losing control over the examination. The Board plans to address this issue at a future meeting.

FUTURE MEETINGS:
August 21–22 in Sacramento.
November 20–21 in Los Angeles.

BOARD OF PHARMACY

Executive Officer: Patricia Harris
(916) 445-5014

Pursuant to Business and Professions Code section 4000 *et seq.*, the Board of Pharmacy grants licenses and permits to pharmacists, pharmacies, drug manufacturers, wholesalers and sellers of hypodermic needles. It regulates all sales of dangerous drugs, controlled substances and poisons. The Board is authorized to adopt regulations, which are codified in Division 17, Title 16 of the California Code of Regulations (CCR). To enforce its regulations, the Board employs full-time inspectors who investigate accusations and complaints received by the Board. Investigations may be conducted openly or covertly as the situation demands.

The Board conducts fact-finding and disciplinary hearings and is authorized by law to suspend or revoke licenses or permits for a variety of reasons, including professional misconduct and any acts substantially related to the practice of pharmacy.

The Board consists of ten members, three of whom are public. The remaining members are pharmacists, five of whom must be active practitioners. All are appointed for four-year terms.

MAJOR PROJECTS:

Attorney General Issues Opinion Regarding Out-of-State Pharmacies. On March 3, the Attorney General's Office filed Opinion No. 91-305, responding to the following three questions submitted by Assemblymember Tricia Hunter: (1) whether California laws governing pharmacies apply to out-of-state mail order pharmacies which fill prescriptions and mail them to people in California; (2) whether California's current regulation of out-of-state mail order pharmacies is consistent with the commerce clause of the U.S. Constitution; and (3) under California law, whether a generic type drug listed on the negative drug formulary established by the Director of Health Services may be substituted for a brand name drug by an out-of-state pharmacy when filling prescriptions and mailing them to people in California. *[11:3 CRLR 101]*

The opinion answered all three questions affirmatively, under specified conditions. Regarding the first question, the Attorney General noted that Business and Professions Code section 4084.6 prohibits an out-of-state pharmacy from doing business in California unless it obtains an out-of-state distributor's license from the Board of Pharmacy, or is registered with the Board as a nonresident pharmacy. Out-of-state drug distributors are required by law to comply with Chapter 9 of the Business and Professions Code, which contains most of the statutes that govern pharmacies in California, and Division 21 of the Health and Safety Code. Nonresident pharmacies must comply with Business and Professions Code sections 4050.1 and 4383, and Health and Safety Code section 11164. Thus, the opinion concluded that California laws do apply in limited circumstances to out-of-state pharmacies which fill prescriptions and mail them to people in California; the extent of their applicability depends on how the particular pharmacy is licensed.

Regarding California's regulation of out-of-state pharmacies, the Attorney General noted that in determining whether a state-created impact on interstate commerce falls within permissible bounds, the U.S. Supreme Court established a "balancing test" in *Pike v. Bruce Church Inc.*, 397 U.S. 137, 142 (1970). Under that test, where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits. According to the opinion, a local purpose which has traditionally been favored by the Court is one promoting the health and safety of a state's inhabitants. Based on its findings that the state will be given considerable latitude given the subject matter of the regulation, the laws are applied indiscriminately to in- and out-of-state pharmacies, and the burden on interstate commerce is "clearly minimal in relation to the legitimate state purpose of protecting the health and welfare of California residents," the Attorney General's Office concluded that California's regulation of out-of-state pharmacies does not offend the Commerce Clause.

Regarding the third question, the Attorney General noted that, with certain exceptions and qualifications, Business and Professions Code section 4047.6 allows a pharmacist to substitute a generic drug for a brand name drug when filling a prescription. Business and Professions Code section 4047.7 provides that one such exception applies when the generic drug type or drug product has been listed on the "negative drug formulary" by the Director of the Department of Health Services (DHS); if a drug is listed by the DHS Director on the negative drug formulary, a pharmacist may not substitute it for a brand name drug. The Attorney General found that compliance with section 4047.7 is required of all pharmacies in California and any pharmacy licensed as an out-of-state drug distributor pursuant to Business and Professions Code section 4084.6. However, because pharmacies registered as nonresident pharmacies need comply only with Business and Professions Code sections 4050.1 and 4383 and Health and Safety Code section 11164 in order to maintain their registration and do business in California, pharmacies registered as nonresident pharmacies may substitute a generic type drug listed on the negative drug formulary established by the DHS Director for a brand name drug when filling prescriptions and mailing them to people in California. According to the opinion, however, no drug is currently listed on the negative drug formulary.

FDA Clarifies Policy Regarding New Drug Repacking. Last July, the Board sought clarification of the U.S. Food and Drug Administration's (FDA) Compliance Policy Guide (CPG) 7132c.06, which states that "each step in the manufacture and processing of a new drug or antibiotic, from handling of raw ingredients to final packaging, must be approved by FDA, whether carried out by the original manufacturer or by some subsequent handler or repacker of the product. Pharmacists are not exempt from these statutory requirements; however, the agency regards mixing, packaging, and other manipulations of approved drug [sic] by licensed pharmacists, consistent with the approved labeling of the product, as an approved use of the product if conducted within the practice of pharmacy, *i.e.*, filling prescriptions for identified patients." The Board asked FDA to clarify whether "the breaking down of bulk drugs for prescription or known need" constitutes manufacturing. Specifically, the Board asked whether manipulation by a pharmacist of an FDA-approved drug constitutes manufacturing (which requires registration as a manufacturer) when "(1) it is contrary to the manufacturer's package insert, or (2) it is prepared for a specific patient in advance, but in anticipation of, a prescription, or (3) it is prepared in anticipation of receiving one or more prescriptions for the product, as manipulated, but for a specific patient." *[12:1 CRLR 91; 11:4 CRLR 104]*

In March, the FDA issued CPG 7132.16, entitled "Manufacture, Distribution, and Promotion of Adulterated, Misbranded, or Unapproved New Drugs for Human Use by State-Licensed Pharmacies," in which it clarified its position on compounding by a pharmacy that is not pursuant to a specific prescription. FDA recognized that a licensed pharmacist may compound drugs extemporaneously after receipt of a valid prescription for an individual patient, and stated that "[p]harmacies that do not otherwise engage in practices that extend beyond the limits set forth in this CPG may prepare drugs in very limited quantities before receiving a valid prescription, provided they can document a history of receiving valid prescriptions that have been generated solely within an established professional practitioner-patient-pharmacy relationship, and provided further that they maintain the prescription on file for all such products dispensed at the pharmacy as required by state law."

However, FDA stated that it may, in the exercise of its enforcement discretion, initiate federal enforcement actions against entities and responsible persons when the scope and nature of a pharmacy's activity raises the kinds of concerns normally associated with a manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the Federal Food, Drug, and Cosmetic Act. In general, the FDA will consider the following factors in determining whether compounding by a pharmacy constitutes manufacturing: whether the pharmacy advertises and solicits business from prescribers and/or patients; whether the pharmacy compounds more than it should expect to use based on existing relationships and demands from prescribers; whether there is an inordinate volume of bulk drugs ordered or compounded drugs dispensed compared to existing orders; and whether the pharmacy manufactures products that are readily available commercially or manufactures what are—in effect—unapproved new drugs that vary more than slightly from an FDA-approved drug that is commercially available.

At its March meeting, the Board reviewed FDA's new guide and found it consistent with its own positions.

Patient Consultation Regulations. In August 1990, the Office of Administrative Law (OAL) approved the Board's adoption of new sections 1707.1 and 1707.2, Division 17, Title 16 of the CCR, which requires pharmacists to maintain patient medication profiles for all ongoing patient-consumers and to provide an oral consultation to each patient or patient's agent whenever a new prescription is dispensed, with specified exceptions. Although the regulations were originally scheduled to take effect in March 1991, the Board delayed the effective date until January 1992 in order to provide pharmacists with additional time to prepare for and phase in the changes to pharmacy practice mandated by sections 1707.1 and 1707.2. At a special December 1991 meeting, the Board voted to delay the effective date of the regulations for a second time, in response to claims that—more than one year after their original approval—the industry was still unprepared to implement the regulations. *[12:1 CRLR 91]*

In order to comply with the Administrative Procedure Act, the Board adopted an emergency regulation suspending the implementation of the provisions for 120 days. At its March 18 meeting, the Board conducted a public hearing regarding its decision to change the effective date to November 1. At that hearing, the Board received testimony from the California Association of Public Hospitals (CAPH) in support of the delay; CAPH also advocated tying the effective date of the oral consultation regulations to the implementation of the pharmacy technician regulations, suggesting that the consultation regulations take effect three to six months after the Board's technician regulations are approved (*see supra*). Following the public hearing, the Board adopted the proposed amendments to sections 1707.1 and 1707.2, delaying their effective date until November 1. The Board submitted the rulemaking file to OAL on April 21 and is awaiting OAL's response.

Pharmacy Technicians. Pursuant to AB 1244 (Polanco) (Chapter 841, Statutes of 1991), the Board recently proposed the adoption of regulations defining the functions and qualifications of pharmacy technicians, who may perform packaging, manipulative, repetitive, or other nondiscretionary tasks while assisting, and while under the direct supervision of, a registered pharmacist. On January 21, the Board conducted a public hearing on its proposed amendments to section 1717(c) and adoption of new sections 1793–1793.7, Division 17, Title 16 of the CCR, to define the qualifications and permissible duties of pharmacy technicians.

Existing section 1717(c) lists certain duties which must be performed by a pharmacist and those duties which may be performed by non-licensed personnel, such as typing prescription labels and requesting and receiving refill authorization subject to prior review by a pharmacist. The Board proposes to incorporate portions of this section into new sections 1793.1 and 1793.3. Specifically, proposed section 1793.1 would list functions which only a pharmacist may perform and which may not be delegated to a pharmacy technician; section 1793.2 would identify the tasks which a pharmacy technician may perform under the direct supervision and control of a licensed pharmacist, including removing drugs from stock, counting, pouring, or mixing pharmaceuticals, placing the products into a container, affixing labels to containers, packaging and repackaging; and proposed section 1793.3 would describe and update tasks which may be performed by non-licensed personnel who are not pharmacy technicians, to include the entry of prescriptions into a computer record system.

Proposed section 1793.4 would establish registration requirements for pharmacy technicians, and authorize the Board to issue a certificate to an applicant who has met any of the following requirements: has obtained at least an associate of arts degree in a field of study directly related to the duties performed by a pharmacy technician; has completed a training course specified and approved by the Board; is eligible to take the Board's pharmacist licensure exam; or has one year's experience (a minimum of 1,500 hours) performing the tasks of a pharmacy technician while assisting a pharmacist in the preparation of prescriptions in specified facilities. Section 1793.5 would specify the training courses which are acceptable to the Board in satisfaction of the requirement in section 1793.4. Section 1793.6 would establish requirements for pharmacies employing technicians; in particular, it clarifies that nonpharmacist personnel must work under the direct supervision of a registered pharmacist, the supervising pharmacist must be on the premises at all times, and the pharmacist must indicate that all prescriptions prepared by a technician have been checked by initialing the prescription label before the medication is given to the patient. The subsection also requires a technician to wear identification clearly identifying him/her as a technician.

In response to comments from the industry, the Board modified its proposed language in various significant respects. For example, regarding technician qualifications, the Board eliminated language which would have provided that a person shall be deemed to have "equivalent experience" if he/she has at least three years of experience in a pharmacy and has passed an examination, as specified. Instead, the modified language provides that a person shall be deemed to

have equivalent experience if he/she has at least 1,500 hours of experience performing specified duties in a pharmacy in the preceding three years.

Also, the Board increased from 120 to 240 the number of hours required to be provided by specified technician training courses seeking to be approved by the Board. In addition, the Board eliminated a requirement that such training programs provide instruction on the general chemical and physical properties of drugs handled in a pharmacy.

The Board approved the language of the regulations as modified, and released it for a fifteen-day public comment period which ended on February 14. Following the public comment period and approval by the Director of the Department of Consumer Affairs (DCA), the Board submitted the rulemaking file to OAL on April 17.

Locked Storage and Emergency Delivery Requirements for Medical Device Retailers. On January 22, the Board held a public hearing on its proposed adoption of new sections 1748.1 and 1748.2, Title 16 of the CCR, regarding the proper storage of dangerous devices at medical device retailer (MDR) retail sites, and the delivery of devices by MDRs to patients after hours or in emergency situations. Since July 1991, the Board of Pharmacy has licensed MDRs as a separate class. MDRs are non-pharmacy firms that may dispense, upon prescription, dangerous devices such as hypodermic syringes and other items that are marked by the manufacturer as available upon prescription only. Each retail site of an MDR must have a Board-licensed individual designated as "in charge." This individual may be a pharmacist or an "exemptee," a separately-licensed individual authorized to dispense dangerous devices.

Proposed section 1748.1 would provide that an MDR may use locked storage (a lock box or locked area) for the emergency dispensing of dangerous devices. Locked storage may be installed or placed in a service vehicle of the MDR for purposes of delivery, set-up, or after-hours emergency service of dangerous devices to patients having prescriptions on file for the dangerous device. No hypodermic needles or syringes may be stored in this locked storage. Section 1748.1 would also provide that dangerous devices shall be furnished from the locked storage only upon the oral or written authorization of an exemptee to an employee of the MDR who operates the service vehicle; the service vehicle and the locked storage contained therein shall be locked at all times; a current inventory and record of all dangerous devices placed into and furnished from the locked storage shall be maintained by the MDR for three years; within 72 hours of furnishing a dangerous device from the emergency storage, the exemptee shall be responsible for checking the contents of the locked storage and noting the dangerous devices furnished on the inventory; and the exemptee shall be responsible for checking the contents of the locked storage on a weekly basis.

Proposed section 1748.2 would permit an MDR to keep a dangerous device in a retail area of the premises during the absence of an exemptee, if the device is of sufficient size and weight as to make removal "difficult."

At the January 22 hearing, the Board received comments urging it to relax proposed section 1748.1, which appears to limit emergency dispensing from the lock box to "prescriptions on file for the dangerous devices," and to preclude emergency dispensation for newly-prescribed devices. The Board also received requests to expand its definition of "exemptees" to include licensed health care providers; an exemptee is a person, other than a pharmacist, who is authorized to dispense dangerous devices. The Board noted that it is authorized to regulate dispensers, not health care providers. It further noted that DHS and other agencies regulate health care providers and home health care agencies, and are responsible for their use of dangerous devices for replacement or pursuant to a new prescription. The Board then adopted the regulations as originally proposed. At this writing, the rulemaking file awaits review and approval by OAL.

Partial Filling of Schedule II Prescriptions. As originally proposed, new section 1745, Title 16 of the CCR, would allow partial filling of Schedule II controlled substance prescriptions for terminally ill patients who are in chronic pain, under certain circumstances. Following a public hearing last October, the Board modified its proposed language to also allow partial filling when the prescription is for an inpatient of a skilled nursing facility; the Board released the modified text for a fifteen-day comment period. *[12:1 CRLR 91]* During that period, the Board received comments from the California Medical Association (CMA), which expressed concern over the Board's use of the terms "chronic, continuing pain" and "terminally ill." In response to CMA's concerns, the Board deleted the chronic pain requirement and revised the definition of "terminally ill" to mean a patient for whom a licensed physician has made and documented a diagnosis of illness or disease that will result in death. The Board released the new language for an additional fifteen-day comment period which ended on February 14. At this writing, the proposed section is undergoing legal review prior to being submitted to DCA and OAL.

Part-Time Pharmacist-in-Charge Regulation. In 1991, the Board promulgated section 1709.1, Title 16 of the CCR, which was developed to clarify statutory requirements regarding the pharmacist-in-charge; specifically, the regulation requires that this pharmacist have full knowledge of the daily operations of a pharmacy and specifies that a pharmacist may be pharmacist-in charge at only one pharmacy. According to the Board, after the regulation took effect, it learned that this situation had a negative impact on several pharmacies which operate on a part-time basis, with non-overlapping hours, for which the sole pharmacist at each served as pharmacist-in-charge at both. To remedy this problem, the Board published on April 10 notice of its intent to amend section 1709.1 to allow a pharmacist to be the pharmacist-in-charge at two pharmacies if only one of these pharmacies is open at any given time and if that pharmacist is the only pharmacist at each pharmacy. *[12:1 CRLR 91–92]* The Board was scheduled to conduct a public hearing on this amendment on May 27 in Sacramento.

Other Regulatory Action. The following regulatory changes are also being pursued by the Board:

–Licensure of Drug Wholesalers. The Board's proposed amendments to section 1780, which would change California's requirements for drug wholesalers so that they meet or exceed the standards of the federal government under the Prescription Drug Marketing Act of 1987, were submitted to OAL for approval on May 9. *[11:3 CRLR 101–02]*

–Compounding for Office Use. Proposed new section 1716.1 defines the quantity of compounded medication which a pharmacist may furnish to a prescriber for office use under Business and Professions Code section 4046(c)(1). Proposed new section 1716.2 specifies the minimum types of records that pharmacies must keep when they furnish compounded medication to prescribers in quantities larger than required for the prescriber's immediate office use or when a pharmacy compounds medication for future furnishing. *[11:3 CRLR 102]* These proposed regulations were also submitted to OAL for approval on May 9.

LEGISLATION:

SB 2044 (Boatwright), as amended

April 2, would declare legislative findings regarding unlicensed activity and authorize all DCA boards, bureaus, and commissions, including the Board of Pharmacy, to establish by regulation a system for the issuance of an administrative citation to an unlicensed person who is acting in the capacity of a licensee or registrant under the jurisdiction of that board, bureau, or commission. *[A. CPGE&ED]*

AB 3415 (Tucker), as amended May 7, would exclude from the definition of "dangerous devices" any prosthetic or orthopedic devices that do not require a prescription. This bill would also delete an existing provision of law which requires that any retailer who sells prosthetic or orthotic dangerous devices on the premises have a prescribed fitting room under certain circumstances. *[S. B&P]*

AB 3286 (Tucker), as amended May 13, would permit a medical device retailer to dispense, furnish, transfer, or sell a dangerous device to a licensed physical therapist. *[A. Floor]* A similar bill, ***AB 2379 (Baker)***, was dropped by its author.

AB 2638 (Boland), as amended May 13, would exempt a chiropractor acting within the scope of his/her license from prohibitions against furnishing dangerous drugs or devices. This bill would also provide that a medical device retailer may dispense, furnish, transfer, or sell a dangerous device to a licensed chiropractor. *[A. Floor]*

AB 2525 (Brown), as amended April 22, and ***SB 1418 (Moore)***, as amended April 28, would each establish the Clean Needle and Syringe Exchange Pilot Project, and would authorize pharmacists, physicians, and certain persons authorized under the pilot project to furnish hypodermic needles and syringes without a prescription or permit as prescribed through the pilot project. *[A. Floor, S. Floor, respectively]*

SB 1986 (Marks), as introduced February 21, would prohibit disability insurers that provide coverage for pharmaceutical services from requiring their insureds or persons covered by the policy to obtain pharmaceutical services exclusively from nonresident pharmacies, and would provide that insurers may not impose any limitations on coverage of pharmaceutical services provided by in-state pharmacies that are not also imposed on nonresident pharmacies. *[S. InsCl&Corps]*

AJR 63 (Bronzan), as amended May 7, would urge the President and Congress to authorize the FDA to investigate a new transitional drug category available only through licensed pharmacists, with the goal to decrease the time needed for the FDA to approve a drug for over-the-counter status. *[A. Health]*

AB 3133 (Hunter), as amended April 27, would specify that no provision of law prohibits the sale of dangerous devices to licensed home health agencies and licensed hospices, as defined. *[S. B&P]*

AB 2743 (Lancaster), as amended April 9, would amend Business and Professions Code section 4038 to delete the exemption of pharmacies and licensed manufacturers from the definition of the term wholesaler. *[A. Floor]*

AB 2070 (Isenberg), as amended August 19, would generally make it unlawful for specified healing arts licensees to refer a person to any laboratory, pharmacy, clinic, or health care facility solely because the licensee has an ownership interest in the facility. However, a licensee could make those referrals if the person referred is the licensee's patient of record, there is no alternative provider or facility available, and the licensee certifies that to delay or forego the referral would cause an unneeded health risk to the patient. *[S. Rules]*

SB 664 (Calderon). Existing law prohibits pharmacists, among others, from charging, billing, or otherwise soliciting payment from any patient, client, customer, or third-party payor for any clinical laboratory test or service if the test or service was not actually rendered by that person or under his/her direct supervision, unless the patient is apprised at the first solicitation for payment of the name, address, and charges of the clinical laboratory performing the service. As amended March 12, this bill would also make this prohibition applicable to any subsequent charge, bill, or solicitation. This bill passed both the Senate and the Assembly and is currently awaiting Senate concurrence in Assembly amendments.

AB 1226 (Hunter), as amended March 30, would repeal Business and Professions Code section 4047.7, which requires the Director of the Department of Health Services to establish a formulary of generic drug types and drug products which the Director determines demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted, would pose a threat to the health and safety of patients receiving medication if that medication is substituted by a pharmacist in lieu of a brand name drug prescribed by a prescriber. *[S. B&P]*

AB 855 (Hunter). Under existing law, registered pharmacists are required to inform patients of the harmful effects of the prescription drugs not previously dispensed to the patient, and to provide a label or enclosure with the drug container containing certain information. As amended May 4, this bill would require that a health facility ensure that each of its patients receives a consultation from a pharmacist, physician, or registered nurse regarding medications received at the time of discharge. *[S. B&P]*

SB 917 (Kopp) would require certain health care service plans that propose to offer a pharmacy benefit or change their relationship with pharmacy providers to give written or published notice to pharmacy service providers of the plan's proposal, and give those providers an opportunity to submit a bid to participate in the plan's panel of providers on the terms proposed. *[A. Desk]*

AB 819 (Speier). Existing law generally provides that it is not unlawful for prescribed health care professionals to refer a person to a laboratory, pharmacy, clinic, or health care facility solely because the licensee has a proprietary interest or co-ownership in the facility. As amended January 29, this bill would instead provide that it shall be unlawful for these licensed health professionals to refer a person to any diagnostic imaging center, clinical laboratory, physical therapy or rehabilitation facility, or psychometric testing facility which is owned in whole or in part by the licensee or in which the licensee has a proprietary interest, and would provide that disclosure of the ownership or proprietary interest does not exempt the licensee from the prohibition. It would, however, permit specified licensed health professionals to refer a person to such a facility which is owned in whole or in part by the licensee or in which the licensee has a proprietary interest if the person referred is the licensee's patient of record, there is no alternative provider or facility available, and to delay or forego the needed health care would pose an immediate health risk to the patient. *[S. B&P]*

SB 1033 (Marks), which would have permitted pharmacists to manufacture, measure, fit to the patient, sell, and repair medical devices without regard to whether they bear a specified legend relating to a federal prohibition against dispensing without a prescription, died in committee.

LITIGATION:

In ***People v. Joseph Doss***, No. B046265 (Apr. 1, 1992), the Second District Court of Appeal affirmed the conviction of Doss, a pharmacist and the owner of Medical Memorial Pharmacy, for possession for sale of four controlled substan-

ces. The court noted that the evidence, taken in the light most favorable to the judgment, established that Doss ordered and took possession of large quantities of certain controlled substances in high dosages; the drugs were of a type rarely prescribed by physicians but in high demand among the illegal street trade. On appeal, Doss contended that evidence was legally insufficient to warrant its submission to the jury and factually insufficient to sustain his convictions; Doss also challenged the trial court's denial of his motion to suppress evidence obtained by the state Board of Pharmacy inspector during his audit of Doss' pharmacy records.

The Second District noted that "this case squarely presents the issue whether a pharmacist is immune from prosecution for illegal possession of controlled substances, absent evidence he removed the drugs from pharmacy premises." Doss contended that Business and Professions Code section 4230 immunizes him from prosecution because he is a pharmacist and there was no evidence he withdrew the missing drugs from the pharmacy premises; section 4230 provides that "[n]o person shall have in possession any controlled substance, except that furnished to such person upon the prescription of a physician, dentist, podiatrist, or veterinarian. The provisions of this section do not apply to the possession of any controlled substance by a manufacturer or wholesaler or a pharmacy or a physician or podiatrist or dentist or veterinarian, when in stock in containers correctly labeled with the name and address of the supplier or producer." The court rejected Doss' arguments, stating that the "obvious purpose of...section 4230 is to authorize the possession for sale of certain controlled substances by licensed pharmacists, on pharmacy premises, to those holding valid prescriptions. It does not confer blanket immunity on a pharmacist to deal drugs illegally from behind the counter or to possess them with that intent." Finding that section 4230 does not confer blanket immunity on a pharmacist to possess controlled substances for any purpose on pharmacy premises, the Second District found that the case was properly submitted to the jury.

Next, the court examined the factual sufficiency of the evidence. The prosecution's evidence established that from January 1987 through April 18, 1988, Doss' pharmacy ordered from one pharmaceutical wholesaler 4,000 tablets of Glutethimide (Doriden) in the highest dosage available; at least three of the proof of delivery slips appeared to bear Doss' signature. During that same period, Doss' pharmacy ordered from another wholesaler 2,500 Biphetamine, 1,200 Dilaudid, 2,800 Tuinal, and an additional 11,500 Glutethimide; these orders were also for the strongest dosages available, and a number of invoices and driver manifests showing delivery of the four drugs to Doss' pharmacy appeared to bear the signature "J. Doss" as the person accepting the shipment. On April 18, 1988, following a report from a drug wholesaler that Doss' pharmacy had ordered an excessive amount of Glutethimide, Board of Pharmacy inspector Martin Levine conducted an audit of Medical Memorial Pharmacy. That audit revealed that the pharmacy had no purchase records for Glutethimide, Biphetamine, Dilaudid, or Tuinal; the pharmacy had no prescriptions for the lawful distribution of any of the four drugs during the period January 1987 through April 18; Doss had not performed the Drug Enforcement Administration-required inventory for the period in question; and the pharmacy had none of the four drugs in stock. Doss provided no explanation for the missing drugs, and said he was unaware of any thefts from the pharmacy during the fifteen-month period.

The Second District found that the jury was entitled to conclude from the evidence that Doss possessed the four controlled substances for the purpose of selling them outside the legitimate practice of his pharmaceutical business. Noting the undisputed evidence showing that the pharmacy ordered and received the drugs and that Doss took possession of some of them, that all of the drugs disappeared from the pharmacy without a single record to account for their lawful distribution and without any report of a theft or burglary, and that the drugs were of a kind rarely prescribed by physicians but in demand on the street and that Doss was aware of such demand, the court concluded that the jury had "more than sufficient evidence to convict defendant on all four counts."

Finally, Doss contended that the trial court improperly refused to suppress evidence gained from the audit conducted by the Board of Pharmacy's inspector on April 18, 1988. The trial court denied Doss' motion to suppress the results of Levine's audit, finding that Doss lacked a reasonable expectation of privacy in the pharmacy records; the court specifically noted that the audit was conducted pursuant to Business and Professions Code sections 4231 and 4232, which expressly authorize warrantless inspections of highly regulated businesses.

The Second District affirmed the trial court's denial of the motion to suppress, noting that it is well settled that warrantless searches of pervasively regulated and licensed businesses are permissible under the Fourth Amendment, if conducted pursuant to statutory authorization. The Second District stated that "[i]t is undisputed that pharmacies are closely regulated businesses in California. It is equally clear that state statutes authorize administrative inspections of pharmacies." The court concluded that under both the statutory scheme and the circumstances of this case, defendant had no reasonable expectation of privacy in the pharmacy records, and that given the pervasive regulation of the pharmaceutical industry and Doss' particular familiarity with it, there can be no legitimate claim that he maintained any expectation of privacy in the pharmacy records.

RECENT MEETINGS:

At the Board's January meeting, staff reported that the Department of Finance had approved the following budget change proposals, which have been included in the Governor's proposed 1992–93 budget: a $74,000 increase in funding to the Pharmacist Recovery Program, the Board's diversion program for substance-abusing licensees; $39,000 to add one clerical position to the Licensing Unit to process examination applications; $45,000 to add one clerical position to the Enforcement Unit on a limited-term basis; $68,000 to produce an inspector procedure manual; and $145,000 to add one Associate Governmental Program Analyst and one Office Technician to implement the pharmacy technician program, and one office assistant to assist in the registration of applicants. These changes must be approved by the legislature in its 1992–93 budget bill.

Also at its January meeting, the Board heard a presentation from Rebecca Armato of Integrated Medical Systems, Inc. (IMS), regarding the computerized transmission of prescriptions and refill authorizations. IMS has developed Rx Manager, a software program that allows prescription and refill authorizations to be transmitted between pharmacies and physicians electronically over communication networks. The Board noted its March 1990 policy decision stating that it believes facsimile transmission of prescriptions is legal and subject to the same requirements as orally-transmitted prescriptions. The Board then created a subcommittee to formulate recommendations regarding proposed regulatory actions authorizing the electronic transmission of prescriptions and refill authoriza-

tions.

At its March 18–19 meeting, the Board discussed the recent recommendation of the Legislative Analyst's Office (LAO) to abolish all independent boards and bureaus within DCA, replace them with advisory boards, and consolidate the licensing and enforcement functions of these agencies into the Department; LAO contends that such an action would increase the efficiency and cost-effectiveness of state regulation of trades and professions. (*See supra* agency reports on LAO and DCA for related discussion.) Following a discussion, the Board unanimously agreed that its enforcement, consumer complaint handling, and licensing functions should remain separate from a consolidated unit within DCA, due to the specialized nature of pharmacy enforcement and the increasingly sophisticated nature of pharmacy practice.

Also at the March meeting, the Board discussed a request from the California Pharmacists Association (CPhA) to alter the Board's enforcement procedure. Specifically, CPhA had directed its staff to work with Board staff to accomplish the following changes: (1) before referral of an administrative action against a licensee to the Attorney General's Office, Board staff would provide an opportunity for the licensee to discuss the proposed action with Board staff; and (2) Board staff would provide notice to the licensee of any referral to the Attorney General's Office. Executive Officer Patricia Harris noted that throughout the investigation process, every opportunity is given to the licensee to provide information to the inspector. However, discussion of an investigation at the supervisory level would probably bog down the system, increase workload, and further delay an already lengthy process. Harris recommended that the Board not change the process as to do so would be contrary to public policy. The Board made no motion to amend its process, instead suggesting that the Board provide more education and information about the enforcement process to alleviate licensees' apprehensions without compromising investigations and administrative actions.

FUTURE MEETINGS:

October 14–15 in Los Angeles.

BOARD OF REGISTRATION FOR PROFESSIONAL ENGINEERS AND LAND SURVEYORS

Executive Officer: Darlene Stroup
(916) 920-7466

The Board of Registration for Professional Engineers and Land Surveyors (PELS) regulates the practice of engineering and land surveying through its administration of the Professional Engineers Act, sections 6700 through 6799 of the Business and Professions Code, and the Professional Land Surveyors' Act, sections 8700 through 8805 of the Business and Professions Code. The Board's regulations are found in Division 5, Title 16 of the California Code of Regulations (CCR).

The basic functions of the Board are to conduct examinations, issue certificates, registrations, and/or licenses, and appropriately channel complaints against registrants/licensees. The Board is additionally empowered to suspend or revoke registrations/licenses. The Board considers the proposed decisions of administrative law judges who hear appeals of applicants who are denied a registration/license, and those who have had their registration/license suspended or revoked for violations.

The Board consists of thirteen members: seven public members, one licensed land surveyor, four registered Practice Act engineers and one Title Act engineer. Eleven of the members are appointed by the Governor for four-year terms which expire on a staggered basis. One public member is appointed by the Speaker of the Assembly and one by the Senate Rules Committee.

The Board has established four standing committees and appoints other special committees as needed. The four standing committees are Administration, Enforcement, Examination/Qualifications, and Legislation. The committees function in an advisory capacity unless specifically authorized to make binding decisions by the Board.

Professional engineers are registered through the three Practice Act categories of civil, electrical, and mechanical engineering under section 6730 of the Business and Professions Code. The Title Act categories of agricultural, chemical, control system, corrosion, fire protection, industrial, manufacturing, metallurgical, nuclear, petroleum, quality, safety, and traffic engineering are registered under section 6732 of the Business and Professions Code.

Structural engineering and geotechnical engineering are authorities linked to the civil Practice Act and require an additional examination after qualification as a civil engineer.

On February 24, Governor Wilson appointed Ted Fairfield to serve as the Board's civil engineer member. Fairfield, founder of a civil engineer consulting firm in Pleasanton, has been registered as a professional civil engineer in California since 1962.

MAJOR PROJECTS:

Professional Land Surveyor Blue Ribbon Panel Controversy. PELS currently administers its own land surveyor examination, which is prepared by CTB McMillan/McGraw Hill (CTB) under a contract which extends until 1993. In October 1991, PELS passed a motion to resume the use—as of April 1993—of the national examination prepared by the National Council of Examiners for Engineering and Surveying (NCEES) for purposes of licensing land surveyors. The Board then appointed a blue ribbon panel of land surveyors to review the national examination and develop a supplemental California-specific exam to be administered with the national exam.

At PELS' February 14 meeting, Board member David Slawson indicated that the panel would recommend that PELS postpone the use of the NCEES professional land surveyor exam until 1994. In the interim, the panel recommended that PELS retain the current examination prepared by CTB. Following a lengthy discussion, the Board tabled the matter until its next meeting.

At its April 17 meeting, PELS resumed its discussion regarding the panel's recommendation. Additionally, the Board discussed the apparently recent revelation that many of the blue ribbon panel members had worked as subject matter experts to develop and grade California's current examination sold to the Board by CTB, and had received reimbursement for travel, lodging, and subsistence in excess of $250 within the past twelve months from CTB. Based on these facts, Department of Consumer Affairs (DCA) legal counsel Don Chang opined that it may be inappropriate for the Board to consider some of the panel's recommendations. However, by a vote of 8–4, PELS agreed to postpone the implementation of the NCEES and the California-specific professional land surveyor exam to allow for the reorganization and new membership of the blue ribbon panel, and to work with NCEES to strengthen its exam; PELS agreed to retain the current CTB exam in the interim. The Board also directed Executive Officer Darlene Stroup to obtain