California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

Enforcement Committee and Work Group on E-Pedigree

Summary of the Meeting of September 28, 2006

Radisson Hotel
500 Leisure Lane
Sacramento, CA 95815

9:30 -12:30

Present: Stan Goldenberg, Board Member and Acting Chair
Rob Swart, PharmD, Board Member
Ruth Conroy, PharmD, Board Member

Absent: Bill Powers, Board President

Also Present: Virginia Harold, Interim Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Karen Cates, Assistant Executive Officer
Joshua Room, Deputy Attorney General
Tim Daze, Board Member

Call to Order:

Acting Chairperson Stan Goldenberg called the meeting to order at 9:35.

The individuals present introduced themselves

Formulary of Drugs Under Development by the Bureau of Naturopathic Medicine for Naturopathic Doctors

Gloria St. John, Executive Director of the California Naturopathic Doctors Association, provided information about California's regulation of naturopathic doctors, a relatively new licensing program enacted by SB 903 (Burton) in 2003. Today there are about 200 naturopathic doctors licensed in California by the Bureau of Naturopathic Medicine, a bureau in the Department of Consumer Affairs. Naturopathic doctors must earn 60 hours of continuing education to renew their licenses every two years, of which at least 20 hours must be in pharmacotherapeutics. She added that naturopathic medicine is a

form of primary care that is an art, science, philosophy and practice involving diagnosis, treatment and prevention of illness.

Naturopathic doctors are allowed to prescribe hormone and epinephrine for anaphylaxis independently and to prescribe Schedule III through IV drugs under protocol with an MD. To furnish and order drugs, NDs must obtain a furnishing number from the bureau, which requires completion of a 48-hour course in pharmacology.

Naturopathic doctors can administer, order and prescribe food, extracts of food, nutraceuticals, vitamins, amino acids, minerals, enzymes, botanicals and their extracts, botanical medicines, homeopathic medicines, all dietary supplements and non prescription drugs, consistent with the following routes of administration: oral, nasal auricular, ocular, rectal, vaginal, transdermal, intradermal, subcutaneous, intravenous, and intramuscular. The bureau states that NDs may use ocular and intravenous routes of administration only if they are clinically competent to do so.

Senate Bill 907 specified that the Bureau of Naturopathic Medicine establish a Naturopathic Formulary Committee to determine the formulary from which naturopathic doctors will prescribe. The committee is comprised of an equal number of physicians, pharmacists, and naturopathic doctors. The committee makes recommendations regarding the prescribing, ordering and furnishing authority of an ND and the required supervision and protocols for these functions. The formulary is to be submitted to the Legislature by January 1, 2007 regarding the prescribing and furnishing authority of an ND, and the required supervision and protocols for the use of IV and ocular routes of prescription drug administration.

Ms. St. John stated that 13 states license NDs, and nine of these states allow NDs to prescribe independently with no MD oversight. No state reports disciplining NDs for prescribing. The committee concluded that there are only a limited number of MDs who possess the training and philosophy needed to supervise NDs. Moreover, the few MDs who do qualify have difficulty obtaining adequate malpractice coverage. Based upon these factors, the committee believes that MD supervision of NDs is untenable.

The Naturopathic Formulary Committee recommends:

- Inclusion Formulary: Pursue changes to California law to allow NDs to be able to independently prescribe without MD supervision from the committee-recommended formulary.
- IV Therapy: NDs should be able to practice without MD supervision after completing specific CE comprised of a 25-hour course, with 14 hours of practicum, and a refresher course every five years. Upon completion, NDs will be able to independently administer drugs listed in the IV formulary via the IV route.
- Chelation Therapy: Any ND who performs this therapy (used to detoxify for heavy metal exposures) must complete a 12-hour CE course in addition to the IV therapy course.

Ms. St. John distributed a proposed formulary to the Enforcement Committee. She indicated that she would be happy to make a similar presentation to the full board.

After some discussion, Chairperson Goldenberg invited Ms. St. John to present this information to the board at its October Board Meeting.

Plan B Emergency Contraception Becomes Over-the-Counter for Patients 18 and Older

In mid-August, the FDA reclassified Plan B from prescription status to over-the counter status for emergency contraception for patients aged 18 and older. For patients 18 years and younger, Plan B remains a prescription drug.

In California existing law contains provisions that allow a specially qualified pharmacist to prescribe and dispense emergency contraception, using a variety of drugs, including Plan B (California Business and Professions Code section 4052, and California Code of Regulations section 1746).

The committee reviewed a number of questions and answers developed by staff to explain implementation of the law in California.

Although OTC, Plan B may be sold only by pharmacies and must be kept behind the pharmacy counter. Anyone, a pharmacist, pharmacist intern, pharmacy technician or clerk may sell the drug. Individuals who are 18 and order may purchase the drug. No records of these sales are required.

If the patient is less than 18, then the pharmacist, if qualified, may write a prescription for Plan B or any other medication authorized in the state protocol for emergency contraception or in the protocol established with a physician. In this case, the emergency contraception drug is a prescription drug, and all requirements for dispensing prescription drugs apply, including consultation by the pharmacist.

Also, other drugs listed in the state protocol for emergency contraception remain prescription drugs, not over-the-counter, regardless of the age of the patient or purchaser.

Several changes were suggested to the questions and answers.

Once finalized, the questions and answers will be added to the board's Web site.

Work Group on E-Pedigree

Supervising Inspector Nurse provided a Power Point presentation on changes to California's e-pedigree requirements that were amended into SB 1476. At the time of this meeting, the Governor had not yet acted on this bill to sign, veto or let become law without his signature on this bill.

Senate Bill 1476 would delay implementation of e-pedigree requirements in California until 2009, with the board having the ability to delay implementation until January 1, 2011.

The board drafted additional amendments into SB 1476 that would clarify that the e-pedigree system must interoperable through all levels in the distribution system, that serialization is needed to product container, that the board must be notified if counterfeit drugs or fraudulent pedigrees are suspected, that drugs returned to a wholesaler must maintain the same pedigree, that repackagers must maintain the pedigree into repackaged items, and that drug samples do not require pedigrees.

Chairperson Goldenberg emphasized that the e-pedigree work group meetings over the next few years will be crucial to being able to develop necessary regulations and move forward timely with implementation of these requirements that are necessary to ensure a safe distribution system for patients.

EPCglobal provided a PowerPoint Presentation about industry's progress in developing unified standards for electronic pedigrees. There continues to be progress in development, and testing on a "last call working draft" version of a standard is underway. The purpose of this standard is to ensure that different entities in the supply chain can all access the pedigree and interpret it in the same manner.

Among the issues to be resolved include decommissioning of a chip to protect patient privacy, item level tagging – whether high frequency or ultrahigh frequency would be best. It may the third quarter of 2007 before the standard for item tagging is ready. Mike Rose of Johnson and Johnson stated that 2-d bar codes are being examined as well.

EPCglobal reported on a pilot study conducted; recently six companies were given seven of the most challenging scenarios and test data to create pedigrees against. A total of 42 pedigrees were tested. Their pedigrees were compared, line-by-line, with the expected outcome from the standard. There were no changes to the standard.

Concern was expressed by Board Member Daze about the proposed delay of electronic pedigree requirements until 2009, and whether patient safety is being adequately considered.

McKesson provided a brief overview of the "On Track" pilot program underway which is seeking answers among various entities in the supply chain to e-pedigree issues such as data sharing, track and trace visibility, tag data components, tag frequency and reading ranges, and changes needed in current business processes. Generation 1 will be completed in December 2006, when a generation 2 study will begin.

Johnson and Johnson stated that they are working to implement the e-pedigree requirements but they believe implementation is still 4-5 years away. The infrastructure is not ready, and that not all products really need electronic pedigrees.

During 2006-08, Johnson and Johnson will be working on building the structure to use e-pedigrees, and test 3-5 products using both RFID and 2-D bar code technology.

In 2010, the standards will be deployed, and they believe that 50 percent of their products will be tagged by 2011. But implementation cannot be fully achieved until 2011-2012.

The company emphasized the importance of interoperability – of one standard used by everyone, and indicated that regulations to require a specific standard may be required.

The California Retailers Association stated that one standard is needed because pharmacies are at the end of the process and cannot function with multiple electronic pedigree systems, each requiring unique equipment. At this stage, the CRA cannot offer a timeline for implementation because they are waiting for the drug manufacturers and wholesalers to refine the standards. The CRA also emphasized that they are participating in the On Track and EPCglobal standards setting and pilot tests of electronic pedigrees.

Stat Pharmaceuticals provided information about its operations as a secondary wholesaler, and the association of secondary wholesalers the company is part of, which is not a part of the EPCglobal group. Gene Alley stated the difficulty that the FDA's authorized distributor and paper pedigree standards that will go into effect in December 2006 will have on such companies as his. He added that by exempting authorized distributors from pedigree requirements but requiring secondary wholesalers to obtain pedigrees from the authorized wholesalers, especially since the authorized distributors will not provide pedigrees, will force companies such as his out of business. Chairperson Goldenberg asked that he come to the October Board Meeting to provide a presentation.

Adjournment:

There being no additional business, Chairperson Goldenberg adjourned the meeting at 12:30.