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

LICENSING COMMITTEE
WORKGROUP ON COMPOUNDING
Meeting Summary

DATE: June 9, 2004

TIME: 1:30 p.m. – 4:00 p.m.

LOCATION: Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA 91505

Workgroup Members: Ken Schell, Pharm.D., Chair

Staff Present: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Dennis Ming, Supervising Inspector
Robert Ratcliff, Supervising Inspector
Joshua Room, Deputy Attorney General

Call to Order/Introductions

Chair of the workgroup, Dr. Schell, called the meeting to order at 1:30 p.m. Individuals attending the meeting were all invited to participate and were asked to introduce themselves.

Dr. Schell stated that the workgroup was formed in part to respond to a request from the Department of Health Services to further consider the criteria used by the board to determine when a compounding pharmacy should be considered a manufacturer. It is the board's goal to work with the compounding profession in trying to respond to the request from DHS as well as to identify "gaps" in pharmacy law related to pharmacy compounding, and to address them.

Compounding Issues

Overview of Pharmacy Law Related to Compounding – Application of USP 797

Dr. Schell stated that at the last meeting, there were questions as to how the recently approved U.S. Pharmacopeia (USP) General Chapter 797 (effective January 1, 2004) on pharmaceutical compounding of sterile preparations might affect California pharmacy practice and the pending regulations promulgated by the board. USP Chapter 797 provides procedures and requirements for compounding sterile preparations. It is intended to be applicable to health care institutions,

pharmacies, physician practice facilities, and other facilities where compounded sterile preparations are prepared, stored and dispensed. Many of the participants had previously voiced the opinion that USP 797 has the force of federal law and may void the board's pending regulations if the USP requirements are more restrictive.

At Dr. Schell's request, the board's liaison counsel with the Attorney General's Office, Deputy Attorney General Joshua Room, made a brief presentation on USP 797. He first noted that there are at least two areas of possible regulation with regard to compounding: regulations aimed at the strength or purity of the resulting drug(s); and regulations aimed at controlling the circumstances in which those drugs are compounded. The Board of Pharmacy has only sought to regulate the latter, and has not yet attempted to regulate drug strength, purity, adulteration, etc. This has typically been the province of the federal government, through the FDA. Because the regulation of compounding is being led by the states, this may constitute a "gap" in regulation.

DAG Room went on to explain that USP 797 is not incorporated by reference into the board's statutes or regulations. The Food and Drug Administration Modernization Act of 1997 (FDAMA) did incorporate the two USP chapters related to compounding, USP 795 and USP 797. USP 795 relates to compounding of nonsterile products and covers most compounding activities of community pharmacies. USP 797 details good practices for compounding sterile products, which includes home IV admixtures, eye drops and similar products. These standards were incorporated into FDAMA; however, since FDAMA was invalidated, the standards currently have no apparent force in federal law. They do remain as elements of the FDA's Enforcement Compliance Guide.

DAG Room stated that since California does not incorporate by reference the standards of USP chapters <795> or <797>, these standards do not control the board's enforcement of its own regulations regarding pharmacy compounding. They are standards that are considered best practices and any compounder would be wise to consider whether they are presently in compliance with USP 797, but the enforcement authority of the board is presently guided by its own separate regulations.

It was noted the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) will be requiring pharmacies to meet the standards of USP 797 for purposes of accreditation.

Overview of California Pharmacy Law on Compounding

Supervising Inspector Dennis Ming identified the pharmacy law that regulates compounding. He directed the group's attention to Bus. & Prof. Code sec. 4127 - 4127.6, CCR, title 16, sec. 1716.1 and 1716.2 and sec. 1751 – 1751.12. He stated that the proposed amendments to the regulations that would update the regulations on compounding of injectable sterile drug products were disapproved by the Office of Administrative (OAL) because of the requirements for building standards in the pharmacy. According to OAL, any changes to building standards must be approved by the Building Standards Commission. The standards were removed from the proposed regulation and placed instead in accompanying legislation. If the legislation is enacted, the building standards would take effect July 2006. The board has noticed this change in the pending regulation for a 15-day comment period and will act on the change at its July meeting.

Supervising Inspector Ming emphasized that current pharmacy regulations only govern the physical circumstances, procedures, and recordkeeping requirements for compounding drugs and do not address quality, strength or end product testing. He stated that this is a "gap" in pharmacy law. Whether a pharmacy compounds one drug for a patient or many, the patient needs to be assured that the compounded drug meets the USP standard.

Identification of Compounding Issues

Compounding versus Manufacturing

The workgroup reviewed the subcommittee report on compounding versus manufacturing. There was general discussion as to the proposed changes made to the compliance guide that the Board of Pharmacy adopted in 1995. The workgroup noted that the subcommittee identified the sections of pharmacy law that defined manufacturer and pharmacy. It was suggested that the subcommittee review these sections of law to determine if the law should be amended to define compounding and the subcommittee may want to incorporate the guideline(s) as part of the definitions in law. The workgroup also asked the subcommittee to address central fill as a definition in pharmacy law. The workgroup further requested that an explanation be provided with the guidelines, particularly as to non-adoption of definitional factors proposed by the FDA.

Non-Prescription Compounding

The workgroup discussed a subcommittee proposal regarding the compounding of non-prescription drugs. It was noted that this is the process whereby a pharmacy compounds from ingredients in a strength that would not normally require a prescription (over the counter strengths). The proposal was modeled after other states and would permit such practice to take place without a prescription and only be available upon request by a patient.

It was noted that when the FDA determines that a drug is nonprescription, then the labeling of that drug is complete enough that it is considered safe for self-use without the oversight of a health practitioner. The board's position is that if a compounded drug is considered a nonprescription drug (because the strengths are equal to that of a nonprescription drug) then it must meet the labeling requirements of the federal FDA.

It was stated that the Board of Pharmacy's position that a prescription is required for compounded nonprescription drugs (even if the strength of compounded drug would not deem it a prescription drug) is contrary to the direction given by DHS, Food and Drug Branch. It was suggested that further clarification be sought from the DHS.

FDA Notice on Compounded Veterinary Medications

Dr. Schell noted that the FDA, Office of Compliance, Center of Veterinary Medicine (CVM) sent a letter to all state boards of pharmacy advising that the compounding of new animal drugs is only permitted if conducted in accordance with the Animal Medical Drug Use Clarification Act (AMDUCA) and its implementing regulations. It was stated that neither the AMDUCA nor

the regulations permit compounding from bulk drugs. Further, they contend that they require that compounding be done by or on the order of a licensed veterinarian, with the context of a valid veterinarian/client/patient relationship and from approved human or veterinary drugs. They further state that in an effort to determine the extent of the illegal veterinary compounding activities CVM is issuing inspection assignments to FDA field offices to inspect certain pharmacies. These pharmacies were selected after evaluating trade complaints and promotional materials submitted to CVM over the last few years.

A letter was sent from the American Pharmacists Association, International Academy of Compounding Pharmacists and the National Community Pharmacists Association expressing serious concern with the CVM letter and regarding what was perceived as a change in the FDA enforcement policy. The signatories urged the FDA to retract the letter.

The workgroup discussed concern by the various pharmacy organizations about the FDA's position regarding the compounding of veterinary drugs and efforts to address these concerns with the agency.

Next Meeting Date

Dr. Schell stated that the next meeting date for the Workgroup on Compounding Issues is September 22, 2004, in Oakland.

Adjournment

Dr. Schell thanked the participants for attending and adjourned the meeting at 4:00 p.m.