drug to the wholesaler and/or pharmacy, the transaction to the "third party logistics" carrier must be recorded on the pedigree. There was disagreement that this type of transaction constitutes a change of ownership. In some situations, the manufacturer is still the owner until the prescription drug reaches the wholesaler and/or pharmacy, in another example; the change in ownership of the prescription drug is immediate upon leaving the manufacturer and is transferred to the wholesaler and /or pharmacy.

During the discussion, requests were made to the committee that the Board of Pharmacy form an ad hoc committee that included all representatives of the industry to address the intricacies of the new law and its application. It was suggested that the board review the new Arizona law as a model for the distribution of prescriptions drugs from a chain wholesale distribution center to its chain pharmacy stores. It was questioned in this an example where a chain pharmacy had its own wholesale distribution center for distribution to its own pharmacies whether the pedigree would be required since a "change of ownership" of the prescription drug would not take place. It was explained that the way the law is written it requires that the pedigree information be recorded when there is a change of ownership. The board cannot advise whether or not a change has taken place in the example that was provided for chain pharmacy stores.

There was also a comment regarding the licensure of out-of-state wholesalers who ship into California. It was requested that the board consider amending the law to only require licensure of those wholesalers that ship over a specified amount of prescription drugs into California.

Another suggestion recommended that the board consider requiring an electronic pedigree for only a subset of prescription drugs such as controlled substances for the initial implementation in 2007. Concern was expressed that California law is different from the Florida pedigree law in that California requires the pedigree to be initiated by the manufacturer. Because the technology is evolving in this area, there is apprehension that each manufacturer will have its own and varied pedigree system that the wholesaler and eventually the pharmacy will have to work with. While the industry anticipates the use of RFID technology, California law only requires an electronic pedigree. There is concern about the compatibility of systems. In addition, California pedigree requirements although specific only to California may require manufacturers to initiate an electronic pedigree on all its prescription drugs because the manufacturer will not be able to differentiate which prescription drugs are going to be distributed in California.

Others commented such as the Healthcare Distribution Management Association (HDMA) that it has many questions that would be more appropriate for discussion if a workgroup were formed. Committee Chair Powers encouraged that additional questions be submitted to staff in advance of any future meetings. HDMA further stated that it is working on an initiative for the federal licensure of prescription drug distributors. Because many states are trying to address this complex issue, it has become a burden for wholesalers to comply with many different state requirements. The intent of federal licensure would set one standard nationwide. Unfortunately,

as the states have witnessed, the absence of any federal initiative requires the states to step in to assure the safety of its citizens.

It was noted that at the National Association of Chain Drugs Stores (NACDS)/HDMA RFID Healthcare Adoption Summit in November 2005, Randall Lutter, Associate Commissioner for the FDA announced that the FDA Counterfeit Drug Task Force is going to hold a public workshop in January or February 2006. The purpose of the meeting is to facilitate RFID standard-setting and coordination of issues, discuss the implementation of the pedigree requirements of the Prescription Drug Marketing Act (PDMA) and reaffirm FDA's commitment to facilitate and drive the adoption of electronic track/trace technology.

Committee Chair Powers stated that the next step is to bring forward the request that the Board of Pharmacy form an ad hoc committee to discuss and facilitate the implementation of the electronic pedigree requirement. The board will consider this request at its meeting on February 1, 2006.

Proposal to Amend B&P §4040(c) to Allow a Pharmacy to Accept a Fax Prescription from a Patient

Executive Officer Patricia Harris provided the committee with a proposal to amend B&P § 4040(c) to allow a pharmacy to accept a fax prescription from a patient provided that the pharmacy has the original prescription before dispensing the prescription medication to the patient. She stated that the proposal came from a consumer as a result of a complaint. Current law only authorizes a pharmacy to accept a fax prescription from a prescriber. In the specific complaint, the pharmacy was accepting a fax from the patient; however, the pharmacy stopped the practice because of the law. The consumer was not happy that he could no longer fax his prescription to the pharmacy.

The proposal is an option for pharmacies to implement. Concern was expressed that patients would fax their prescriptions (especially a controlled substance prescription) to various pharmacies to have it filled. There was also concern that accepting a fax from a patient would disrupt a pharmacy's workflow. It was discussed that this proposal is an option for pharmacies to implement as a service to patients if it chose to do so. Also, it would be incumbent on the pharmacy to obtain the original prescription prior to dispensing the medication to the patient to prevent the patient from having the same prescription filled at several different pharmacies. There was also discussion that the patient would more than likely forget to bring in the original prescription when picking up the dispensed medication. It was stated that the patient would have to return with the original prescription. The decision to allow for a patient to fax a prescription would be a customer service decision that each pharmacy would need to make.

Committee Chair Powers stated that this proposal would be discussed at the February board meeting.

Proposal to Amend B & P §4073(b) to Indicate the Prohibition of Generic Substitution by a Prescriber on an "Electronic Data Prescription"

The committee was provided with a proposed amendment to B&P § 4073(b) to update pharmacy law regarding the prohibition of generic substitution by a prescriber on an electronic data transmission prescription. Current law requires the physician to personally indicate either orally or on the prescription "Do Not Substitute" or words of similar meaning. If a prescriber checks a box indicating no substitution, then he/she must initial the box or checkmark.

The purpose of the amendment is to clarify that a physician is not required to manually initial an electronic data transmission prescription in order to prohibit generic substitution. It is presumed that prescriber is already electronically verified for the data transmission prescription and there is no additional need for the handwritten initial. Concern was expressed that software programs would automatically default to "Do Not Substitute."

Moreover, it was noted that the Centers for Medicare and Medicaid Services (CMS) issued its final rule on November 7, 2005, that covers transactions involving the electronic transmission of prescriptions and certain other information for covered Part D drugs prescribed for Part D eligible individuals. Essentially CMS has interpreted the federal law to preempt all contrary State laws that are applicable to a prescription that is transmitted electronically not only for those individuals who are enrolled in Part D, but for all Part D eligible individuals. Categories that are anticipated by CMS include state laws prohibiting e-prescribing, state laws prohibiting transmissions through intermediaries, state laws requiring certain language if not consistent with the federal Act and state laws requiring handwritten signatures. Therefore, this proposal is consistent with the final rule issued by CMS.

Review of Citation and Fine Program

Chair William Powers stated that at the June Enforcement Committee meeting, the California Retailers Association (CRA) requested that the review of the board's Citation and Fine Program be placed on the agenda for discussion the next Enforcement Committee meeting.

As requested, the matter was on the agendas for both the September and December Enforcement Committee meetings. The committee was provided an overview of the investigation process, historical data that gave a three-year summary of the citation and fine program since its inception, which included, the number of citations issued, the type of citations issued and the violations, the number of appeals and the result of those appeals.

No comments were provided.

Importation of Prescription Drugs

Chair Powers reported that the importation of prescription drugs is an ongoing issue that continues to be on the agenda for the meetings of the Enforcement Committee and Board of Pharmacy. Articles that have appeared since the last board meeting were provided.

Government Accountability Office (GAO) Report on the Purchase of Anabolic Steroids without a Prescription

Committee Chair Powers explained that the GAO report was issued in November 2005 at the request of Representative Henry Waxman. Representative Waxman requested the GAO investigate whether anabolic steroids can be purchased without a prescription and test whether such purchases are easily made. He also asked that the GAO identify common sources of illegal anabolic steroids, and significant challenges law enforcement officials encounter in investigating, prosecuting, and deterring criminal anabolic steroid traffickers.

A summary of the report concluded that the GAO investigators easily obtained anabolic steroids without a prescription through the Internet. After conducting Internet searches, they found hundreds of Web sites offering anabolic steroids commonly used by athletes and bodybuilders for sale. Then the investigators used an e-mail account in a fictitious name to place 22 orders. From these orders, the GAO received 10 shipments of anabolic steroids; all were shipped from foreign countries. They also received 4 shipments from within the United States but the substances contained, though marketed as anabolic steroids or other "muscle building" products, were not anabolic steroids according to the FDA. The GAO referred the evidence concerning the purchases to the DEA and to the FDA for appropriate action.

Proposed Meeting Dates

The subcommittee selected March 16, 2006, for the next meeting date. The meeting will be held in Sacramento.

Adjournment

Chair Powers adjourned the subcommittee meeting at 11:15 p.m.