

**California State Board of Pharmacy** 400 R Street, Suite 4070, Sacramento, CA 95814-6237 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 & TIME:

April 29 and 30, 2003

LOCATION:

California Department of Consumer Affairs 400 R Street, Suite 1030 Sacramento, CA 95814

**BOARD MEMBERS PRESENT:** 

John Jones, President Donald Gubbins, Vice President Caleb Zia, Treasurer Dave Fong Stanley Goldenberg Clarence Hiura Steve Litsey William Powers John Tilley Andrea Zinder

STAFF PRESENT:

Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Dennis Ming, Supervising Inspector
Ron Diedrich, Deputy Attorney General
Dana Winterrowd, Department Legal Counsel

### Tuesday, April 29, 2003

#### CALL TO ORDER

President Jones called the meeting to order at 8:35 a.m. on Tuesday, April 29, 2003.

### **ANNOUNCEMENTS**

#### • Supervising Inspectors

President Jones announced that Joan Coyne and Dennis Ming were promoted into the two new supervising inspector positions. Dr. Coyne has been with the board eight years and will oversee the Pharmacists Recovery Program and the Probation Program. Dr. Ming has been with the board three years and will oversee the Sterile Injectable Compounding Pharmacy Licensure Program.

#### • Pharmacists May Obtain Six Hours of Continuing Education Credit for Attending One Full Day of a Pharmacy Board Meeting.

President Jones stated that continuing education hours may be earned by pharmacists who wish to learn more about the issues and operation of the board by attending a board meeting. A pharmacist may acquire six CE hours once a year by attending one full day of the board's quarterly meetings. (Board members are not eligible for this CE.) A pharmacist must attend the full business day of the board meeting to earn the continuing education credit; no partial credit will be given for attendance at part of a meeting.

This is the first meeting where CE has been offered.

### • Pharmacists Recovery Program

President Jones announced that effective July 1, 2003, the board will provide its Pharmacists Recovery Program through a new contractor. The new firm will oversee all such programs for the Department of Consumer Affairs' healing arts boards, except for that of the Medical Board. There should be no substantial program differences from the participants' or board's perspectives.

### Board Packets

President Jones stated that the board will no longer mail board packets to individuals, and instead will post the material on its Web site for viewing and downloading. President Jones added that board members will continue receiving board packets and the board agenda will continue to be mailed to interested parties.

### • Fred T. Mahaffey Award

• President Jones announced that the California State Board of Pharmacy has won the "Fred T. Mahaffey Award" from the National Association of Boards of Pharmacy. This award applauds a significant contribution to the protection of the public through the enforcement of state and federal laws that advance the NABP's goals and objectives. The board won the ward for its requirements for quality assurance program to evaluate and prevent prescription errors.

President Jones added that this is the second time that the board has won this award. The board received the first award in 1997 for its public education program.

# • Board Member Terms Expired

President Jones stated that effective June 2003, terms would expire for Board Members Steve Litsey and Caleb Zia. Both Dr. Litsey and Dr. Zia have served as board members for an additional one-year grace period after their terms expired in June 2002.

President Jones acknowledged Dr. Litsey who has served on the board since 1998 and was board president from 2001 to 2002. Dr. Litsey oversaw the implementation of a number of key legislative proposals including the quality assurance program regulations and the sterile injectable compounding licensing program. President Jones presented Dr. Litsey with an engraved clock to commemorate his achievements on the board.

President Jones acknowledged Dr. Zia who has served on the board since 1995 and oversaw the board's public education function including creation of *Health Notes*, the expansion of the board's Web site, development of the new "Notice to Consumers" poster and translation of the board's education materials into languages other than English and Spanish. Dr. Zia also has been a strong advocate of educational training for pharmacy technicians. Dr. Zia served as board treasurer for eight years. Dr. Zia also received an engraved clock recognizing his contributions to the board.

# **COMMITTEE REPORTS AND ACTION**

# LICENSING COMMITTEE

• Request from the Accreditation Commission on Healthcare for Approval to Accredit Pharmacies pursuant to Business and Professions Code section 4127.1(d)

Chairperson Fong stated that California law soon would require pharmacies compounding sterile injectable drug products to obtain a license from the board. In order to obtain such a license, the pharmacy must first be inspected by the board and found in compliance with board standards for sterile compounding. However, pharmacies that are accredited by the

April 29 and 30, 2003, Board Meeting - Page 3 of 32 pages

Joint Commission on the Accreditation of Health Care Organizations or other accreditation agencies approved by the board are exempt from the additional license requirements. Exempted pharmacies must still comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license.

The Accreditation Commission for Health Care (ACHC) requested approval as an accreditation agency by the board. The ACHC currently accredits both home infusion pharmacies and specialty pharmacies that deliver biotech drugs and other specialty products. The ACHC revisits each accredited entity every three years. Currently, 11 California pharmacies are accredited by the ACHC.

Chairperson Fong stated that during the Licensing Committee meeting on March 4, 2003, the committee discussed ACHC's request for approval by the board as an accreditation agency. Stuart Venook, representing ACHC, provided an overview of the accreditation process. He stated that the company reviews the pharmacy's policies and procedures in advance of the site visit, they observe nurses at the home, review patient records, and they validate the pharmacy's processes through the site visit and review the complaint log. ACHC is located in North Carolina and was formed as an alternative to JCAHO, which primarily accredits hospitals. He stated that they have over 400 clients in 43 states.

Chairperson Fong stated that the committee requested that ACHC submit additional information to be provided as part of the evaluation process. They requested the names of the 11 California pharmacies that are currently accredited, the number of pharmacies that have been denied accreditation or issued a "provisional" accreditation (and specifically any in California). Supervising Inspector Dennis Ming visited an ACHC accredited pharmacy. He also provided the board with a comparison analysis of JACHO's requirements and those of ACHC. The two agencies had markedly similar requirements.

- MOTION: That the Board of Pharmacy accept accreditation from the Accreditation Commission on Healthcare (ACHC) and thereby make pharmacies accredited by ACHC exempt from licensure pursuant to Business and Professions Code section 4127.1(d), with a five-year time limit.
- MSC: POWERS/GOLDENBERG

SUPPORT: 9 OPPOSE: 0

# • Proposed Criteria for Approval of Accreditation Agencies Pursuant to Business and Professions Code section 4127.1(d).

Chairperson Fong stated that in order to meet the requirements of the new law empowering the board with the ability to approve accreditation agencies, the Licensing Committee requested that criteria be developed under which to evaluate the agencies. The board's approval should be based on the accreditation agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards. The following factors were developed for board consideration when evaluating an agency: periodic inspections, documented accreditation standards, evaluation of surveyors' qualifications, acceptance of the accreditation by major payors, unannounced inspections of sites, board access to an accreditor's report on pharmacies, length of time in operation, ability to accredit in other states, length of accreditation and process for reaccredidation.

MOTION: Licensing Committee: That the Board of Pharmacy accept the criteria developed by the Licensing Committee as a guide when evaluating and approving accreditation agencies pursuant to Business and Professions Code section 4127.1(d).

SUPPORT: 9 OPPOSE: 0

• Implementation of the Licensure and Inspection Program for Pharmacies that Compound Injectable Sterile Drug Products

Chairperson Fong acknowledged Supervising Inspector Dennis Ming for the implementation of the injectable sterile compounding program. Chairperson Fong stated that the application forms are available on the board's Web site and the board has received five applications. To assist pharmacies with compliance, the board has developed a self-assessment form that will be available on the board's Web site as well. The initial licensure inspection will be by appointment and all inspectors will be trained on the inspection process. Training is set for the first week in May.

# • Report from the Ad Hoc Committee on Pharmaceutical Benefit Managers (PBM) Regulation

Chairperson Fong stated that at the January board meeting, the board created the Ad Hoc Committee on Pharmaceutical Benefit Managers (PBMs) Regulation. This committee is comprised of the board's public members and is functioning under the auspices of the Licensing Committee.

Mr. Powers stated that the first PBM meeting was held March 4, 2003. Minutes of the meeting were distributed. Mr. Powers stated that the second meeting is scheduled for June 4 and the committee will discuss recommendations as to the regulation of PBMs that will be presented to the board at the July 21 and 22 Board Meeting. Chairperson Fong facilitates the Ad Hoc Committee on PBMs.

#### **ENFORCEMENT COMMITTEE**

• Request to Amend CCR, title 16, sec. 1771(c) - Notification of the Patient and Prescriber When an Error Occurs

April 29 and 30, 2003, Board Meeting  $\,$  - Page 5 of 32 pages

Mr. Goldenberg stated that the California Society of Health-System Pharmacists (CSHP) requested that the Enforcement Committee consider its proposal to amend the quality assurance regulation adopted last year. The CSHP's position is that while the current version may work well in an ambulatory setting, it presents some logistical issues in the inpatient setting. Specifically, California Code of Regulation section 1711 requires the pharmacist to notify the patient and the prescriber that a medication error has occurred and the steps required to avoid injury or mitigate the error. In the inpatient setting there is concern about the potential for being cited for lack of compliance because a patient was not *immediately* notified of a medication error. Also, under current regulations, if a medication error were to occur, the patient and the prescriber must be notified immediately, but there is no requirement that the pharmacist and the prescriber collaborate in notifying the patient, or in proposing the next step(s). This may actually do the patient a disservice, by not requiring a collaborative effort in solving the problem.

Mr. Goldenberg stated that Kaiser Permanente also provided language modifications to the quality assurance regulation. The modification required that the patient be notified only if the wrong medication was administered or ingested. The committee stated that there are situations where a patient has received the wrong medication, but has not taken the medication. Nevertheless, it is still important that the patient and the patient's prescriber be notified, especially if it means that the patient has not received the appropriate medication, thus delaying therapy.

Chairperson Goldenberg suggested that stakeholders meet to develop language to bring to the board.

Morton Farina, pharmacist, stated that many patients often use several different pharmacies to fill their prescriptions making it even more important to communicate to patients and their prescribers when an error occurs.

- MOTION: Refer any proposed modification to the Enforcement Committee for consideration, and encourage language from various stakeholders to amend California Code of Regulation section 1771(c). for board consideration at the July 2003 Board Meeting.
- MSC: TILLEY/HIURA

SUPPORT: 9 OPPOSE: 0

# • Enforcement Options Regarding the Importation of Prescription Drugs from Canada through Storefront Facilities

Chairperson Goldenberg stated that recently storefront operations such as Rx Depot, Rx Canada, and American Drug Club have opened in California for the primary purpose of

April 29 and 30, 2003, Board Meeting - Page 6 of 32 pages

facilitating the shipment of prescription drugs from Canadian pharmacies to California patients.

According to the federal Food and Drug Administration (FDA), the importation of prescription drugs is illegal under federal law and the (FDA) is responsible for enforcing this law. However, until March 2003, the FDA had not taken any action. Obtaining discounted prescription drugs from Canada attracts more than 2 million Americans per year. Some patients claim they can save up to 80 percent on their prescription drug costs. Purchasing drugs from Canada has been vigorously endorsed by congressional representatives and other elected officials. Seniors state that for many it is their only option for obtaining their prescription medication. There has been no documented evidence of any patient being harmed from receiving prescription medications from Canada.

Last month, the FDA in collaboration with the Arkansas State Board of Pharmacy issued a warning letter to the storefront operations in that state advising that the FDA considers operations to be illegal and a risk to the public health. The FDA stated its concerned that the firms were making misleading assurances to consumers about the safety of their drugs. The FDA acted in conjunction with the Arkansas board, which also issued a letter instructing the firms to cease violating state law immediately. Also, the Okalahoma Board of Pharmacy in conjunction with its Attorney General sought injunctive relief against a storefront operation in that state.

The FDA believes that these storefront operations expose the public to the significant potential risks associated with unregulated imported prescription medications. Many of these storefront companies often state incorrectly to consumers that the FDA condones their activities and even that their prescriptions are FDA approved, which may lead consumers to conclude mistakenly that the prescription drugs sold by the foreign pharmacies have the same assurance of safety as drugs actually regulated by the FDA because the medications are not subject to FDA's safety oversight, they could be outdated, contaminated, counterfeit, or contain too much or too little of the active ingredient. In addition, foreign dispensers of drugs to American citizens may provide patients with incorrect medications, incorrect strengths, medicines that should not be used in people with certain conditions or with other medications, or medications without proper directions for use.

Mr. Goldenberg asked if the storefronts provide medication directly to patients, and are the patients required to have a prescription from their health care providers. He recommended that the board obtain a legal opinion to determine the board's role.

Mr. Powers expressed concern that Congress is not acting responsibly to regulate prescription drugs by establishing pricing controls. Many consumers, especially seniors, cannot afford to purchase their prescriptions in California and often must make hard choices on whether to spend their money on prescription drugs or spend the money on

housing, food, etc. The most important issue for regulators should be to protect patient health. He added that to his knowledge there have not been any problems with the drugs that come from Canada.

Mr. Goldenberg requested public comment.

John Cronin stated that purchasing drugs from Canada is illegal but asked who is enforcing the law. He stated that the Board of Pharmacy does have this authority and has enforced laws regarding distribution of drugs over the Internet. He added that with maintenance medications it might be difficult to know if a medication is counterfeit and the patient has failed to receive prescription drug therapy.

Gary Passmore, representing Congress of California Seniors, stated that he recognizes that seniors need access to safe and affordable prescription drugs in California. He suggested that the board take a balanced approach to find the best solution. He stated that many consumers are buying prescription drugs in Canada out of desperation and if the option to purchase prescriptions in Canada is removed, other means might be used that may not be as safe and could place consumers at even greater risk. Mr. Passmore suggested that the board take an aggressive approach with the pharmaceutical manufacturers and lobby the Legislature to create programs that would help solve this problem.

Mr. Passmore stated that the Congress of California Seniors' position is that the storefronts are not breaking the law anymore than teaching people to use the Internet. But the board should go after "fly-by-night operations."

Mark Yeung, representing the Greenlining Institute, submitted written testimony dated April 29, 2003.

On behalf of the Greenlining Institute, a statewide nonprofit public policy advocacy coalition of thirty-nine church, business, consumer and civil rights organizations as well as Greenlining's health project, Bridges to Health, which strives to ensure that all Californians have access to affordable health care and access to affordable prescription drugs.

We are shocked that the California Board of Pharmacy is considering a President Bush anti-consumer position that will prevent America's poor and senior citizens from obtaining life-saving medicines at prices afforded to Canadians.

What this Board should do is recommend to Governor Davis, the Secretary of State and Consumer Services methods by which all Californians can obtain the same drugs at the same prices that Canadians pay. Californians could save \$12 billion a year and our State's health programs could save two billion a year or more.

The vast majority of this Board of Pharmacy is appointed by the Governor. Therefore, we hold the Governor and his cabinet responsible for your actions. We believe that at a minimum, the Board, in coordination with the Governor and the Secretary of State and Consumer Services take the following actions:

- 1. Joint consumer groups to obtain from Attorney General Bill Lockyer a legal opinion that will allow the State, independent Indian nations, and consumer nonprofits to obtain prescription drugs at the same prices Canadians pay or in the alternative, to purchase directly from Canada.
- 2. The Governor should support, along with senior citizens and consumer groups, legislation that will allow our sovereign State, the 5<sup>th</sup> largest economy in the world, and an economy far greater than Canada, to require pharmaceutical companies to see prescription drugs at the lowest price available in the Western hemisphere.

As a first step, Greenlining and other consumer groups have discussed this issue with the Governor's staff, the Secretary of State and Consumer Affairs, Senator Richard Alarcon and Attorney General Bill Lockyer. We are also in the process of meeting with leaders of Indian nations that have clear legal authority to import prescription drugs from Canada and sell them at reduced Canadian prices.

We urge this board to stop being controlled by the Bush administration's FDA. We urge this Board to become advocates for all Californians, particularly the poor, and we urge the Board to have a plan that will enable Californians to save \$12 billion a year and help solve our budgetary crisis.

#### • Written Testimony dated April 29, 2003, provided by Maria Christina Salem, Chairperson for Senior Action Network

The FDA does not represent senior citizens' interests. It represents the interests of global pharmaceutical companies. Therefore, this Board of Pharmacy should not be carrying out the pharmaceutical industry's agenda by blocking senior citizens from importing drugs from Canada. Instead, this Board should be asking the Governor and the Governor's cabinet secretary for help in ensuring that all Californians can save \$12 billion a year through the importation of prescription drugs from Canada. We urge the Governor to make this one of his highest priorities. We urge the Governor to set up a meeting with seniors, low-income consumers, church and consumer groups and possibly Indian nations to discuss a plan to work together to save California \$12 billion a year.

#### Written Testimony dated April 29, 2003, provided by Icela Pelayo, representing Hermandad Mexicana Nacional

April 29 and 30, 2003, Board Meeting - Page 9 of 32 pages

When your Executive Officer, Patricia Harris, told the *San Francisco Chronicle* that she was advocating the Bush Administration's anti-consumer position, no one consulted with the Latino or immigrant community. We hold your Executive Officer, the Secretary of Consumer Affairs, and the Governor responsible for this neglect.

We urge you to make amends. First, issue a statement that protects and encourages all persons that seek to import drugs from Canada at affordable prices. Second, urge Governor Davis to ensure that a Latino, representing the immigrant community, is appointed to the Board of Pharmacy, since there is a pending vacancy. Third, have the next Board of Pharmacy meeting at a location that will allow the poor to be effectively represented, including ensuring that the proceedings are multilingual.

# • Mister Phillips, Legal Fellow, Greenlining Institute and graduating law student at University of California Hastings Law in San Francisco, offered the following testimony:

Mr. Phillips stated that the Board of Pharmacy does not have African American representation on the board. It also needs to develop drug policies to aid the public in getting lower cost drugs.

Dr. Zia stated that he was appointed to the board for his contacts with minority groups. It is his position to consider consumers and especially minority consumers when making board decisions and he considers himself to be a spokesman for all minorities. He added that the board must determine the cause of why drugs are more expensive in California.

### • Morton Farina, Pharmacist

Mr. Farina stated that pharmacists are highly trained and capable of reviewing a patient's drug regimen with the physician to assure that the patient is not taking unnecessary prescriptions. Eliminating unnecessary medications would help reduce prescription drug cost.

# • Lucille Blasta

Lucille Blasta, representing the California Women's League, stated that she buys her prescription drugs from Canada because the five drugs she takes costs \$3,000 per year in California and the same drugs purchased in Canada are \$1,000. She stated that she has not had any problems with the drugs that she receives from Canada.

# • Karen Rauch

Karen Rauch, representing the Gray Panthers and AARP, stated that the costs of prescription drugs are an unjust issue to seniors.

# • Don Sherral

Don Sherral stated that direct-to-consumer advertising by manufacturers has resulted in consumers taking more prescription drugs and this also drives up the cost of prescriptions. The drug manufactures have put pressure on the board to support their issues, now consumers are putting pressure on the board to support them.

Dr.. Hiura stated that as a senior citizen, he understands the issue that consumers face but he expressed concern that there is a risk to purchasing drugs from Canada and the cost savings is not worth the risk.

Mr.Tilley stated that as a pharmacy owner, he sees consumers daily who must make hard choices between purchasing their prescription drugs and paying rent or buying food. The system is flawed and unfortunately, seniors and those who cannot afford their medications suffer the most. He stated that perhaps California pharmacies should be allowed to purchase drugs from Canada, which would be less expensive than wholesale prices.

Ms. Zinder recommended that the board seek more information on this issue before a decision is made.

Dr. Fong stated that the board has the responsibility to educate and inform the public as well. He encouraged the board to move forward and to be engaged in the issue.

Mr. Powers suggested that the board produce a brochure on the issue of importation of drugs from Canada that outlines current law and address questions consumers should be asking.

President. Jones stated that the Department of Consumer Affairs has offered their resources to assist the board in public outreach efforts.

Chairperson Goldenberg suggested that along with presenting information to the public, the board should try to evaluate this complex situation comprehensively, and have policy and procedures that help to motivate other decision makers to take action where action has not been taken.

Mr. Powers stated that the board should seek solutions to find affordable prescription drugs.

Mr. Steinberg stated that he promotes the purchase of prescription drugs from Canada and suggested that the board produce a brochure translated in many languages to protect seniors. The board should also consider a larger education program than simply handing out brochures. He suggested that a surcharge be placed on pharmaceutical companies to avoid price gouging.

MOTION:	That the Board of Pharmacy develop an educational brochure on purchasing drugs from outside the US and ways to reduce drug costs.

M/S/C: POWERS/ZINDER

SUPPORT: 9 OPPOSE: 0

## • Implementation of Federal HIPAA Requirements

Mr. Goldenberg stated that at the last board meeting, it was reported that licensees were seeking clarification about their obligation to account for the disclosure of protected health information (PHI) when an inspector reviews this information during a routine inspection. Licensees stated that they were unclear about when such a release of patient information must be documented. Inspectors may skim through hundreds of hard copy records and/or computerized files in one inspection. Concern was expressed that the time to document each viewing will add a significant amount of time to the inspection process, increasing the burden and impeding the ability of the board to perform a thorough inspection.

The National Association of Boards of Pharmacy wrote to the director of the Office of Civil Rights requesting guidance in this area. The NABP expressed concern that such a requirement would adversely affect patient care as pharmacies divert time away from patient care activities in an attempt to comply with this accounting requirement, without a resulting enhancement of the confidentiality of patient records. The NABP asked for a supporting position that a standard investigatory review of prescription files (quick viewing of or skimming) would not constitute disclosure for which an accounting is then required.

Richard Campanelli, the director of the Office of Civil Rights, responded to the NABP on April 1, 2003. He concluded that the "skimming" of patient files by state investigators is a disclosure of protected health information, and such disclosures must be included in an accounting of disclosures if requested by the patient.

Chairperson Goldenberg stated that under the guidance of Staff Counsel Dana Winterrowd, the board would be revising its inspection form to include a written statement advising licensees of the board's authority to perform an inspection. Upon the completion of an inspection, the inspector will provide to the licensee those patient records that were reviewed so that the licensee can make a proper accounting of the disclosure.

When the inspector is performing an investigation, the inspector will provide a medical release for the protected patient information, an investigative subpoena, or an investigative demand. The investigative demand will include a statement of facts demonstrating why the information is relevant and why de-identified information cannot reasonably be used. The receipt that the inspector provides for the records can be used by the licensee to account for the disclosure.

## • Task Force with Medical Board of California on Prescriber Dispensing

Chairperson Goldenberg stated that at the October 2002, board meeting, a task force was formed with the Medical Board of California on the issue of prescriber dispensing. The boards agreed to the task force after a meeting on this issue last September with the Department Director Kathleen Hamilton and other interested parties.

The purpose of the meeting was to discuss a recent Court of Appeal decision that concluded that Pharmacy Law does not prohibit a physician from dispensing or selling drugs on a for-profit basis to his or her patients for the condition for which the patient sought treatment. The California Medical Association (CMA) requested that the following issues also be addressed regarding dispensing by physician groups: accountability, ordering of drugs, common storage, and the use of an assistant for dispensing.

It is the board's position that there is no authority for a group of physicians to purchase prescription drugs for communal use, except as specifically authorized by law. There is disagreement with this interpretation and thus the request from CMA to address the commingling of drugs by physician groups.

For background information, the Enforcement Committee drafted a Compliance Guide on prescriber dispensing that was discussed at its public meetings in July 2000 and September 2001. Essentially the Compliance Guide stated that the issue of prescriber dispensing for profit was the jurisdiction of the Medical Board of California and that the dispensing of drugs by physicians groups (where the drugs are commingled) is the practice of pharmacy and falls within the jurisdiction of the Board of Pharmacy. The Board of Pharmacy has yet to take a formal position on this compliance guide.

Chairperson Goldenberg stated that Board of Pharmacy representatives would be John Jones and Stan Goldenberg. The Medical Board representatives will be Steve Rubins, M.D. and public board member Lorie Rice (Associate Dean at the UCSF, School of Pharmacy and former executive officer for the Board of Pharmacy).

The meeting date and location has not been finalized. However, when it has, the meeting will be publicly noticed.

# PUBLIC EDUCATION AND COMMUNICATIONS COMMITTEE

Chairperson Powers reported that the Public Education Committee met April 8, 2003, in a teleconferenced meeting.

Chairperson Powers reported that the March 2003 *The Script* was printed and mailed to California pharmacies and placed on the board's Web site for downloading. The next issue will be published during the summer of 2003. Consultant Hope Tamraz will write the articles.

The CPhA's Education Foundation is printing and mailing the March 2003 issue to California pharmacists. The board is grateful for this collaboration and assistance.

Chairperson Powers reported that the "Drug Therapy Considerations in Older Adults" issue of *Health Notes* has been printed and is being mailed this month. This issue was developed by UCSF with federal funding, and the CSHP obtained a grant to print the issue. The board will pay for postage and graphic design services.

# LEGISLATION AND REGULATION COMMITTEE

### • Adoption of Amendments to CCR 1775 et seq. – Citation and Fine

Chairperson Litsey added that one recommendation of the Joint Legislative Sunset Review Committee was for the board to revise its citation and fine process to designate the executive officer as the issuing authority for citations and fines. This would make the Board of Pharmacy's practices consistent with other boards in the Department of Consumer Affairs. The board has proposed modifications to regulation to implement this recommendation.

Chairperson Litsey stated that the notice of proposed action to amend the board's cite and fine regulation was published on February 21, 2003, and the 45-day comment period closed on April 7, 2003. The regulation was noticed without a regulation hearing and no hearing was requested by anyone. The board also received no comments during the 45-day written comment period. The Office of Administrative Law (OAL) must approve the proposed regulation changes before they become effective.

Mr. Fong stated that from a licensee's standpoint, the language clearly outlines how the citation and fine process works.

John Cronin, representing the California Pharmacists Association (CPhA), stated that the CPhA did not request a hearing on this regulation and that they understand the need for formulization of the cite and fine process based on the recommendation from the Joint Legislative Sunset Review Committee.

MOTION: Legislation and Regulation Committee: Adopt the proposed regulation to revise the citation and fine process to permit the executive officer to issue citations and fines (section 1775 et seq.). (Note: See attached language).

SUPPORT: 9 OPPOSE: 0

• Consideration to Sponsor the Addition of Section 4106 in the Annual Omnibus Bill

Chairperson Litsey stated that the Legislation and Regulation Committee suggested language to reduce workload associated with providing license verification to interested

April 29 and 30, 2003, Board Meeting - Page 14 of 32 pages

parties to allow license verifications from the board's Web site to be accepted by those needing to verify licensure. This would be faster for the requestor and result in fewer verification requests being submitted to board staff. This is particularly of concern for wholesalers wishing to ship prescription drugs to newly licensed pharmacies.

Ms. Harris added that the board is in the process of creating a public disclosure screen on the Web site that would display disciplinary actions. She added that this process is in a testing phase where all probationers will be initially listed. It is anticipated that the disclosure screen will be on the board's Web site in approximately three months.

- MOTION: Legislation and Regulation Committee: Seek to add section 4106 to the Business and Professions Code as follows:
  - <u>4106:</u> For purposes of license verification, a person may rely upon a printout from the board's Web site that includes the license issuance and expiration dates, of any board-issued license.

SUPPORT: 9 OPPOSE: 0

#### • AB 103 (Reyes) – Drug Marketing

Chairperson Litsey stated that as amended April 22, 2003, this bill would prohibit "inappropriate marketing" of prescription drugs by drug manufacturers to health professionals and others with influence over prescription drug prescribing.

Chairperson. Litsey stated that this bill codifies pharmaceutical marketing guidelines and defines inappropriate marketing behavior. Enforcement of inappropriate marketing behavior would fall on the Board of Pharmacy.

Mr. Powers recommended a support position on this bill and to impose a fee on manufacturing companies to pay for the expenses linked with the proposed provisions.

The board discussed the issue and why California would need additional guidelines if federal guidelines are in place. Since the board does not regulate drug manufactures, this would expand the scope of the board's mandate. There was concern that there were no enforcement sanctions answered.

The board recommended that board staff work with the author of the bill towards a support position on this bill.

MOTION: Oppose AB 103 (Reyes) unless amended and board staff should work with the author's office on amendments to work towards a support position.

April 29 and 30, 2003, Board Meeting - Page 15 of 32 pages

M/S/C: POWERS/FONG

SUPOPORT 9 OPPOSE 0

#### • AB 261 (Maddox) – Backroom Clinics

Chairperson Litsey stated that this bill would increase the penalty for unlicensed dispensing of dangerous drugs or dangerous devices to include the option of felony prosecution. He added that the sponsors believe that the public health threat posed by backroom clinics warrants granting prosecutors the opportunity to charge these cases as felonies.

MOTION: Legislation and Regulation Committee: Support AB 261 (Maddox).

SUPPORT: 9 OPPOSE: 0

### • AB 521 (Diaz) – Drug Information

Mr. Riches stated that AB 521 is sponsored by the California Congress of Seniors and the Senior Legislature to educate seniors about their medications. Mr. Riches stated that as amended April 22, 2003, the bill would add a provision to existing law that requires pharmacists (either orally or in writing) to advise patients of the harmful effects of a drug when those effects impair one's ability to drive a vehicle or when taken in conjunction with alcohol.

This bill would require any drug that is listed in board regulations that have an interaction with another drug or prescription or non-prescription drug to trigger either oral or written notification of those interactions. If provided in writing, the written notification must be provided in a 12-point type font.

Mr. Goldenberg expressed concern that this bill would place an additional burden on the pharmacy without consumer benefit because drugs do interact with other drugs; it is significant interactions or adverse interactions that should be discussed.

Mr. Riches responded that this would apply to any prescription dispensed, including mail order prescriptions.

Mr. Goldenberg stated that if there is a problem with the current method of counseling patients, the board should specifically address the issue.

Mr. Powers stated that the board has a responsibility to respond to the Legislature and this requirement might help consumers to be better informed about taking their prescriptions. He added that it might not be the best solution for everyone.

Mr. Powers stated that the SMARxT program educates consumers about prescription drugs and interactions with other medications, including over-the-counter medications. The SMARxT program also encourages consumers to contact their pharmacist for advise on their prescription medications. Mr. Powers added that the problem remains that many people are harmed by incorrectly using their prescription drugs.

Rich Mazzoni, representing Albertsons, expressed concern that this requirement would result in an added expense to the pharmacy, an increase the amount of paper work and programming needed to generate the required documentation for the pharmacy. He added that this bill is broadly written and would diminish the value of the pharmacist because too much information would be provided with every medication, making it harder to identify important information.

Steve Gray, representing Kaiser Permanente, expressed concern that AB 521 seems to establish a different standard of practice. He added that the current statute requires that a warning be given with drugs that interact with alcohol to cause harmful effects. The language in the bill refers to other medications including non-prescription drugs that need to be included in the warning. Mr. Gray stated that it would be impossible to convey all of this information without the use of a computer and the database would not include non-prescription drugs. Mr. Gray stated that Kaiser's position is that pharmacists know critical drugs and the critical non-prescription drugs that interact with them.

Mr. Gray stated also expressed concern about the written requirement to use a 12-point type font.

MOTION:	Take no position support AB 521 (Diaz) as amended April 22, 2003.			
M/S/C:	ZIND	ER/POWERS		
SUPPORT:	4	OPPOSE:	5	

### • AB 746 (Matthews) – Medi-Cal Fraud

Chairperson Litsey stated that this bill would require health professional licensing boards (including the Board of Pharmacy) to revoke a license if the licensee is convicted of more than one charge of Medi-Cal fraud.

Chairperson Litsey stated that the Legislation and Regulation Committee recommends a support position on AB 746 because it grants the board greater authority to take disciplinary action against licensees convicted of Medi-Cal fraud.

MOTION: Legislation and Regulation Committee: Support AB 746 (Matthews).

SUPPORT: 9 OPPOSE: 0

#### • AB 1363 (Berg) – Hypodermics

Chairperson Litsey stated that this bill is intended to increase the availability of clean needles and syringes to reduce the transmission of blood-borne diseases such as hepatitis and HIV. The bill would accomplish this by both removing the prescription requirement for needles and syringes and broadening the law permitting clean needle exchange programs operated by local governments.

MOTION: Legislation and Regulation Committee: Support AB 1363 (Berg).

SUPPORT: 9 OPPOSE: 0

#### • AB 1460 – Nation) – Laboratory Directors

Chairperson Litsey stated that this bill would permit pharmacists to act as a laboratory director if they receive training required of laboratory directors and the laboratory performs only waived tests.

Chairperson Litsey stated that the Legislation and Regulation Committee recommends a support position on this bill because it intends to provide pharmacists with greater ability to manage patient's drug therapy.

MOTION: Legislation and Regulation Committee: Support AB 1460 (Nation).

SUPPORT: 9 OPPOSE: 0

#### • SB 151 (Burton) – Triplicate Prescriptions

Chairperson Litsey stated that this bill would repeal the requirement for the triplicate prescription form and would substitute a forgery and counterfeit resistant prescription form. The committee recommends a support o this legislation based upon the board's longstanding policy favoring the repeal of the triplicate requirement for Schedule II controlled substance prescriptions.

This bill would repeal the triplicate after a transition period of approximately 6 months, and replace it with a forgery and counterfeit resistant prescription pad for all controlled substances (schedules I-V).

President Jones stated that this bill would eliminate paperwork, benefiting pharmacy practices and law enforcement and he expressed support of the bill.

April 29 and 30, 2003, Board Meeting - Page 18 of 32 pages

MOTION: Support SB 151 (Burton) – Triplicate Prescriptions.

SUPPORT: 9 OPPOSE: 0

# • SB 175 (Kuehl) – Veterinary Drugs

Chairperson Litsey stated that this bill would redefine "dangerous drugs" to include veterinary drugs and include veterinarians in existing prescriber dispensing statutes. Chairperson Litsey stated that SB 175 would clarify the board's regulatory authority over veterinary drugs. He added that the recommended amendments provided in the board packet would make technical changes to the bill.

Mr. Riches stated that the board has worked with the Veterinary Medical Board and Veterinary Medical Association during the past year and this bill closes the ambiguity in current law.

MOTION:	Legislation and Regulation Committee: Support if amended, SB
	175 (Kuehl) – Veterinary Drugs

SUPPORT: 9 OPPOSE: 0

### • SB 361 (Figueroa)

Chairperson Litsey stated that as introduced, this bill provides a vehicle for the Board of Pharmacy's extension of its program and contains statutory recommendations approved by the Joint Legislative Sunset Review Committee.

Chairperson Litsey stated that this bill would be discussed during the Organizational Development Committee portion of the board meeting.

### • SB 393 – (Aanestead) – Technician Checking Technician

Chairperson Litsey stated that the Legislation and Regulation Committee recommends a support if amended position on this bill because it implements much of the board's existing policy supporting technicians checking technicians in hospitals. The committee recommends an amendment specifying the training required for pharmacy technicians who are permitted to check technicians in statute rather than in board regulations.

Teri Miller, representing the California Society of Health System Pharmacists, stated they provided language to staff and intend to incorporate the language into the bill that would specify training requirements so the board would not have to go through the regulatory process to establish training requirements.

MOTION: Legislation and Regulation Committee: Support if amended, SB 393 (Aanestead) – Technicians Checking Technicians.

SUPPORT: 7 OPPOSE: 0 ABSTAIN: 2

#### • SB 545 (Speier) – Emergency Contraception

Chairperson Litsey stated that this bill would delete the training requirement for dispensing emergency contraception under protocol and would limit pharmacists' judgment regarding appropriate patient consultation. The committee expressed concern that the bill does not recognize the practice of pharmacy outside of a pharmacy. The committee recommends amendments restoring the training requirements and deleting the restrictions on patient consultation.

Mr. Riches stated that this bill is in response to objections that some pharmacists began charging high separate consultation fees for this practice following enactment of emergency contraception legislation allowing pharmacists to dispense to patients without a specific prescription.

Mr. Cronin stated that if pharmacists were not paid for these services, few pharmacists would do it decreasing patient access to emergency contraception.

Mr. Cronin stated that the CPhA opposes SB 545 and encouraged the board to oppose.

Ms. Miller stated that the CSHP also opposes this bill unless it is amended because pharmacists cannot provide a service for which they are not paid.

Mr. Gray stated that emergency contraception is being provided by student health services, by community free clinics and by other pharmacists working in non-pharmacy environments. Mr. Gray stated that Kaiser did a study concerning the cost to implement the service and the cost varied according to the age of patients whereas younger patients require more time. He added that many pharmacies are providing this service without separate fee as part of a public service and some pharmacies charge only \$10.

MOTION:	Legislation and Regulation Committee: Oppose unless amended on SB 545 (Speier) – Emergency Contraception				
SUPPORT:	4 OPPOSE: 5				
MOTION:	That the Board of Pharmacy take no position on SB 545 (Speier) – Emergency Contraception				
M/S/C:	ZINDER/ZIA				

April 29 and 30, 2003, Board Meeting - Page 20 of 32 pages

SUPPORT: 3 OPPOSE: 6

President Jones stated that this bill diminishes the board's accomplishments on the issue of emergency contraception because it no longer makes it a requirement for special education and prohibits charging for services where these services are wanted and needed.

Mr. Zia stated that this is a free country we should not be subjected to any regulation that forces you to do something that you are morally opposed to.

MOTION: Oppose SB 545 (Speier) – Emergency Contraception M/S/C: JONES/TILLEY SUPPORT: 6 OPPOSE: 3

#### • SB 774 (Vasconcellos) – Hypodermic Needles

Chairperson Litsey stated that SB 774 would expand access to clean needles and syringes. This bill repeals the requirement for a prescription to purchase hypodermic needles and syringes at retail and permits individuals who are 18 years of age or older to purchase up to 30 hypodermic needles and syringes in a single transaction.

Dr. Fong expressed concern that SB 774 requires pharmacies that sells needles to provide onsite disposing of needles. This makes an additional record-keeping requirement and reporting of the number of needles sold each month.

MOTION:	Legislation and Regulation Committee: Support SB 774 (Vasconcellos) – Hypodermic Needles				
SUPPORT:	5	OPPOSE:	5		
MOTION:	Support SB 774 (Vasconcellos) if amended to address the disposal problems and record keeping problems.				
M/S/C:	FONG	G/JONES			
SUPPORT:	8	OPPOSE:	0	ABSTAIN:	1

#### • SB 490 (Alpert) – Emergency Contraception

April 29 and 30, 2003, Board Meeting - Page 21 of 32 pages

Chairperson Litsey stated that this bill would provide that a pharmacist might dispense emergency contraception either under a protocol with a physician or pursuant to a protocol approved by the Board of Pharmacy and the Medical Board. The bill would require a pharmacist to obtain specified training before furnishing emergency contraception

Mr. Riches stated that this legislation has been largely modeled after similar requirements in New Mexico. Physicians are hesitant to enter into these protocols and sponsors believe that this limits availability to patients. A statewide protocol has been proposed as a solution.

MOTION:	Legislation and Regulation Committee: Support SB 490 (Albert) – Emergency Contraception.			
M/S/C:	POWI	ERS/JONES		
SUPPORT:	9	OPPOSE:	0	

#### • SB 506 (Sher) – Animal Drugs

Chairperson Litsey stated that this bill would require the board to collect reports of wholesale sales of all antibiotics in California.

Mr. Riches stated that the author of SB 506 is concerned about antibiotic misuse and the problems it poses such as drug-resistant bacteria and other public health issues. The first step in gathering information about the problem.

Mr. Riches stated that staff has concerns with this bill because it is proposing a new program at a time when the board is facing severe staff and budgetary cutbacks.

MOTION: Oppose SB 506 (Sher) M/S/C: TILLEY/JONES SUPPORT: 9 OPPOSE: 0

#### • Recently Approved

#### Section 1717(e) – Delivery of Medications

This regulation eliminates the waiver process established by 1717(e). The waiver process permitted pharmacies to depot drugs for delivery to patients at non-pharmacy locations. Instead, the regulation now permits pharmacies to depot drugs at any location where the patient receives health care services. This regulation became effective March 12, 2003.

April 29 and 30, 2003, Board Meeting - Page 22 of 32 pages

### Section 1720.4 – Foreign Graduates

This regulation specifies procedures for foreign graduates who cannot obtain verifiable transcripts to become eligible to take the pharmacist license examination. This regulation became effective March 13, 2003.

## Section 1745 – Partial Filling of Schedule II Prescriptions

This regulation updates the board's requirements for partial filling consistent with recent statutory changes to Schedule II prescription requirements. This regulation took effect March 12, 2003.

### • Pending Regulations

#### Section 1732.05 – Continuing Education

This regulation will recognize continuing education credits approved by other California health professions licensing boards. The 15-day comment period closed on March 28, 2003.

#### Section 1751 – Sterile Compounding

This regulation will establish guidelines for the compounding of sterile drug products. The 45-day comment period ended on April 7, 2003. The board adopted amendments with modifications during today's hearing. These changes will be noticed for a 15-day comment period.

#### Section 1775 – Citation and Fine

This regulation designates the executive officer as the issuing authority for citations and fines. The 45-day comment period ended on April 7, 2003. The board adopted amendments earlier during this board meeting. The rulemaking file will be compiled and submitted after this board meeting.

#### • Awaiting Notice

### Section 1707.5 – Hospital Central Fill

This regulation will permit central refill operations for hospitals. The board conducted an informational hearing at October 2002 board meeting.

### Section 1709.1 – Pharmacist-in-Charge at Two Locations

This regulation will permit a pharmacist to serve as pharmacist to serve as pharmacist-incharge at two locations.

### Section 1715 – Pharmacy Self Assessment

This regulation will update the pharmacy self assessment form to reflect recent changes in pharmacy law.

### Section 1717.4 and 1717.2 – Electronic Prescriptions and Electronic Records

This regulation will make changes to board regulations to conform them changes enacted in to Assembly Bill 2240 and require that pharmacists confirm the authenticity of any electronic prescription in which there is an uncertainty or ambiguity. It will also repeal section 1717.2; the notice to consumers required by this section has been superseded by amendments to California law that substantially strengthened privacy protections.

#### Section 1717.4 – Authentication of Electronic Prescriptions

This regulation will require pharmacists to authenticate electronic prescriptions before filling.

#### Section 1764 – Wholesaling

This regulation will impose dollar volume limits on wholesale drug transfers by pharmacies, impose dollar volume limits on transfers between wholesalers, and require pedigrees for drug shipments under specified circumstances. The Enforcement Committee conducted an informational hearing on this proposal at its December 2002 meeting. Currently the Enforcement Committee is reworking the proposal.

#### • Section 1793.3 – "Clerk-Typist" Ratio

This regulation will eliminate the clerk/typist ratio.

Chairperson Litsey acknowledged all of the efforts of Paul Riches to oversee board legislative and regulatory efforts.

### ORGANIZATIONAL DEVELOPMENT COMMITTEE

#### **Board President's Report**

• Board Wins National Association of Boards of Pharmacy's (NABP) Fred T. Mahaffey Award

President Jones announced that the board had won the NABP's Fred T. Mahafey Award for the board's efforts in developing the quality assurance program requirements for prescription errors. This is the second time in six years that the board has won this award.

# • Mandatory Ethics Training for Board Members and Designated Staff must be completed in 2003

President Jones stated that board members and designated staff must periodically take state-mandated ethics training. This training must be completed during 2003, and is available from the Internet or via videotape.

#### • Status of Strategic Plan Revision for 2003/04

President Jones stated that the board will revise and update its strategic plan during the next day session of the board meeting and encourages public input in this process. Consultant Lindle Hatton will lead the board in this effort.

#### • Public Outreach Program

President Jones stated that the board has continued public outreach efforts including the first presentation of a continuing education program for pharmacists at CPhA's Annual Meeting and another at the San Diego Chapter of the California Pharmacists Association. President Jones stated during these outreach programs, special interest is on how inspectors conduct their investigations and what they are looking for when they come into a pharmacy. This was a popular presentation. It also allows pharmacists to ask specific questions regarding their particular type of practice and obtain answers from the board. More of these presentations are planned.

#### • Sunset Review Process

President Jones stated that on April 2, the Joint Legislative Sunset Review Committee (JLSRC) held its hearing on its staff recommendations for the board. Incorporated into these recommendations were draft recommendations of the Department of Consumer Affairs (they were draft recommendations because the Administration had not yet approved them). During the hearing, the board concurred with the recommendations of the JLSRC.

On April 7, the Joint Legislative Sunset Review Committee voted 5-0 to adopt the recommendations of the JLSRC staff. The recommendations arising from the sunset review are an aggregate of recommendations of the Department of Consumer Affairs and the JLSRC. The recommendations are:

1. The licensing and regulation of the pharmacy profession should be continued and a board structure should be maintained.

April 29 and 30, 2003, Board Meeting - Page 25 of 32 pages

- 2. Add two public members to the board.
- 3. Make all committee meetings of the board public meetings.
- 4. The board should adopt the NAPLEX.
- 5. Modify the citation and fine program to exclude the involvement of board members and delegate to the executive officer the authority to issue citations and fines.
- 6. The board should not require all its investigators to be pharmacists.
- 7. The board should use the department's online consumer complaint form.
- 8. The board should expand its consumer outreach and education, and work with the department to develop additional materials.
- 9. The board should establish a reliable method of communicating and surveying those who have filed complaints, and review its survey instrument to provide meaningful data.
- 10. The board should work with the department's Office of Privacy Protection on ensuring patient privacy.

Chairperson Gubbins stated that the Organizational Development Committee supports the board's proposal to revise the program requirements for pharmacy technicians and that the board continues to accept graduation from schools of pharmacy and the elimination of the 1500 hour equivalent experience requirement for clerk typists. The committee would like to assure that the board continues to ensure that pharmacists are offering consultation on new medications where prescribed by law and that consumers would not be charged for separate fees.

Chairperson Gubbins stated that many of these are legislative issues. President Jones stated that he anticipates a smooth adoption of these proposals.

Chairperson Gubbins stated that the committee reviewed a copy of the Legislative Counsel's legal opinion of what "actively engaged in the practice of pharmacy" means with respect to Business and Professions Code section 4001 regarding the appointment of professional members to the board. This was one of the initial recommendations of the JLSRC in November 2002. The opinion concludes that "actively engaged" in this instance means the performance of one or more functions for which an active pharmacist license is required." And actively engaged means "holding a pharmacist license issued by the California State Board of Pharmacy other than an inactive or retired pharmacist license and performing an activity on a full-time or part-time basis that requires an active pharmacist license."

# • Findings of the Operational Audit of the Board of Pharmacy by the Department of Consumer Affairs, Internal Audits Office

Chairperson Gubbins stated that the Department of Consumer Affairs' Internal Audits Office released the report of its operational audit of the board in late March 2003. This

April 29 and 30, 2003, Board Meeting - Page 26 of 32 pages

audit started October 1, 2002, and was completed in February 2003. The audit looked at the board's internal controls, compliance with all state requirements, the licensing of pharmacists and technicians, enforcement matters and cashiering. Chairperson Gubbins added that the department typically audits every agency undergoing sunset review.

Chairperson Gubbins reported that the findings and recommendations for the board arising from this operational audit are:

- 1. The loan of \$6 million from the Pharmacy Board Contingency Fund to the state's General Fund will negatively impact on the board's future operations if not repaid in a timely manner.
- 2. Although the board's evidence room access controls are adequate, management could strengthen inventory controls and safety awareness.
- 3. The board's licensing activities are adequate but could benefit from improvements.
- 4. The board's enforcement program allows it to address consumer complaints, but continued improvements are needed to strengthen its operations.

Chairperson Gubbins stated that progress reports to the department on the board's actions to incorporate these changes would be prepared every six months. Copies of these status reports will be shared with the board.

# • Budget Update for 2002/03 and 2003/04

Ms. Herold reported that the state is facing a huge budget deficit now estimated as \$35 billion.

Ms. Herold stated that a number of additional cost containment controls have been placed on state agencies besides hiring freezes and the elimination of vacant positions:

In the 2002/03 budget, the board lost four positions and \$185,000 in associated funding for these positions.

In February 2003, the board learned that any out-of-state travel would not likely be approved, allowing the board to redirect about \$20,000 to the board's AG program line item.

Also in February, all agencies were required to cut their in-state travel budgets by 35 percent (in the case of the board, this is \$52,100).

All training requests, contracts and purchases now undergo additional review by the department as a means to reduce expenses, and approval is significantly harder to attain. Ms. Herold reported that on April 1, the Administration directed all agencies to identify cuts in their personnel services budgets of 10 percent for 2003/04, and to prepare a list of surplus employees to lay off. This will amount to a \$353,000 reduction for the board, the elimination of all vacant positions and the elimination of overtime and board member honoraria. However, the board should not have to lay off any staff; although it will have to continue to redirect work and stop performing some functions in order to complete the most important tasks.

#### • Transfer of Board's Reserve and Proposed Fee Increases

The board loaned \$6 million from its fund to the state's General Fund this budget year. This has left the board with a looming deficit of its own at the beginning of 2004/05 which will grow to at least a \$2.7 million deficit (or 4.2 months of expenditures) by June 30, 2005.

The Internal Audits Office of the department noted in its audit report on the board, that the board's fiscal condition will require repayment of the loan to begin late in 2003/04.

During the sunset review hearings in early April, the department repeated that repayment of a general fund loan would occur before any agency has to increase fees. The board is working with the department and the Department of Finance to assure repayment of the loan before the board has a deficit.

Meanwhile, the department recalculated its budget assumptions that indicate that the board would not repayment of the loan until late in 2003/04 (about June 2004).

#### • 2002/03 Budget Reductions

The board reviewed the board's budget. The board's final budget for last year (2001/02) was \$7,514,523

The board's initial budget for 2002/03 (Sept. 2002 when the state's budget was enacted) was \$7,481,000.

The board's revised 2002/03 budget (Dec. 2002) was reduced to \$7,386,597 (due to the loss of funding for four positions eliminated by the Administration because the positions were vacant).

#### • Budget Change Augmentations for 2002/03

At the last meeting, staff indicated a need to seek a deficiency augmentation for this fiscal year to continue access to legal services from the AG's Office. As of February 1, the board had spent \$587,520 for AG services. Estimates continue to confirm that

April 29 and 30, 2003, Board Meeting - Page 28 of 32 pages

the board will spend \$1 million for AG services this year, or \$230,000 more than the budgeted amount.

During development of the augmentation request, the board determined that it could redirect \$230,000 from several unfilled positions for several months, and from out of state travel and from printing as a result of reducing the number of newsletters and *Health Notes* published (which also reduced postage expenses). These redirections eliminated the need for the deficiency request. However, AG spending has been capped at \$1 million because the board will not be able to redirect additional money to this line item.

### • Budget Change Augmentations for 2003/04 and 2004/05

Ms. Herold stated that the board's staff would pursue two proposals.

- 1. The board will continue to have problems with funding in its AG budget next year. The board has spent \$1 million the last three years for AG services, and to reduce the budget to the amount allocated (\$777,000) would result in a 25 percent reduction from prior years' spending. This year, the board withdrew some aging AG cases and reduced the number of AG cases referred as cost containment strategies required by the board's budget condition, and still the budget will be \$1 million. Nevertheless, the importance of the AG services to the board's consumer protection mandate require that a BCP be prepared to augment funding to historical levels of spending.
- 2. Additionally, the board will need to do a job analysis in 2004 for the pharmacist exam or if NAPLEX is approved, for the CA specific portion of the exam. The costs for this will be approximately \$25,000.

### • Personnel Update

Ms. Harris stated that the board has promoted Joan Coyne and Dennis Ming into the two new supervising inspector positions created/reclassified this year. Dr. Coyne has been with the board eight years and will oversee the Pharmacists Recovery Program and Probation Program. Dr. Ming has been with the board three years and will oversee the Compounding Pharmacy Licensure Program.

Lynee Ritchie resigned from her receptionist position in February.

Ms. Harris stated that the board has six vacant positions:

- Two inspectors (one new position for compounding, the other from the promotion of Dennis Ming)
- One staff analyst (enforcement) April 29 and 30, 2003, Board Meeting - Page 29 of 32 pages

- One associate analyst (licensing of sites)
- One office technician (licensing of sites)
- One office technician (receptionist)

To meet the 10 percent reduction for 2003/04 in personnel expenses required by the Governor, the board would eliminate all these positions, and reduce its annual personnel expenses to 230,000 - all but 23,000 of the 253,000 the board must target for elimination.

Ms. Harris stated that inspector interviews were conducted in March to compile a new list of pharmacists interested in working for the board as inspectors. Additionally, the Labor-Management Task Force held its second meeting to deal with inspector issues; this is a task force required by the collective bargaining contract for inspectors.

# • Future Meeting Dates

Chairperson Gubbins stated that the committee has identified the following as proposed future meeting dates:

# 2003 Meeting Dates: (Currently scheduled):

- July 21-22, San Diego
- October 29-30, Bay Area

# 2004 Meeting Dates: Proposed (all dates are Wednesdays and Thursdays):

- January 21-22, Orange County (CPhA will hold its annual meeting at the end of January and beginning of February)
- April 21-22, Sacramento
- July 21-22, San Diego
- October 20-21, San Francisco (CSHP will hold its Seminar either the first week in November or earlier in October in Long Beach or Palm Springs)

### **APPROVAL OF MINUTES**

### Full Board Minutes January 22 and 23, 2003

President Jones asked if there were any corrections to the minutes. There were none.

MOTION:	Approve the January 22 and 23, 2003, Board Meeting Minutes.				
M/S/C:	JONE	S/ZIA			
SUPPORT:	9	OPPOSE:	0		

# **ELECTION OF OFFICERS**

#### President

MOTION:	Nominate Don Gubbins for president.			
M/S/C:	TILLEY/no second			
MOTION:	Nominate John Jones for president			
M/S/C:	POWERS/HIURA			
SUPPORT:	9 OPPOSE: 0			

### Vice President

MOTION:	Nominate Don Gubbins as vice president.				
M/S/C:	GOL	DENBERG/HI	URA		
SUPPORT:	9	OPPOSE:	0		

### Treasurer

MOTION:	Nominate John Tilley as treasurer			
M/S/C:	ZIA/G	OLDENBERG		
SUPPORT:	9	OPPOSE:	0	

April 29 and 30, 2003, Board Meeting - Page 31 of 32 pages

#### **ITEMS FOR PUBLIC COMMENT**

Mr. Litsey referred to SB 361 that contains the board's sunset recommendations and omnibus provisions and asked the board to consider taking a position on this bill.

MOTION:	Support SB 361 (Figueroa) – Extends the board's sunset date; adopts NAPLEX; revises pharmacy technician qualifications; establishes new enforcement tools; contains board – submitted technical provisions.					
M/S/C:	ZIA/I	LITSEY				
SUPPORT:	7	OPPOSE:	0	ABSTAIN:	2	

#### **ADJOURNMENT**

There being no further business, President Jones adjourned the meeting at 4:45 p.m.

#### **CLOSED SESSION**

The Board of Pharmacy moved into closed session to confer with legal counsel, pursuant to Government Code section 11126, subdivision (e), concerning pending litigation and pursuant to Government Code section 11126(c)(3) to deliberate upon disciplinary cases.

#### Wednesday, April 30, 2003

### STRATEGIC PLANNING

President Jones stated that this updating session would be lead by Lindle Hatton as the Organizational Development Committee's public meeting. President Jones added that the objective of the meeting is to revise the board's current plan into a more traditional plan.

The board worked to revise its strategic plan.

#### **REINSTATEMENT**

The board moved into closed session pursuant to Government Code section 11126 (c)(3) to deliberate upon disciplinary cases and the petitions for reinstatement.