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

Licensing Committee

Meeting Summary
September 20, 2006

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

Present: Ruth Conroy, PharmD, Chairperson
Clarence Hiura, PharmD, Board Member
Susan Ravnan, PharmD, Board Member

Virginia Herold, Interim Executive Officer
Karen Cates, Assistant Executive Officer
Joshua Room, Deputy Attorney General
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector

Chairperson Conroy called the meeting to order at 9:30 a.m.

ACPE Celebrates Its75 Birthday

The committee viewed a brief video-montage DVD prepared by the Accreditation Council for Pharmacy Education, showing the history of this organization since its formation 75 years ago. The pictorial review showed changes in pharmacy over this period.

Request to Add the Exam for the Certification of Pharmacy Technicians as a Qualifying Methods for Pharmacy Technician Registration

Kenneth W. Schafermeyer, PhD, RPh, Director of Education for the Institute for the Certification of Pharmacy Technicians, provided an overview of the development of a new certification examination for pharmacy technicians.

Currently, pharmacy technicians may become qualified for registration in California by one of four methods:

1. Possessing an associate degree in pharmacy technology

2. Completing a course of training specified by the board in regulations (accredited by ASHP, provided by the armed forces, or at least 240 hours of instruction covering specific topics)
3. Graduating from a school of pharmacy recognized by the board
4. Being certified by the Pharmacy Technician Certification Board.

A new pharmacy technician examination has been brought to the board's attention, the Exam for the Certification of Pharmacy Technicians (ExCPT).

The ExCPT is now accepted by Connecticut, New Jersey, Minnesota, Oregon and Virginia as a qualifying route for registration. The exam is computer administered six or seven days a week in 700 locations nationwide. The National Community Pharmacists Association and the National Association of Chain Drug Stores support use of the exam, and were involved in its development.

Dr. Schafermeyer distributed a number of documents describing the ExCPT. He stated that of the 26 states that require registration of pharmacy technicians, 11 have agreed to use the ExCPT examination as a qualifying route to registration (in several of these states the approval is proceeding but is still pending).

Dr. Schafermeyer stated that the ExCPT is a 100-question, multiple-choice examination. He described how the ExCPT is developed and validated using a job analysis and content outline. He identified the expert examiners for the test, and stated that the exam is psychometrically validated. He said that individuals can apply to take the examination approximately 48 hours before actually taking it at a scheduled time and location, and they must be at least 18 and have a high school diploma or GED. Candidates with a drug-related felony cannot be certified.

Board members and those in the audience asked a number of questions about the ExCPT, which is a competing exam of the PTCB exam.

The committee asked staff to review the ExCPT and see if it meets the requirements of Business and Professions Code section 139, which establishes requirements for examination programs for California-licensed occupations.

Staff will collect and compile this information and provide a report to a future meeting of the Licensing Committee. Meanwhile Dr. Schafermeyer will be offered the opportunity to present an overview of the examination to the board at the October 25th meeting.

Should the board approve the use of the ExCPT, a statutory modification to Business and Professions Code section 4202 would be required.

Emergency Preparedness for California Pharmacy

Dana Grau, PharmD, of the Emergency Preparedness Office, Emergency Pharmaceutical Services Unit in the Department of Health Services, provided

information about planning and preparing for disaster response. His office exists to protect the health of Californians against large-scale public health emergences, including bioterrorism attacks, nuclear attacks, disease outbreaks such as pandemic influenza as well as natural disasters such as those caused by hurricanes and earthquakes. Dr. Grau stated that his office is a conduit for the receiving resources of the Strategic National Stockpile from the Centers for Disease Control.

Dr. Grau described the Strategic National Stockpile as a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration, airway maintenance supplies and medical /surgical items. The stockpile will supplement and re-supply state and public agencies for any emergency, anywhere at anytime within the US. The stockpile is shipped to the designated location within 12 hours. Additional shipments arrive, if needed, within 24 to 36 hours. When necessary, the inventory of the stockpile can be modified to contain only several pharmaceuticals.

These drugs will need to be stored in a single state warehouse, depending upon where the disaster is located, and the DHS wants to be certain that the location, which would be secret, would be licensed.

In the event of a bioterrorism event, mass dispensing of medications to large numbers of asymptomatic people will occur at points of dispensing (PODs), allowing hospitals to treat the ill. Plans are to provide medications, such as antibiotics, to 100 percent of the identified population within 48 hours.

Large numbers of licensed individuals, such as pharmacists and nurses will be used to provide mass dispensing of the medications.

Dr. Grau stated that getting medications from the single state warehouse into the hands of the people who need them is a tremendous challenge to protect the public.

Dr. Grau stated that the DHS has identified potential warehouse locations throughout California from which the Strategic National Stockpile can be deployed. The actual site used will depend on the location and scope of the emergency. None of these sites is yet licensed as a drug wholesaler, and some may not meet all requirements of a licensed wholesaler. The permit for the site would be requested for activation upon the management decision of the DHS.

Additionally, local health departments are locating potential sites that can be used to receive, store and stage drugs and medical supplies delivered from the state warehouse site and to the PODs.

The DHS provided a list of 11 questions to frame the discussion for a system under which medications can be shipped, stored and distributed in the event of a declared disaster, most of which are not authorized within existing law for nonemergency drug distribution. These questions will be explored with the DHS and in a future Licensing Committee meeting.

Dr. Grau also asked for the board's assistance in publicizing training and preregistration of pharmacists, pharmacy technicians and pharmacist interns for disaster response. Concern about possible liability and violating state pharmacy laws is a concern keeping many pharmacists from becoming involved in this area.

The committee strongly noted its support to work with the DHS to aid in planning for disaster response. The first step will be the development of a policy statement that will be publicly released, placed on the board's Web site and highlighted in the next board newsletter.

The committee directed that this statement be provided to the board for action at the October meeting.

An Overview of 340B Drug Programs

Chairperson Conroy directed the committee to materials in the packet describing 340 B Drugs. The material was provided for information only, and was not an endorsement of the provider's program.

Transfers of NAPLEX Scores to Other States

At the July Board Meeting, the board directed that staff determine why 26 states will not accept NAPLEX scores earned in California if later the pharmacists wish to transfer the score to become licensed in that state.

Ms. Herold stated the review has not yet been started but will be completed and shared with the committee in December. Ms. Herold added that she had contacted the NABP for its insight, and was advised that::

1. California's acceptance of NAPLEX scores only if earned after January 1, 2004, may account for much of the reason why California scores are not accepted by these states; essentially because California does not fully accept NAPLEX scores earned by their pharmacists, but instead requires retaking the NAPLEX for many of a state's already licensed pharmacists.
2. Misunderstanding about what exams California will accept from their states (e.g., requiring passing of the old California licensure exam).

The NABP believes that education about California's requirements may help resolve some of this problem. Ms. Herold will contact these states one at a time to conduct the survey and hopes to provide education as well as obtain information.

Foreign Pharmacy Graduate Equivalency Commission Certifications

California law requires foreign-educated pharmacists to be certified by the Foreign Graduate Equivalency Commission (FPGEC) to satisfy the educational equivalency requirement with that of domestic pharmacy school graduates.

Since 1991, California has required foreign-educated pharmacists to pass the Test of Spoken English (TSE) as a condition of taking the pharmacist licensure examination. The TSE is administered by Educational Testing Service worldwide, and has been validated to assess the spoken English proficiency of those for whom English is not their original language.

In 1997, the FPGEC began requiring a TSE score of 50 as a component of FPGEC certification. Recognizing the duplication of this requirement with California's requirement, California law was amended in the late 1990s to require foreign-educated candidates who became FPGEC certified before January 1, 1998 to continue to provide a passing score on the TSE, but those certified after this date need to provide a TSE score directly to the board (due to the FPGEC's TSE requirement).

In a few months, Educational Testing Service will no longer administer the TSE, but instead rolled these requirements into the TOEFL iBT exam. The FPGEC has begun accepting the TOEFL iBT exam as part of its requirements to become FPGEC certified.

However, in recent months, the board has heard from several foreign-educated pharmacists who became FPGEC certified before 1998, and thus are required to complete the TSE requirement. However, these applicants have been unable to pass the TSE. The applicants have expressed concern about how they will qualify to take the pharmacist licensure examination in California if the TSE is no longer administered.

The FPGEC has agreed to recertify these individuals who have not earned a passing TSE upon passage of the TOEFL iBT.

Update on AB 595 on Compounding by Pharmacies and Recent Action by the US District Court, Western District of Texas

Ms. Herold updated the committee on the status of AB 595 – and why the bill was dropped in the closing moments of the 2006 Legislative Session. Assembly Bill 595 was sponsored by the board, and would have established requirements for pharmacies that compound medication. One provision would have allowed pharmacies to contract with other pharmacies to obtain compounded medication, if the pharmacy had a patient-specific prescription for the compounded medication. The Department of Health Services was opposed to this provision, and in May submitted amendments that would have required a separate licensure program with annual inspections for any pharmacy that compounded medications for another pharmacy pursuant to a contract. Instead, the board developed amendments in attempts to remove the opposition of the DHS that were amended into the bill formally in late August. However, once the amendments appeared in print, Kaiser Permanente, the California Pharmacists Association and Grandpa's Pharmacy opposed the bill. At this point, AB 595 was dropped. Meanwhile in Texas, a US District Court decision restricted the FDA's regulation of pharmacy compounding based on a lawsuit filed by several Texas pharmacies.

During the Licensing Committee Meeting, Deputy Attorney General Joshua Room provided an overview of the likely minimal impact the Texas decision might have upon California. He walked the committee through the decision and the somewhat confusing law as to pharmacy compounding, an area of overlapping and complementary jurisdictions between the federal government (which licenses and regulates manufacturers, along with counterparts in the states) and the states (which license and regulate pharmacies and pharmacists).

> In a decision on cross-summary judgment motions issued August 30, 2006, U.S. District Court Judge Hon. Robert Junell (Western District of Texas) reached three primary conclusions: (a) drugs compounded by a pharmacist for an individual patient pursuant to a prescription from a licensed practitioner are implicitly exempt from the definitions of "new drug" in 21 U.S.C. § 321(p)(1) and (v)(1) (and are therefore not required to be the subject of new drug applications/approvals before being provided to patients); (b) so long as the compounding pharmacies (1) conform to applicable local laws that regulate pharmacy, (2) are regularly engaged in dispensing drugs or devices upon receipt of a prescription from a licensed practitioner in the course of his or her practice, and (3) only manufacture, prepare, propagate, compound, or process drugs/devices in the regular course of their business of dispensing or selling drugs at retail, they are exempted by the language of 21 U.S.C. § 374(a)(2) from the more detailed inspection of records authorized by the third sentence of 21 U.S.C. § 374 (the "records inspection"), though they are still subject to the more general (facilities) inspection authorized by the first sentence of 21 U.S.C. § 374; and (c) pharmacies may compound drugs for non-food animals from legal bulk ingredients (contrary to FDA CPG 608.400 and a Notice distributed to Boards of Pharmacy by the FDA on April 2, 2004).
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> For conclusions (a) and (c), Judge Junell relied heavily on language in 21 U.S.C. § 353a exempting those drugs compounded by pharmacists under the conditions outlined in Section 353a (basically, pursuant to an individual prescription arising from an established physician-patient relationship) from the requirements of Sections 351(a)(2)(B) [drug adulterated if not produced in conformity with good manufacturing practices], 352(f)(1) [drug misbranded unless label has adequate directions for use], and 355 [necessity of new drug application before introducing new drug into interstate commerce]. Section 353a was added in 1997 by the Food and Drug Modernization Act (FDAMA). As enacted, Section 353a also included prohibitions on pharmacy or pharmacist advertising or promotion of compounded drugs. Those prohibitions were almost immediately struck down by a federal District Court on First Amendment grounds, though at the District Court level the remainder of Section 353a was left standing (severed). However, when the case got to the Ninth Circuit U.S. Court of Appeal (which

covers California, Nevada, Oregon, Washington, etc.), the Ninth Circuit said these provisions were not severable and invalidated ALL of Section 353a. The case was subsequently appealed to the U.S. Supreme Court (Thompson v. Western States Medical Center, 535 U.S. 357 (2002)), but ONLY on the question of the validity of the provisions struck down (and not on the severability question). The U.S. Supreme Court affirmed the invalidation of the prohibitions on advertising and promotion on First Amendment grounds, but did not address the question of severability of these provisions from the remainder of Section 353a.

So, the continuing validity of Section 353a is left in a somewhat confusing limbo, as it has been invalidated entirely within the Ninth Circuit (the Ninth Circuit's decision is binding on any federal court in California, Nevada, etc.), but not elsewhere. The Western District of Texas is within the jurisdiction of the Fifth Circuit U.S. Court of Appeal. As Judge Junell pointed out, he was not bound to abide by the Ninth Circuit's invalidation of ALL of Section 353a. He chose not to follow that decision, and concluded that the provisions of Section 353a other than the prohibitions on advertising and promotion were severable, and remained in effect. It was in reliance on those "other" provisions that he reached the conclusions that he did.

Within California (or elsewhere within Ninth Circuit jurisdiction), however, Judge Junell's decision is of limited effect. First, as a general rule, a federal District Court order is enforceable and binding only as to the case in which the order is issued, and as to the parties involved in that case. Though it might be PERSUASIVE to another District Court hearing a similar case, in the absence of some special circumstances (e.g., a nationwide class action, or order otherwise applied more generally), an order by a District Court is not binding even on another Judge in the same District Court, let alone on a Court in another jurisdiction, for instance in California. There is nothing in this order that suggests this order is binding on anyone other than these ten plaintiffs, and the FDA with regard to its interpretation or enforcement of the laws as to these ten plaintiffs.

Second, application of this decision as even PERSUASIVE authority in a federal District Court in California (or elsewhere in the Ninth Circuit) is very unlikely given that the decision relies on a rejection of the Ninth Circuit's decision not to sever the rest of Section 353a from the provisions found to violate the First Amendment. A District Court anywhere in the Ninth Circuit would not have that option, as it would be bound to follow the Ninth Circuit's decision invalidating all of Section 353a. Though it is possible that a District Court could conclude that Section 353a, despite its invalidation, reflects Congressional intent and

thus should be used as a tool for interpreting other sections within the FDA's jurisdiction (e.g., 21 U.S.C. § 321), that is unlikely.

Therefore, if a similar case were to arise in a District Court in California (or anywhere in the country, including in the Western District of Texas), there is no requirement that the Judge in that case follow the decision issued by Judge Junell. This is not to say that this decision may not be persuasive to another judge facing a similar issue. However, this decision is not "law" within the State of California, and on the same facts another judge might reach the opposite conclusion. Likewise, there is at least theoretically nothing preventing the FDA, despite this decision, from seeking to enforce "new drug" provisions against a compounding pharmacy in California or attempting to pursue inspections under the "records provision" of 21 U.S.C. § 374. However, the FDA will probably take this decision into account in deciding whether to do so, because it will almost certainly be raised by any pharmacy challenging such action as persuasive authority as to the FDA's action(s).

Doug Wills of Grandpa's Pharmacy, asked for the board's assistance in pursuing enactment of a new version of AB 595 in the next Legislative Session. Ms. Herold stated that the board would review and take a position on the bill that the profession introduces and sponsors. She added that the board still has regulations pending that were developed in 2004 as part of the Compounding Task Force that the board may take up in the interim.

Competency Committee Report

Ms. Herold stated that a quality assurance review of the exam started in mid-August and should be completed before mid-October, when release of CPJE scores will resume.

The Department of Consumer Affairs has a contract for test administration services used by a number of regulatory entities in the department for occupational license testing. It is through this contract that the board administers the CPJE. The contract is set to expire in December 2006, but monthly extensions will be available for several months. Unless a new contract is in place, the board may be unable to use these test facilities for the CPJE after all extensions have run out (Spring 2007). A new request for proposals has been released, and a contract should be awarded on October 20; however, several prior contracts awarded for this service have been appealed and the contracting process has been invalidated. The board continues to watch this process closely.

The Competency Committee met for its annual work and planning session in August. New members have been added to the committee so that the committee could be split into two groups. This will reduce the time commitment and work required of each

committee member, who have actually had to work more to produce the new CPJE exam than they did on the old exam.