California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES

DATE: January 24, 25, 2001

TIME: 9:00 a.m. - 5:00 p.m.

LOCATION: Sheraton Gateway Hotel
Los Angeles Airport
San Clemente Room
6101 W. Century Blvd.
Los Angeles, CA 90045

BOARD MEMBERS PRESENT:
Robert Elsner, President
Steven Litsey, Vice President
Caleb Zia - Treasurer
Darlene Fujimoto
Richard Mazzoni
Andrea Zinder
John Jones
Donald Gubbins
William Powers
Holly Strom

STAFF PRESENT:
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
William Marcus, Deputy Attorney General
LaVonne Powell, Department Legal Counsel

CALL TO ORDER

President Elsner called the meeting to order at 9:00 a.m. on Wednesday, January 24, 2001.

ANNOUNCEMENTS

President Elsner acknowledged Lynn Morris, Deputy Director of Board Relations for the Department of Consumer Affairs, who was in attendance.

President Elsner introduced new board inspectors Julie Hutchinson, Robert Kazebee, Valerie Sakamura, Sarah Lopez, Janice Dang and Jeff Smith, who were in attendance.

COMMITTEE REPORTS AND ACTION

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Chairperson Zia reported that the Communication and Public Education Committee met in a teleconference meeting on January 5, 2001.

Chairperson Zia stated that during the committee's annual public meeting scheduled later in the afternoon, the public will be able to provide comments on a proposed update to the "Notice to Consumers" poster that by board regulation, is posted in every pharmacy. He noted that the revision includes questions consumers should understand before taking prescription medication.

He added that once the wording for the revised notice is finalized, the board would need to adopt the text as an amendment to regulation section 1707.2 of the California Code of Regulations. The board will also redesign the poster so that it is more attractive and interesting to read.

Chairperson Zia reported on other major items from the Communication and Public Education Committee that included:

- 2001 *Pharmacy Lawbooks* have been updated and will be mailed to California pharmacies later this month, along with a CD ROM version. The total cost to the board of this is $65,000.
- The January 2001 *Script* was ready for mailing by the Post Office on January 15, 2001.
- Three issues of *Health Notes* have been reprinted to replenish board supplies:
    1. Women's Health
    2. Anticoagulation Therapy
    3. Developmental Disabilities

  Cost for reprinting all three: $34,600.

- New issues of *Health Notes:*

    1. UCSF has completed its work on the manuscript for "Alternative Medicines' and the board is waiting for the graphic designer to complete other projects to layout this issue.
    2. "Pharmacists' Care" is being edited.
    3. The board is awaiting notice from UCSF regarding its ability to obtain federal funding for "Geriatrics." If UCSF is unable to find alternative funding, the board agreed to contract with UCSF to develop this issue.
    4. The board received approval of its budg*et* change proposal for $100,000 to develop, design and mail a *Health Notes* on quality assurance programs for prescription errors, implementing SB 1339. Funding for this issue is for 2001/02.

- The board's website is being used to highlight current topics and events of interest. For example, information about the FDA's recommendation to remove OTC products containing phenylpropylamine from sale was added. Additionally, the board created a link to the Department of Health Services' website to facilitate access to the Medi-Cal price for the top 50 drugs, making price quotes more accessible to Medicare patients eligible for SB 393 discounts.

LICENSING COMMITTEE REPORT

Chairperson Holly Strom reported on the committee meeting on January 11, 2001.

- **Request from the Hoopa Valley Tribal Council to authorize a non-California licensed pharmacist to act as the pharmacist-in-charge in a California licensed pharmacy – Proposed Language**

    Ms. Strom reported that the board has been updated previously on various requests from the Hoopa Indian Tribe for a waiver of licensure requirements for a pharmacy to be located on tribal ground that would serve both members of the tribe and California residents from outside the reservation. A pharmacy that is operated on an Indian reservation to serve the members of the tribe is not required to have a pharmacy permit. If the pharmacy is to serve other California residents, as proposed by the Hoopa Indian Tribe, then a California pharmacy permit is required with a California licensed pharmacist-in-charge.

    The Hoopa Indian Tribe states it has been unable to hire a California licensed pharmacist and has proposed different solutions such as applying for a nonresident permit or waiving the requirement for a California licensed pharmacist-in-charge.

    Ms. Strom referred to AB 108 (Strom-Martin) that would authorize the board to issue a pharmacy license to a pharmacy with a pharmacist-in-charge licensed in another state.

Bruce Young, California Retailers Association, requested that the board take an oppose position on this legislation for the protection of consumers, since it would greatly reduce the board's ability to regulate pharmacies because it would have no jurisdiction over the pharmacist-in-charge.
Andrea Zinder expressed concern that the board would not be able to take any action against violations if this legislation were enacted. She stated that she opposes the legislation.

President Elsner and board member Rich Mazzoni also expressed concern that the board would not have jurisdiction over a non-licensed pharmacist.

President Elsner introduced Danny Jordon, self-governance coordinator and director of commerce for the Hoopa Valley Tribal Council. Mr. Jordon was invited to attend the board meeting to present the tribe's concerns to the board and request the board's support in efforts to seek the authority to hire a non-California licensed pharmacist to operate the pharmacy.

Mr. Jordon stated that the tribe operates a clinic on a reservation where it provides pharmaceutical care to both Indians and non-Indians. He added that the clinic is a legal provider of fee-for-service. Mr. Jordon stated that the goal is to provide health care to remote areas of the reservation where the situation is complicated by a 50 percent unemployment rate.

Mr. Jordon reported that the Hoopa tribe has experienced difficulty in employing pharmacists to work on the reservation. He added that this bill would serve to economically stimulate their economy by creating jobs within the community as well as provide health care on the reservation.

Mr. Jordon added that this bill will authorize the establishment of a business in Hoopa and would provide for a for-profit business adventure.

Mr. Jordon reported that the tribal clinic contract requires compliance with California law requiring a registered pharmacist in the clinic. He added that funding comes from the federal government and tribal funds.

Mr. Jordon stated that the tribe wants to determine how California recognizes and works with these tribes to create economies. He added that they want cities, counties, and state government to embrace the issue of tribal jurisdiction and bring it into the fold of economic development and health care.

Mr. Jordon responded to the concern expressed by the board for the health and safety of consumers. He noted that the Hoopa tribe proposed a MOA with the Board of Pharmacy that states that the Hoopa tribe would adopt and enforce the California pharmacy law, with the exception of using a licensed pharmacist. He added that initially AB 108 was a Hoopa-specific issue. Since then, other tribes have come forward with similar problems and the bill is now written to apply to every tribe in California. Another provision in the legislation is that the tribes will give preference to employment of California licensed pharmacists.

Ms. Strom encouraged these tribes to recruit from the pharmacy schools.

John Jones asked if efforts are being made to educate tribal members to pursue education for pharmacy positions.

Mr. Mazzoni asked how the tribe would determine a reasonable attempt to secure a California licensee and he asked if the concern is logistical or cost.

Mr. Jordon responded "both."

Deputy Attorney General William Marcus reported that under this legislation, the board would be required to help each tribe locate pharmacists to fill positions and there is no limitation to where a pharmacy is located, so long as a tribe owns the land.

Ms. Strom asked if licensed physicians were used in tribal clinics.

Mr. Jordon responded that physicians are not required to be licensed and that pharmacists are the only health care providers operating on a reservation that requires a California license.

Bill Powers stated that he is sympathetic to the health concerns in tribal communities but he expressed concern for remote areas where there is a lack of heath care and the need for consumer protection. He questioned why an out-of-state pharmacist who is willing to work on the reservation is unwilling to take the pharmacist exam, especially considering the salary is substantially above what other pharmacies are willing to pay. He asked if the tribe is also considering Internet sales and mail order.

Mr. Powers asked if there are provisions in the bill for discipline.

Robert LaWinter, Telepharmacy Solutions, stated that his company has experience with two tribes who faced the same problems. They resolved the issue by adopting new technology that could dispense drugs to the Indian population from a pharmacist who could be 50 to100 miles away and counsel these patients via video screen.

Phil Burgess, National Director of Pharmacy Affairs, Walgreens, stated that he opposes this legislation. He stated that drugs that are purchased at a significant discount will create a disadvantage to the community pharmacy by driving consumers away. He added that this is not in the best interest of the consumers if the board cannot regulate these pharmacists.

Mr. Jordon stated that it is the Hoopa Valley tribe's goal to create alternatives to casino business on tribal reservation.

LaVonne Powell, Staff Counsel, stated that this legislation differs from the initial intent of discussions with the tribe, which was to allow the tribal pharmacy to hire a non-licensed pharmacist with the intent to move in the direction of licensure. She added that as it now stands, there would be no motivation to move in the direction of licensure under these provisions.

Mr. Jordon stated that regardless of the outcome by the board, the Hoopa Valley Tribe is committed to working with the cities, counties and state government on this. He added that they are willing to work with the board on amendments.

MOTION: Oppose AB 108

M/S/C: LITSEY/MAZZONI

SUPPORT: 8 OPPOSE: 0 ABSTAIN: 1

Lynn Morris, Deputy Director, Board Relations, Department of Consumer Affairs, stated that the Administration does not feel that AB 108 is the way to go. However, the Administration does support efforts to help the Hoopa Valley Tribe and others to broaden their economic base.

Ms. Morris recognized the board's efforts in working with the department on this issue. She suggested that the board move forward with two positive steps during negotiations; she suggested that the board seek incentives for pharmacists to work on reservations and consider reciprocity. She referred to a letter from the director requesting the board's plan for reciprocity and a report.

President Elsner stated that reciprocity was a major topic during the Pharmacy Manpower Task Force Meeting held the previous day. He noted that there was a number of arguments in support and a number of arguments in opposition. He added that it is now up to the task force as well as the board's licensing committee to objectively explore the pros and cons of reciprocity.

Mr. Powers expressed concern for the cost of prescription drugs and he suggested that the board explore ways to deliver low cost drugs, especially to seniors.

Mr. Jordon thanked the board for the time spent on this issue.

- **Final Report on the Long Beach Memorial Hospital/UCSF Study on Technicians Checking Technicians – request to continue study and amend CCR 1793.7(b)**

  Ms. Strom stated that in May 1998, the board granted a waiver pursuant to California Code of Regulation section 1731 to the UCSF, School of Pharmacy in conjunction with Long Beach Memorial Medical Center at Cedars-Sinai Medical Center. The purpose of the waiver was to permit a study of technicians in a unit-dose drug distribution system to check the work of other technicians. The waiver was granted until November 1, 2000. Ms. Strom reported that at the October 2000 Board Meeting, the board extended the waiver to February 1, 2001, and requested that UCSF, Long Beach Memorial Medical Center (LBMMC) and Cedars-Sinai Medical Center (CSMC) present the final report to the board at this meeting.

  Peter Ambrose, Associate Clinical Professor, UCSF, presented this study to the board. He stated that he is the principal investigator for the University regarding the technician study. He noted that representatives from Cedars-Sinai Medical Center also were in attendance at the meeting.

  Dr. Ambrose stated that both Cedars-Sinai Medical Center and Long Beach Memorial Medical Center requested that UCSF sponsor and participate in this experimental program.

  Dr. Ambrose stated that the study included a baseline check for accuracy of pharmacists and an accuracy study with the technicians who were going forward with the certification process. He referred to the success rate of the accuracy in checking unit-dose medication cassettes reported in the study as follows:

  Table 1
  Accuracy of Pharmacists Checking Unit-Dose Cassettes

Institution	No. of Pharmacists	No. of Doses	Mean Accuracy
CSMC	15	12,626	98.85 %
LBMMC	14	23,203	99.89%
Total	29	35,829	99.52%

  Table 2
  Accuracy of “Certified” Technicians Checking Unit-Dose Cassettes

Institution	No. of Technicians	No. of Doses	Mean Accuracy
CSMC	25	106.744	99.88%
LBMMC	17[a]	54,966	99.89%
Total	41[b]	161,740	99.88%

[a] Two technicians did not complete the 3500 dose requirement to become qualified.
[b] One technician worked and participated for both institutions.

Dr. Ambrose indicated that continuing the pilot project pending enabling legislation should yield additional information, including to support proposed legislation.

Mr. John Cronin, California Pharmacists Association, stated that the CPhA opposes technicians checking technicians. He added that this proposal severs the relationship of the pharmacist in the pharmacy.

MOTION: Support technicians checking technicians in the inpatient setting. To ensure quality patient care, such programs should be conducted under the supervision of the pharmacist and should include: appropriate training of the checking technicians, demonstrated proficiency of meeting desired accuracy standards of the checking technicians and ongoing quality assessment of checking technicians.

M/S/C: STROM/FUJIMOTO

SUPPORT: 8 OPPOSE: 0 ABSTAIN: 1

MOTION: Move forward with legislation or a regulation change to allow technicians to check technicians in the inpatient setting if there is a quality assurance program in place and certification, audit review and ongoing checking.

M/S/C: LITSEY/GUBBINS

SUPPORT: 7 OPPOSE: 0 ABSTAIN: 2

MOTION: Consider the request to extend the waiver pursuant to California Code of Regulation section 1731.7(b), to continue the study to authorize technicians checking technicians in a unit-dose drugs distribution system until the end of the Legislative Session 2002.

M/S/C: JONES/MAZZONI

SUPPORT: 9 OPPOSE: 0

- **Recommendation to Issue Pharmacy Permits to Remote Pharmacy Sites**

Ms. Strom reported that at previous meetings, the Licensing Committee directed staff to work with counsel to draft statutory language that would authorize a pharmacy to use an automated dispensing device to dispense medication from a pharmacy site without a pharmacist physically present. This proposal would address the committee's number one strategic objective. At the last board meeting, the committee presented the language to the board. The board referred the language back to the committee and requested that the language be changed to clarify that the board would only authorize the licensure of the "remote pharmacy" when there is certification of a pharmacist shortage in the pharmacy service area.

Ms. Strom stated that the committee reviewed the proposed language that defines "automated dispensing device," and authorizes a "remote pharmacy" to use an automated dispensing device under specified conditions. These conditions are:

- that the pharmacy has certified that there is a pharmacist shortage in the pharmacy's service area,
- the pharmacist provides consultation via a two-way audio and video device,
- a technician or licensed health care provider furnishes the dispensed medication,
- the pharmacist can access the dispensing device outside the pharmacy premise and is responsible for stocking the device.

MOTION: The committee recommends that the board sponsor legislation for remote pharmacies containing the above-listed provisions.

SUPPORT: 7 OPPOSE: 0 ABSTAIN: 2

MOTION: If legislation is passed, the board will put forth a regulation to address how certification of a shortage of pharmacists is established and clarify if there are any limits to the responsibilities of the pharmacist of the remote pharmacy.

SUPPORT: 9 OPPOSE: 0

- **Recommendation to Clarify Business and Professions Code Section 4161 Regarding Out-of-State Distributors**

Ms. Strom stated that the Licensing Committee considered a request from staff to clarify Business and Professions Code section 4161 regarding out-of-state distributors. This section specifies when the board must license out-of-state distributors. Current language is difficult to understand. Existing state and federal laws do not require out-of-state distributors to be licensed in California if they are only doing business with a California licensed wholesaler. However, a license is required if the out-of-state distributor ships

directly to the pharmacy or to a CA-located practitioner. This amendment makes that clarification.

The committee recommends that the board sponsor this provision in future legislation.

MOTION: Sponsor legislation to clarify Business and Professions Code section 4161 regarding out-of-state distributors.

SUPPORT: 9 OPPOSE: 0

- **Recommendation to Change the Wholesaler and Exemptee Provisions**

Ms. Strom reported that the board's Licensing Committee continuously pursues efforts to streamline regulation requirements while keeping the mandate of public protection.

She added that staff has offered a suggestion to alter how the Board of Pharmacy licenses and regulates drug wholesalers. Under existing law, wholesalers are required to have "qualified supervision" to handle prescription drugs. That supervision can be in the form of a pharmacist or lay person who has obtained a certificate of exemption (called an exemptee) from the board. Exemptee applicants must pass an examination and clear a background check by the board before being issued an exemption certificate. The examination is not competency based, rather it is a test of the applicant's knowledge of pharmacy law provisions that apply to wholesaling. If the applicant passes the exam and clears the background check, he or she is issued an exemption certificate for a specific location.

Ms. Harris reported that the board is expending considerable resources on creating and administering five separate exams (wholesaler without controlled substances, wholesaler with controlled substances, veterinary food-animal retailers, manufacturers, and home hemodialysis distributors) which simply test the applicant's knowledge of the law. These exams do not address other knowledge and skills required to ensure consumer safety. Furthermore, tying an exemptee to a specific location generates considerable workload for the board by requiring the processing of innumerable changes of location. Approval of these staff changes to a different site in the same company is routine and no consumer safety interest is jeopardized by it as exemptees move from one location to another to satisfy an employer's needs.

Ms. Harris added that accordingly, the committee is recommending a change to the requirements for certification as an exemptee. Instead of a law exam, applicants will be required to complete a training course that meets standards established by the board. The proposal also requires exemptee applicants to have one year of paid work experience and

possess a high school diploma or general education development equivalent. In addition, the proposal severs the connection between the exemption certificate and a specific site. Instead, exemptees will be granted a certificate that permits them to work for any licensed wholesaler. Finally, the proposal requires those applying for a wholesaler's license to designate an exemptee as the supervisor or manager of the facility. This requirement is analogous to the pharmacist-in-charge requirement for a pharmacy, and the proposed language will be modified to reflect this.

MOTION: Seek legislation to amend section 4053 of the Business and Professions Code that would make significant changes to the wholesaler and exemptee provisions.

SUPPORT: 9 OPPOSE: 0

- **Recommendation to Authorize a Pharmacy to Dispense Federally Designated 340B Drugs to Clinic Patients via a Contractual Agreement**

Ms. Strom reported that at the last board meeting, the Board of Pharmacy moved to sponsor legislation that would authorize clinics to contract with pharmacies to dispense federally designated 340B drugs to patients of the clinic without the clinic having to become separately licensed as a wholesaler. Under current law, such an arrangement is not authorized unless the clinic is a wholesaler.

She noted that the 340B Drug Pricing Program was established federally in response to the passage of section 340B of Public Law 102-585, the Veterans Health Care Act of 1992. Section 340B of this law limits the cost of drugs to federal purchasers and to certain grantees of federal agencies such as clinics. Entities that participate in this program benefit from significant savings on drugs which allows the entities to provide in-house pharmacy services to the rural or undeserved population that would have otherwise not received such services.

Ms. Strom stated that under this federal program "covered entities" such as clinics can contract with a licensed pharmacy to dispense these drugs to patients of the clinics. The board has received requests from clinics to contract with pharmacies to dispense 340B drugs to their underserved patients.

As directed by the board, the Licensing Committee drafted language and is recommending board approval of the language for board sponsored legislation. The language specifies that a licensed clinic may contract with a pharmacy to dispense preferentially priced drugs obtained

pursuant to 340B of the Public Health Service Act. The contracts must comply with the guidelines published by the Health Resources and Services Administration and must be available to the board for inspection. The 340B drugs must be kept separate from other drug stock, excess drug stock must be returned to the distributor and it is unprofessional conduct for a pharmacy to dispense 340B drugs to persons who are not receiving care from a clinic.

Leon Wilde, Public Law Institute, stated that they support the language but suggested that the term clinic be changed to "eligible entity" throughout the language.

Mr. Wilde stated that eligible entities are prescribed by law under the Veterans Health Care Act and there are approximately 12 categories including tribal health.

Mr. Marcus stated that this would be a major change and if this suggestion were to be made, he suggested that "covered entity" be used.

MOTION: Remove the phrase"clinic eligible" and add "covered entity" to allow pharmacies to dispense federally designated 340B drugs.

M/S/C: STROM/POWERS

SUPPORT: 6 OPPOSE: 3

Mr. Wilde referred to the segregation of pharmacy stock. He stated that he hopes to use an electronic separation as other states use.

Supervising Inspector Judi Nurse expressed concern over the lack of separation of these drugs and accountability issues that may result.

Mr. Wilde stated that there is an automatic reorder mechanism built into the computer to maintain the 340B program that provides a running inventory in place.

Paul Drogichen stated that he anticipates the need for electronic separation for many reasons and he added that this is easily tracked.

Mr. Marcus stated that the board requires drugs received by a pharmacy that are purchased pursuant to 340B of the Public Health Services Act, be segregated from the pharmacy's other drug stock. Also, all records of acquisition and disposition of these drugs must be maintained separately from the pharmacy's other records and computer data is readily retrievable.

MOTION: To allow the pharmacy to separate the 340 drugs from other pharmacy stock either physically or electronically.

M/S/C: POWERS/ZIA

SUPPORT: 6 OPPOSE: 2 ABSTAIN: 1

MOTION: To accept the proposed language to allow pharmacies to dispense federally designated 340B drugs.

SUPPORT: 9 OPPOSE: 0

ANNOUNCEMENT

Mr. Marcus announced that due to the very serious health problems he has had over the last five years, he is retiring from state service. He added that this would likely be his last board meeting.

Mr. Marcus noted his accomplishments during the last 25 years that included areas involving regulation of prescription drugs, pharmacy practice, drugs, controlled substances and pain management policy and administrative law.

Mr. Marcus commended the board for its consistent ability to work productively, even when the board disagrees with a proposal made by someone else. The board usually strives to find a way to deal with pharmacy practice both as it is and as it should be. He added that this is not typical of all other boards and bureaus in this state or other states.

Mr. Marcus noted that one of his most important accomplishments of his state career was to serve as liaison counsel for the Board of Pharmacy.

Mr. Marcus acknowledged the board's executive staff as an exceptional group. He commended Executive Officer Patricia Harris, Assistant Executive Officer Virginia Herold, Manager Karen Cates, Editor Hope Tamraz, Legislative Analysis Paul Riches, Exam Coordinator Ruta Arellano and Supervising Inspectors Judi Nurse and Robert Ratcliff, with whom he has worked closely with over the years.

President Elsner thanked Mr. Marcus for a job well done and acknowledged Mr. Marcus' many abilities as deputy attorney general. He noted that Mr. Marcus will be greatly missed.

Mr. Mazzoni acknowledged Kim Caldwell from the Texas Board of Pharmacy who was in attendance at the board meeting.

MOTION: Approve Fesenius Medical Care's waiver of CCR 1717(e) to deliver prescriptions to dialysis units, subject to License Committee review of policies and procedures.

SUPPORT: 9 OPPOSE: 0

MOTION: Approve Statscrip Pharmacy's waiver of CCR 1717(e) to deliver dispensed prescriptions to AIDS Clinics, subject to License Committee review of policies and procedures.

SUPPORT: 9 OPPOSE: 0

- **Recommendation to Define Wholesaling**

Ms. Strom stated that the board has encountered difficulty prosecuting some wholesale diversion cases because of the manner in which existing law defines a wholesaler. In these cases pharmacies purchase large quantities of drugs at preferential prices and resell them to wholesalers or other pharmacies to generate a profit. Current restrictions on the resale of preferentially priced drugs (section 4380 of the Business and Professions Code) is limited to non-profit institutions and the statutory definition of a wholesaler does not make it clear when a pharmacy must obtain a wholesaler license.

The Food and Drug Administration has established a guideline that defines a pharmacy that generates more than 5 percent of its dollar volume in prescription drug sales through the trade, transfer, or sale of prescription drugs to other licensees as a wholesaler. This guideline

was established during the rulemaking process implementing the Prescription Drug Marketing Act (PDMA), which sought to eliminate such wholesale diversion practices. Because state law has no such clear threshold, it is difficult to prosecute these cases at the state level.

At the October 2000 Board Meeting, the board directed staff to develop a proposed regulation to implement the 5 percent rule in California. The proposed language would incorporate the federal guideline into the board's regulations relating to wholesalers. This provision would permit the board to prosecute these wholesale diversion cases as unlicensed activity as a wholesaler.

Mr. Cronin stated that during the last meeting, he raised an issue regarding central fill pharmacies but he did not see any changes to the language.

Steve Gray representing Kaiser Permanente urged staff to provide the board with an analysis of what this would do under federal law as it relates to FDA and DEA law on wholesalers. He added that it is not just a matter of requiring these pharmacies to get a wholesaler permit issued from the Board of Pharmacy. The implication is that once you do this, you have to get a separate DEA registration for a different activity and other requirements must be considered.

Ms. Harris stated that the language will be presented at the next board meeting during an informational hearing. The board will have a chance to modify the language before that time.

MOTION: Move proposed section 1784 to the California Code of Regulations to future notice as a regulation following the April Board Meeting.

SUPPORT: 9 OPPOSE: 0

- **Status Report on the Review of NABPLEX**

Ms. Strom reported that the committee has initiated a review by the Office of Examination Resources (OER) for the Department of Consumer Affairs of the North American Pharmacist Licensure Examination (NABPLEX).

The OER submitted a proposal for the committee's review. It is anticipated that the board's cost for the review will be approximately $5,000 to $10,000 for travel and expenses and the OER anticipates completion of the project by June 30, 2001. The OER did state that the success of the review is dependent upon the cooperation of the National Association of Boards of Pharmacy. Specifically the access to the test provider's staff, and the NABPLEX documentation about occupational analysis, test plan development, item development, security, passing score procedures and other examination-related information.

The OER proposes to invite four nationally known psychometricians who have directed statewide occupational testing programs to participate in the evaluation. These psychometricians are from California, Colorado, Michigan and Wisconsin. None of these individuals has any association to the board's test or the NABPLEX exam. In addition to the four psychometricians, the board will select a fifth member for the evaluation committee. There will be no charge for the professional services of the psychometricians, however, as part of the contract, the board will reimburse the members for their travel, per diem and related expenses. The OER anticipates at least two meeting of the evaluation committee. The first meeting will be at the site of NABPLEX in Illinois and the second in Sacramento.

Ms. Strom stated that it is the committee's goal to have this review completed by the July board meeting.

- **Competency Committee Report – January 2001 Pharmacist Licensure Examination**

President Elsner reported that the board's January examination was administered on January 9 and 10, 2001, at the Hyatt Regency San Francisco Airport Hotel in Burlingame. There were 600 candidates who sat for the examination. Examination results are scheduled to be released by March 23, 2001. Passing rate information will be available on the board's web site in April.

- **New Member Update**

President Elsner reported that he has appointed Charles C. Stuart to the Competency Committee. Mr. Stuart is the owner of the Columbia Pharmacy in Long Beach and is a preceptor for students from both the USC and UOP Schools of Pharmacy. He has certifications in asthma disease management and anticoagulation drug therapy.

INFORMATION HEARING – Quality Assurance Programs

President Elsner stated that the draft regulation specifying the requirements of quality assurance programs was released at the October 2000 board meeting. He noted that the purpose of this hearing is to solicit input from the public regarding the draft regulation. He added that this informational hearing fulfills the board's desire to hear public comment prior to filing a proposed regulation adoption.

Mr. Elsner stated that the language was developed to fulfill the mandate of Senate Bill 1339 (Chapter 677, Statues of 2000). That legislation requires the board to adopt regulations specifying the requirements of quality assurance programs by September 1, 2001. A formal regulation hearing on the proposed regulations is planned for the April 2001 Board Meeting. The board has received no comment on the draft regulations.

Bruce Young, California Retailers Association, referred to the Governor's extraordinary signing message on this legislation and added that it clearly indicates the Governor's intent to encourage the use of models of existing programs already in the marketplace. He asked the board to examine how the private sector currently handles evaluation of prescription errors.

Alan Pope, Longs Drugs Stores, stated that he would like to submit alternative language to the board. He added that one concern is the use of the term "root cause analysis." Mr. Pope added that the term was misplaced in this regulation and that the regulation should be simplified.

Mr. Pope suggested removal of the term "medication error that actually caused patient harm." He stated that a pharmacy should not be held accountable for a physician's office who calls in the wrong medication.

Mr. Jones referred to the term "root cause analysis" and stated that the intent is for the pharmacy to review its errors and determine the actual cause of the error.

Teri. Miller, California Society of Hospital Pharmacists, stated that the CSHP supports the language as drafted and sees it as a significant move towards protecting patients' health and reducing the level of medication errors. She commended the board for using similar language to JCHO and using processes that are already in place. She added that all hospitals are required to have quality assurance programs in place and they have had this requirement for years. She stated that within the inpatient community, "root cause analysis" is a very familiar term.

Ms. Strom stated that one purpose of the quality assurance regulation is a time-frame reference in the regulation on the medication process that should be reviewed on a regular basis. This will serve as a reminder to regularly review the program, at least annually when the license is due for renewal.

Ms. Miller asked for clarification of section (d) where it states: "The investigation and reporting of an error shall begin as soon as is reasonably possible, but no later than five days from the date the medication error is discovered." She asked if the intent was for the process to begin in five days. The board confirmed this is its intent.

Kim Caldwell, Texas Board of Pharmacy, commended the board's efforts to move forward on the requirements for quality assurance programs that blend the disciplinary guidelines and peer review. He added that this is a positive trend. Further, he added that 80 percent of the medication errors that occur are systematic. He noted that his board found that it was better not to be specific on the requirements of the quality assurance programs and let the pharmacies use what they have in place rather than dictate specifically what must be done. He suggested that the regulation requirements be kept simple so that a program could be adapted to fit the specific practice setting of a given pharmacy. He added that this process is working on a very positive note.

Steve Gray, Kaiser Permanente Medical Care Program, stated that they have had experience with quality assurance programs since 1976. He also suggested that the term "root cause analysis" be removed because of its specific meaning when used in the JCHO context. He added that a typical "root cause analysis" process at Kaiser is a complicated process that will become problematic to the industry.

Ms. Fujimoto requested that a documentation requirement be in place that states the consumer's outcome and the resolution that occurred. She added that based on information received at the SCC meetings, in most instances, the pharmacy did not resolve the issue with the consumer.

John Cronin, California Pharmacists Association, stated that the regulation needs to focus on medication errors. He suggested that it be kept simple and focused on the original intent.

Mr. Houssaymi, a resident at the University of Southern California, stated that they are implementing quality assurance programs at their three pharmacies on campus. Their interpretation of the term "root cause analysis" is a simple investigation getting to the root of the problem. As a result of this, they have devised a form to include pharmacy-based and prescriber-based errors.

Phil Burgess, Walgreens, referred to item (f) and encouraged the board to consider allowing a central location of records, rather than requiring records to be kept in the pharmacy. The requirement to keep the records in the pharmacy for three years would place the pharmacy in a vulnerable position. He added that a one-year time frame would be sufficient and Walgreens would agree to produce the records within 48 to 72 hours.

Cooky Quandt, Longs Drug Stores Inc., referred to the new Health and Safety Code section 1139.63. She added that this specifically deals with medication errors in a hospital and the new requirements that hospitals need to meet.

She recommended that the board remove the term "root cause analysis." She added that Longs Drug Stores strongly supports the board's efforts but has a problem with the language.

President Elsner stated that the board will continue to take written comments and a regulatory hearing will be held during the April board meeting as part of the regulation adoption process.

Mr. Jones stated that the Institute of Medicine is due to release its report on medical errors in the ambulatory setting in March and this is timely issue. Perhaps findings from this report can be integrated into the board's regulation.

REGULATION HEARING

CCR SECTI0N 1760 – Disciplinary Guidelines

President Elsner stated that this regulation hearing is to consider action to amend section 1760 of Division 17 of Title 16 of the California Code of Regulations, dealing with the board's Disciplinary Guidelines.

President Elsner stated that in accordance with Section 1760, the board has produced this booklet for those involved in or who are affected by the disciplinary process: the general public, attorneys from the Office of the Attorney General, administrative law judges from the Office of Administrative Hearings, defense attorneys, board licensees, the courts, board staff and board members who review and vote on proposed decisions and stipulations. The Disciplinary Guidelines are guidelines, not required components in discipline cases.

President Elsner added that the board refers to disciplinary guidelines when taking action to suspend, revoke or place a license on probation.

In order to provide a logical and straightforward document to those who must use these guidelines, the board has restructured and revised the guidelines from the prior version. Because the guidelines are incorporated by reference in section 1760, the board must conduct a rulemaking anytime it wishes to modify the guidelines. As such, the board proposes to repeal the existing Disciplinary Guidelines and to replace the entire text with the revised Disciplinary Guidelines (Rev. 1/2001) which will still be incorporated by reference with this section.

This action of repeal and replacement is designed to afford the affected parties ease in reviewing the proposed language.

President Elsner directed the public on procedures to follow during oral testimony.

Mr. Cronin stated that four different organizations submitted written comments jointly on the Disciplinary Guidelines. He encouraged the board to make the guidelines simple, concise and specific to the facts in a particular case. There should be no fixed penalties.

Alan Pope referred to the NCC/SCC hearings and the disciplinary process when petitioners complain that they are not being treated the same as other pharmacists in similar situations. Mr. Pope added that better communication is needed to convey the different levels of discipline. He added that pharmacists should know what certain terms mean and how they apply to them.

Ron Marks, Attorney, referred to the comments he submitted and stated that the new guidelines reflect discipline to be more punitive and the board may not get the results it hopes. For example, he stated that pharmacies would not settle cases if a notice that the pharmacy is on probation must be posted during the duration of the probation. Consequently, the board will need to go to hearing on more cases which is both more costly for the board and extends the resolution time for the complaint. He added that it would create bad feelings among pharmacists.

Mr. Marks requested that the board allow for a pharmacist-in charge on probation to be the PIC as long as a consultant is hired to check the pharmacy. He requested that there be guidelines about settlement proposals because settlements benefit everyone involved by saving money and time.

At this point there being no further public comment Board President Elsner closed the hearing at 3:00 p.m.

Mr. Marcus stated with regard to reimbursement of board costs, that the current Disciplinary Guidelines provide that failure to pay as specified by the order or on time, can result in revocation without notice and the opportunity to be heard. He expressed concern whether this is appropriate. Mr. Marcus added that the board might want to consider if it really wants to mandate revocation without a prior hearing.

Mr. Marcus added that as the guidelines are written, any violation of probation could be grounds for filing a petition to revoke probation.

Mr. Marcus noted Mr. Marks' claim that the language in the guidelines which states the respondent shall not engage in any activity that requires professional judgment of a pharmacist, is too vague to be enforceable. Mr. Marcus indicated that "professional judgement" is used in statute and is not too vague.

Mr. Marcus referred to the requirement of drug and alcohol screening and stated that it is appropriate to require screening throughout a period of probation. He added that studies have established that substance abuse problems often need more than a single program or even a single year or two to establish recovery. Further, terms of probation may be modified on petition filed by the probationer one year or more from the time the discipline is imposed. Mr. Marcus stated that once a person has demonstrated a substance abuse problem, indicating a difficulty to refrain from abuse, it can be appropriate to restrict access to drugs or alcohol.

Mr. Marcus referred to posting a notice of probation in the pharmacy during the length of probation and he and Ms. Powell questioned whether it is necessary.

Mr. Marcus stated that he agrees with removing a violation 1706.1 as a category 1 violation because a licensee cannot violate the provisions of this regulation regarding board-processing times.

In response to Mr. Marks' questioning how certain statutes and regulations are categorized, Mr. Marcus said that 1716 is a category 1 because it does not take a deliberate deviation from the requirement of a prescription without prior authorization to constitute a violation. That any deviation from requirements of a prescription without prior authorization is a violation of the regulation. When categorizing, the board looks at the minimal violation that could occur and places it within the lower classification.

Ms. Powell stated that the Board of Registered Nursing amended their guidelines to require nurses to work a certain amount of time while on probation.

Mr. Litsey stated that the board could adopt the Disciplinary Guidelines with a stipulation that the recommendations discussed are included.

Ms. Harris suggested that the board remove the automatic revocation if the cost is not paid.

Ms. Powell stated that the board could always file a petition to revoke probation.

Mr. Marcus recommended elimination of the provision making reimbursement of cost automatic grounds for revocation, without the right to a petition to revoke probation. He and Ms. Powell added that the board might want to consider the nursing board language where probation shall be extended for a period of time until the term has been complied with. The board might want to bar a respondent who is suspended or revoked from participating in any activity that requires professional judgment.

MOTION: Adopt the following changes as outlined by Mr. Marcus:

- Remove the failure to pay cost recovery as automatic grounds for revocation.
- Change the language regarding how many hours and under what conditions someone should work to allow for hardship and add to the prohibition of suspended or revoked pharmacist engaging in activity that requires professional judgment a corresponding ban on being a pharmacy technician or exemptee of the board.

M/S/C: FUJIMOTO/JONES

SUPPORT: 9 OPPOSE: 0

Ms. Fujimoto asked the board to consider the issue of posting a notice of probation in the pharmacy and asked the board to consider it only in terms of whether the consumer would benefit from this information.

Ms. Powell stated that it is not a consumer protection issue except it will make the litigant fight harder. She added that this would increase the penalty greatly to the pharmacy.

Mr. Zia expressed concern that without this notice being posted, consumers would not be protected. Simply posting the information on the Internet is not enough.

MOTION: Delete the provision of posting a notice of probation on the premises of a pharmacy.

M/S/C: MAZZONI/GUBBINS

SUPPORT 8 OPPOSE: 1

MOTION: A pharmacist-in-charge can remain PIC during probation as long as a pharmacist consultant checks the pharmacy. Create optional conditions to allow the same language to apply to any pharmacist on probation regardless if he or she is currently a PIC with the condition that the consultant be retained if the individual becomes a PIC.

M/S/C: POWERS/GUBBINS

Motion Dies

MOTION: Remove 1706.1 from the disciplinary guidelines since licensees cannot violate the provisions of this regulation regarding board processing times.

M/S/C: MAZZONI/JONES

SUPPORT: 9 OPPOSE: 0

ENFORCEMENT COMMITTEE

Ms. Fujimoto reported that the committee met on December 12, 2000.

- **Recommendation to Proposed Quality Assurance Regulations**

The committee discussed the proposed regulation and suggested that a provision be added to require procedures advising the patient about the prescription error.

MOTION: Amend the proposed regulations defining quality assurance programs to include as part of the program, procedures on how the pharmacist advises the patient about the prescription errors.

SUPPORT: 9 OPPOSE: 0

- **Recommendation to Cite and Fine for Confidentiality of Medical Information Act (CMIA) – Proposed Regulation**

Ms. Fujimoto reported that the board has encountered cases where pharmacies and pharmacists have negligently committed violations of the CMIA involving patient privacy. In disciplining these pharmacies, the board obtained stipulations through the AG's Office that included fines. Such stipulations only work in situations where the respondent is amendable to such a resolution. Should the respondent fail to be cooperative, the board would be forced to pursue discipline a hearing under the Administrative Procedure Act. Either of the current enforcement options require added expense and time of resolving these matters through the AG's Office rather that through the board's cite and fine program. With a fine the respondent has the option to appeal the fine, which then would be handled by the AG's Office. It is the advice of the AG's Office that the board add cite and fine authority for CMIA violations as expeditiously as possible.

The committee recommends that the board adopt such a regulation.

MOTION: Propose regulations that would permit the board to issue citations and fines for violations of the Confidentiality of Medical Information Act (CMIA).

SUPPORT: 8 OPPOSE: 0

- **Recommendation to Cite and Fine for Internet Pharmacies – Proposed Regulation**

Ms. Fujimoto stated that Business and Professions Code section 4067 was added by SB 1828 (Chapter 681, Statutes of 2000) to authorize the board to issue citations and fines for dispensing drugs via the Internet without a prescription issued pursuant to a good faith examination. This new section authorizes fines up to $25,000 per violation.

Ms. Fujimoto added that the board has encountered cases where this illegal dispensing activity has occurred. However, the enforcement tools available to the board in these cases have been inadequate. This new authority will permit the board to take substantive action against rogue Internet pharmacies when a case can be substantiated. She added that the committee recommends the board adopt such a regulation.

MOTION: Propose regulations to cite and fine Internet pharmacies for violation of Business and Professions Code section 4067.

SUPPORT: 8 OPPOSE: 0

- **Recommendation to Modify Self-Assessment Form to Include Waiver for Off-Site Storage of Records**

Ms. Fujimoto stated that in November, the board's regulation to provide a waiver to permit pharmacies to store pharmacy records offsite took effect. In essence this regulation authorizes a pharmacy to store records offsite so long as the pharmacy has not in the last five years failed to produce records nor has falsified records. The pharmacy storing the records offsite must produce the records within two business days of a request from an inspector or other authorized officer, and a pharmacy must keep all records of acquisition and disposition in the pharmacy for one year for dangerous drugs and two years for controlled substances.

She added that the waiver form and explanation will be sent to pharmacies requesting offsite storage of records. The intent is for pharmacies to use the form, submit it to the board for approval and then the board would return the signed form to the pharmacy, where it must be kept.

Ms. Fujimoto stated that the committee recommends that the self-assessment form be amended to require storage of the off-site waiver in the pharmacy with the self- assessment form.

MOTION: Amend CCR 1707 (pharmacy self-assessment requirement) to include a request from the board that the approved waiver for offsite storage of records be kept in the pharmacy with the self-assessment form.

SUPPORT: 9 OPPOSE: 0

- **Recommendation to Proposed Amendments to CCR 1717.3 (Preprinted, Multiple Check-off Blanks)**

Ms. Fujimoto stated that both the California Pharmacists Association and Kaiser Permanente suggested modifications to the language that would allow a prescriber to prescribe more than one drug from a single preprinted prescription form.

Mr. Ken Sain, retired Supervising Inspector with the Board of Pharmacy, stated that during the early 1980s while he was an inspector, this issue of prescription blanks arose and they were referred to as "laundry lists." He stated that many prescription errors are the result of this laundry list type of practice. He added that he opposes allowing a prescriber to order more than one drug from a single prescription form.

MOTION: Accept the recommended modifications to the proposed amendments to CCR 1717.3 as suggested by the California Pharmacists Association and Kaiser Permanente.

- **Report on December 12, 2000, Meeting**

John Jones reported that Board President Elsner was a guest at the December 12 meeting. He noted that the board has recently hired six new board inspectors, which promises to be a very competent team. The board is moving toward goal resolving all the backlogged cases. He added that this would allow the board to move towards implementation of its routine compliance inspection program that is anticipated for March 1.

Mr. Jones referred to the Enforcement Committee public meeting scheduled for March 13 and requested that the public provide written comments prior to the meeting. He noted that the committee will hold a continuing education meeting in the fall to attract more public participation and attendance.

LEGISLATION AND REGULATION COMMITTEE

Chairperson Mazzoni provided the Legislative and Regulation Committee's report.

- **Pending Regulations**

Self-Assessment Form (Amend Section 1715)

Mr. Mazzoni reported that this proposal would amend section 1715 to make technical corrections:

1) Add references to the board's web site on the letterhead that appears on the instructions and the first page of each form,
2) Add text to the top of each form that encourages PICs to share the forms with appropriate pharmacy staff,
3) Rename the "COMMENTS" "CORRECTIVE ACTION OR ACTION" to reflect a more specific action,
4) Update existing laws that have become changed since the time of the original adoption of the form in 1998 and amend and,
5) Move the compliance date to July 1 of each odd-numbered year.

Teri Miller of the California Society of Health System Pharmacists, referred to item number 5, Duties of a Pharmacist (on both forms). She asked the board to review this to ensure that it reflects current statute.

MOTION: Adopt the proposed amendments to section 1715 including an additional amendment proposed by the Enforcement Committee (to require offsite storage waivers to be stored with the self-assessment form).

SUPPORT: 9 OPPOSE: 0

Preprinted, Multiple Check-off Blanks – Amend 1717.3

Mr. Mazzoni reported that this proposal would facilitate the use of preprinted, multiple check-off prescription blanks by prescribers. Currently, a prescriber must use a separate prescription blank for each drug he or she is prescribing for a patient regardless of whether other drugs preprinted on the form also will be prescribed to the patient.

The board's proposal would amend subsection 1717.3(b) to allow a pharmacist to dispense more than one dangerous drug from a single preprinted, multiple check-off prescription form provided the prescriber has indicated on the form the total number of drugs he or she has selected.

At its July meeting, the board approved moving forward with a 45-day notice for the language. The notice of proposed action was published on August 25, 2000. The 45-day comment period ended on October 9, 2000.

MOTION: Adopt section 1717.3 as modified to include amendments proposed by the California Pharmacists Association and Kaiser Permanente.

SUPPORT: 9 OPPOSE: 0

1717.3 Preprinted, Multiple Checkoff Prescription Blanks

(a) No person shall dispense a controlled substance pursuant to a preprinted, multiple checkoff prescription blank.

(b) ~~No~~ A person ~~shall~~ may dispense more than one dangerous drug from a preprinted, multiple checkoff prescription blank~~.~~ if the prescriber has indicated on the blank the number of dangerous drugs he or she has prescribed.

(c) "Preprinted, multiple checkoff prescription blank," as used in this section means any form used or intended to be used as a written order for an individual for dangerous drugs which order contains or lists more than one drug for which the name, strength, amount or quantity has been preprinted on the prescription blank.

Note: Authority cited: Sections 4005 4008 and 4008.2, Business and Professions Code.

Reference: section 4036 4040, Business and Professions Code and Section 11164, Health and Safety Code.

President Elsner recessed the Board Meeting for the day, but invited those in attendance to remain for the public meeting of the Communication and Public Education Committee.

PUBLIC MEETING OF THE PUBLIC EDUCATION AND COMMUNICATIONS COMMITTEE

Committee Chair Calib Zia convened the meeting at 4:25 p.m.

- **Request for Comments on Proposed Revisions to the "Notice to Consumer" Poster**

Chairperson Zia referred to the board's current "Notice to Consumer" poster and requested public comments for a new poster. He added that under California Code of Regulations section 1707.2(f), this poster and its required wording must be posted in every pharmacy. He shared a draft copy of the text for a new poster with the audience.

Mr. Cronin asked where in law it states that a pharmacist must discuss a patient's new prescription at no charge. He added that there is no prohibition in the law against charging for consultation.

Steve Gray, Kaiser Permanente, also expressed concern for the no-charge language concerning consultation. He added that many pharmacies are trying to provide consultative services and to counsel patients, not only with new prescriptions, but also as part of the ongoing process to assure quality success. He added that pharmacies have been successful in getting patients as well as insurance companies to pay. He expressed concern that the language may mislead the insurance companies to think they cannot pay for such services provided to patients.

Mr. Marcus stated that the board does not address the issue of charge in the "Notice to Consumer" but the board may want to consider it.

Ms. Fujimoto stated that the "Notice to Consumers" should convey that consumers should be getting consultation and what the consultation should include. It should also note how consumers could reach the Board of Pharmacy.

Mr. Jones suggested that it might be appropriate to provide the notice in different languages. Chairperson Zia stated the committee intends to do this.

There being no further business, the public meeting of the Communication and Public Education Committee adjourned.

January 25, 2001

CLOSED SESSION

The board moved into Closed Session pursuant to Government Code Section 11126(c)(3) to deliberate upon disciplinary cases and to consider the Petition for Reinstatement.

The board conferred with Legal Counsel pursuant to Government Code Section 11126(e) regarding the following pending litigation: Doumit v Board of Pharmacy, Sacramento Superior Court Case #98A504499 and Gonzalez v Board of Pharmacy, Sacramento Superior Court Case #99ASO1990.

ORGANIZATIONAL DEVELOPMENT COMMITTEE

Committee Chairperson Steve Litsey reported that the Organizational Development Committee met on January 4, 2001.

He stated that the board has an AG deficiency for this fiscal year projected to be about $400,000 and will need to initiate action to receive supplemental funding for this important budget item.

Ms. Harris stated that the projected AG deficiency was not a surprise; a budget change proposal was submitted July 1, 2000, seeking an AG augment in this year as well as future year budgets. However, the Department of Finance denied the current year augmentation.

MOTION: Move forward with a deficiency request to augment the Attorney General line item by $400,000.

M/S/C: FUJIMOTO/POWERS

SUPPORT: 9 OPPOSE: 0

Mr. Litsey stated that board staff has moved into their new offices and response from staff has been very favorable.

President Elsner stated that during the closed session, the board adopted the following statement:

> Last month the Sacramento County Superior Court Jury awarded a $3 million verdict in favor of Labib Doumit, a former supervising inspector for the Board of Pharmacy. The jury's verdict came as a stunning disappointment to the Board of Pharmacy. The events that were the subject of Mr. Doumit's lawsuit against the board arose over three years ago and were limited to good faith personnel decisions taken by the board's management.
>
> The board stands firmly behind its managers, Executive Officer Patricia Harris and Assistant Executive Officer Virginia Herold who made every effort to act lawfully and to be fair and cordial in their relationship with Mr. Doumit throughout his employment. Ms. Harris made the decision to promote Mr. Doumit to supervising inspector in 1996. Under the direction and guidance of the Department of Consumer Affairs, Ms. Harris used appropriate and lawful methods to correct Mr. Doumit's performance as a supervisor in May 1997 which ultimately lead to his rejection on probation and disability retirement.
>
> The Board of Pharmacy will appeal the jury's verdict and seek review of the legal basis for the damages awarded in this case. The board disagrees with the jury's decision and continues to support its management. The board understands that the jury's verdict in response to Mr. Doumit's allegations did not tarnish the professional and sincere management by Ms. Harris and Ms. Herold that has been in place for the last 10 years.

Executive Officer's Report

- Personnel Update

Ms. Harris reported that Betty Thorson retired from the board in November. Ms. Thorson has been with the board for over five years, and processed mail votes and decisions in disciplinary matters. Ms. Harris added that Ms. Thorson will remain with the board as a retired annuitant to process exemptee applications for wholesalers and medical device retailers.

Ms. Harris reported that Ms. Thorson's prior position in the Enforcement Unit was converted into an office technician position, and Kim deLong, who formerly processed exemptee applications, has been transferred into the enforcement position. Ms. deLong has been with the board for 1.5 years and processed exemptee applications in a non-permanent position created to meet workload demands. Because the Department of Finance denied the budget change proposal that would have made the exemptee processing position permanent, Ms. deLong was transferred into a permanent position. Ms. deLong will now process mail votes and decision letters.

Vicki Almes, who was in a non-permanent analyst position processing consumer complaints, has been transferred into an Enforcement analyst position responding to public requests for information. This was a position formerly filled by Barbara Shelton. Again, Ms. Almes was transferred into this position because the Department of Finance did not approve the establishment of the limited-term complaint processing position Ms. Almes was filling.

Ms. Harris reported that the board has hired and started training six new inspectors since November 8. She added that the board is pleased to have these highly qualified pharmacists join the board.

Starting November 8 were:

- Julie Hutchinson, who formerly worked for 20 years in the community practice setting, as a staff and lead pharmacist. She also holds an MS degree in pharmaceutical economics. Dr. Hutchinson lives in San Diego.
- Sarah Lopez, who has worked as a pharmacist for nearly six years in a community chain-store setting. Dr. Lopez lives in Los Angeles.
- Valerie Sakamura, who has worked as a pharmacist for nearly three years in a hospital setting, principally conducting research in clinical drug therapy trials, and training and supervising technicians, interns and residents. Dr. Sakamura lives in Los Angeles.

Starting December 4 were:

- Robert Kazebee, who has worked as a pharmacist for over 27 years mostly in the community practice setting. He has worked as both an employee pharmacist and as the owner of his own community pharmacy. He has also worked as a drug company representative, and lives in Los Angeles.
- Janice Dang, who has worked as a pharmacist for nearly 12 years in both the community and hospital practice settings. She has served as staff pharmacist, lead pharmacist and consultant pharmacist in her positions. Dr. Dang lives in Los Angeles.

Starting January 2 was:

- Jeff Smith, who has worked as a pharmacist for over 19 years, the last 12 in the community practice setting, specializing in home health care. He also has two years of experience in the hospital setting. Dr. Smith lives in Sacramento.

Ms. Harris reported that the board currently has three inspector vacancies, and 20 pharmacists working for the board. The board has no other vacant positions.

Ms. Harris noted that interviews for the remaining inspector positions are planned in late January with those pharmacists who scored highly in the December 2000 open civil service interviews. The board is seeking Northern California inspectors for at least two of the three vacant positions remaining. The board hopes to have these positions filled by the next board meeting.

Ms. Harris informed the board that Anne Sodergren and her husband Steve had a baby boy, Samuel, in October. Ms. Sodergren has returned to her position as enforcement coordinator with the board on a part time basis, and will continue working part-time for one year before returning full time.

BUDGET REPORT

1. 2000/01 Budget Year

Projected Revenue: $7,098,645

Ms. Harris stated that revenue is projected to be comprised of $5,211,000 in license fees and $547,415 in interest on the board's fund. Also, the board is expected to receive the final repayment of the money borrowed nine years ago to help assist with the state's fiscal crisis. This $1,213,000 is included in the above figure. The revenue estimate also includes $127,230 in cost recovery actually collected through December 31, 2000.

Projected Expenditures: $5,843,780

The board projects approximately $400,000 in over-expenditures at the AG's Office. Without a deficiency augmentation, the board will exhaust its AG funding this month. To prevent this, the board will submit a deficiency augmentation for the year.

Fund Condition: $10,232,244

The board is projected to have 19.7 months remaining in its fund on June 30, 2001, at the projected expenditures level.

2. Budget Change Proposals

The following is the status of the board's budget change proposals submitted for this year and next year.

The Department of Finance disapproved most of the following, in part because the Governor wishes to limit the growth of state government. A 1 percent cap in growth in personnel years was the articulated limit. The board requested 10 personnel years (or nearly 20 percent of our current staff) through program augments, and another 7 personnel years to aggressively implement an Internet drug buy program due to the enactment of SB 1838.

1. BCP for 2000/01 (which was pursued as a "current year" augment)

Attorney General's Office - $383,000 requested to obtain increased AG hours to work board cases.

Status: Denied

The board is looking at a deficiency of about $400,000. The board is unable to redirect sufficient funding from other budget items to cover this deficiency; as such a deficiency augmentation will be sought.

2. BCPs for 2001/00

Enforcement

Consumer Complaint/Mediation Unit -- $189,000 requested augment

- Make permanent the two staff services analyst positions currently filled as temporary positions and add one new position for unit support -- $189,000. A toll-free number for consumers to reach the board will be added to the unit as well, but these costs are "absorbable" (about $1,800 a year, according to the department).

  Status: approved for 1 staff analyst position for $68,000

Attorney General's Office – obtain a one-year augment of $541,000 for 2001/02 and $371,000 ongoing

- Add money to work the backlog of cases awaiting board action and to more immediately complete cases referred there each year.

  Status: approved $541,000 for 2001/02 and $135,000 ongoing, starting 2002/03.

  If the board wishes to seek increased ongoing funding, it will need to do a BCP in July 2001.

Disapproved BCPs:

Enforcement:

Citation and Fine Program -- $134,000 requested augment

- Create one staff services analyst position and clerical support for the proposed expansion in the site and fine program (triggered by a regulation adopted by the board at the July 2000 board meeting to cite and fine for all violations of pharmacy law).

Impact on board: the board will have to implement the expanded citation and fine program without staff augment.

Licensing:

- Add one office technician position to assist with processing applications for individual licenses (the pharmacist, pharmacy technician, foreign graduate and intern programs for audit control, and to back up during periods of high workload) -- $67,000 augment requested
- Establish as a permanent position the office technician position for the wholesaler desk currently filled on a limited-term basis -- $68,000 augment requested
- Establish one office technician position for keeping current pharmacist-in-charge transactions required for all pharmacies -- $68,000 augment requested

Impact on board: the board will seek statutory changes to simplify the exemptee application process (eliminating the exam). The board will be unable to promptly process changes in PIC applications. The board will be unable to readily meet workload surges due to the pharmacist licensure exam as well as audit accountability when issuing permits to individuals.

Communication and Public Education:

- Establish an associate analyst position to oversee the public education program -- $87,000 requested

Impact on board: loss of momentum in its public outreach program as staff or board members have been unable to provide adequate staffing to keep the program running at a more visible level. Substantial reduction of educational materials to the public, and responding to press inquiries at an appropriate level.

Organizational Development:

- Establish in the department's Legal Office one-full-time attorney position dedicated solely to the Board of Pharmacy -- $119,000 requested

Impact on board: loss of much-needed specialization and legal advice to the board, including when reviewing complex ownership structures and in having an attorney attend compliance committee meetings.

- Communication Team Update

Inspector Robert Grimm reported that the Communications Team remains active in serving the staff by addressing work place improvement issues. Staff members continue to provide input to the TCT either anonymously or in person. The TCT then involves management in resolving the issues. Subject matter of the issues range from human relations to the physical facility to policy and procedures. The TCT also serves as the facilitator of quarterly staff meetings.

Recent Accomplishments:

1. The TCT has solicited and identified staff to coordinate "Bullet Proof" training for board staff.
2. An awards program to recognize tenure has been developed for board staff.

Mr. Grimm presented appreciation awards to Board Members Darlene Fujimoto, Don Gubbins and William Powers.

APPROVAL OF MINUTES

Full Board Minutes – October 18,19, 2001

MOTION: Approve the minutes as corrected

M/S/C: POWERS/ZIA

SUPPORT: 9 OPPOSE: 0

Northern Compliance Committee Minutes – November 7, 2000

MOTION: Approve the minutes as corrected

M/S/C: FUJIMOTO/GUBBINS

SUPPORT: 9 OPPOSE: 0

Southern Compliance Committee Minutes – September 26, 2000

MOTION: Approve the minutes as corrected

M/S/C: MAZZONI/JONES

SUPPORT: 9 OPPOSE: 0

Southern Compliance Committee Minutes – September 27, 2000

MOTION: Approve the minutes as corrected

M/S/C: JONES/ZIA

SUPPORT: 9 OPPOSE: 0

Southern Compliance Committee Minutes – October 24, 2000

MOTION: Approve the minutes as corrected

M/S/C: MAZZONI/ZIA

SUPPORT: 9 OPPOSE: 0

NEW BUSINESS/AGENDA ITEMS FOR FUTURE MEETINGS

Mr. Mazzoni reported that at the last Legislative and Regulation Committee meeting, two matters were not resolved. He asked that the following two items be placed on the agenda for discussion at the next April board meeting:

1. Modification of the board's regulation regarding the clerk-typist ratio

2. Modification of the board's regulation to allow a pharmacist-in-charge to be PIC of more than one pharmacy.

Mr. Zia requested that the board reexamine the concept of posting signs in a pharmacy when the pharmacy is on probation. Mr. Zia also asked for board approval to meet with members of the associations to get their input.

Mr. Elsner stated that as the Chair of the Public Education and Communications Committee, Mr. Zia has the authority to explore these issues with anyone.

PUBLIC COMMENT

John Cronin asked why the format of the minutes were changed to provide fewer details about the committee's discussions.

Ms. Powell stated that the purpose of the minutes are to provide a summary of the actions that were taken.

ADJOURMENT

There being no new business, President Elsner adjourned the meeting at 10:55 a.m.

CLOSED SESSION

The board moved into closed session pursuant to Government Code section 11126(c)(3) to consider the Petition for Reinstatement.