



California State Board of Pharmacy

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

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

DATE: July 21, 2004

LOCATION: University of California, San Diego
University Center – Price Center, Ballroom A
9500 Gilman Drive
La Jolla, CA 92093-0076

DATE: July 22, 2004

LOCATION: Hyatt Regency
3777 La Jolla Village Drive
San Diego, CA 92122

BOARD MEMBERS

PRESENT: Stanley Goldenberg, President
William Powers, Vice President (July 21, only)
Ruth Conroy
David Fong
Clarence Hiura
John Jones
Kenneth Schell
John Tilley
Andrea Zinder (July 21, only)

BOARD MEMBER

ABSENT: Richard Benson

STAFF

PRESENT: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judith Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Dennis Ming, Supervising Inspector
Joshua Room, Deputy Attorney General
Dana Winterrowd, Department of Consumer Affairs Legal Counsel

COMMITTEE REPORTS AND ACTION

ORGANIZATIONAL DEVELOPMENT COMMITTEE

Board President's Report

President Goldenberg became president of the board on June 1. This is his first meeting as president. President Goldenberg started the meeting by reading his "President's Message."

President Goldenberg stated that the current structure of the board is seven pharmacists and six public members who have the opportunity to teach and learn from each other. While striving to improve communication between its members and the public, informed members can base decisions on factual evidence and the board's mission to protect consumers.

President Goldenberg stated that during the early 1990s, 10 board members held only five public meetings yearly to conduct all board business. During the middle 1990s in order to increase communication between the public and the board, the board developed a committee structure, and thereby increased the meetings from 5 to up to 25 per year.

President Goldenberg stated that the board's mission is to protect the public. He encouraged stakeholders and the public to provide input through factual presentations and well thought out suggestions during board development of policy. To explore additional means to facilitate communication among the board, the public and stakeholders, President Goldenberg recommended that Chairperson John Tilley designate one or more meetings of the Organizational Development Committee to be open to the public and specifically to seek comments on expanding communication.

President Goldenberg acknowledged Mr. Tilley's experience in working with many organizations and he added that the board would benefit from his experience as he serves as chair of the Organizational Development Committee.

President Goldenberg acknowledged his wife Susan Goldenberg, Art Whitney from the Long Term Care Counsel, Raffi Simonian, former Board President, Steve Gray from Kaiser Permanente and John Cronin from the California Pharmacists Association, who were in attendance. He stressed that during this year, improved communication will be his theme to benefit the public.

- **Recognition of Former Board President John Jones**

President Goldenberg presented former Board President John Jones with an inscribed plaque in recognition of his hard work and dedication as president for the last two years of the Board of Pharmacy.

- **Assignment of Committee Chairs**

President Goldenberg announced the new chairs of the board's committees:

Andrea Zinger - Communication and Public Education Committee
William Powers - Enforcement Committee
John Jones - Legislation and Regulation Committee
Ruth Conroy - Licensing Committee
Kenneth Schell - Competency Committee
John Tilley - Organizational Development Committee

President Goldenberg stated that former committee chairs would report on committee action reports during the board meeting.

Chairperson Tilley encouraged the public and board members to attend future public meetings of the Organizational and Development Committee.

- **Proposed Modifications to Strategic Plan for 2003-05**

Chairperson Tilley stated that at the last board meeting, the board approved its strategic plan for 2004/05. When compiling the final changes to the plan, staff noticed that there was no mention of consumers purchasing drugs from foreign sources in the environmental scan (which was completed in early 2002). The environmental scan identifies issues that impact the board's operations and emerging policies. He added that the committee believes that such an inclusion is necessary in the board's strategic plan for 2004/05.

The committee suggested the following modification:

1. **Cost of medical/pharmaceutical care**

Providing necessary medication for all Californians is a concern; there is an increasing demand for affordable health care services.

~~Regardless~~ Also, spiraling medical care and prescription costs may influence people to take short cuts on their drug therapy or to seek medications from nontraditional pharmacy sources. Tiered pricing is a global reality. Due to global communication, patients can access drugs at different prices, worldwide. Patients seek lower cost medications from these sources because patients assume that prescription drugs are of the same quality as they are accustomed to obtaining from their neighborhood pharmacy. However, the coast of drugs drives unscrupulous individuals (such as counterfeiters and diverters) as well as conscientious health care providers to operate in this markeplace, the former endanger public health and confidence in the prescription drugs patients take.

~~Consequently, tier or bid pricing strategies may evolve by manufacturers.~~

~~Expanded patient rights will lead to higher costs to everyone.~~

John Cronin, representing the California Pharmacists Association, asked what the budgetary impact is to pursue this as a strategic plan objective.

Ms. Herold stated this is a factor influencing board actions and activities. It is not a specific plan of action to be taken by the board. The information is printed on the board's Web site and would not impact the board's budget.

Ms. Harris stated that the strategic plan should identify topics the board addresses. In the case of alternative sources of drugs, this has been a standing agenda item in the Enforcement Committee. A brochure was published for consumers buying drugs on the Internet or foreign sources, and the board has consistently provided technical assistance on pending legislation in this area. She added that these resources are not reflected in the current environmental scan.

Mr. Cronin stated that because the board is funded from licensees he did not feel it was appropriate to publish consumer information that violates federal law, and should include warning provisions about drugs not approved by the FDA and the illegality of importing drugs from outside of the U.S.

MOTION: Organizational Development Committee: Modify Item 1 of the environmental scan of the board's strategic plan for 2004/05, to include issues arising from consumers purchasing drugs from foreign sources proposed by the Organizational Development Committee.

SUPPORT: 9 OPPOSE: 0

- **Proposed Policy Concerning Board Voting**

Chairperson Tilley stated that during the January Board Meeting, a question arose about whether board members who vote as "abstain" during a board vote were actually voting or not. And if voting, how the votes should be tallied.

Chairperson Tilley stated that the committee has worked with the department's Legal Office to craft guidelines for board votes during board meetings and on mail ballots. The committee discussed the need to clarify voting parameters for the board with respect to quorum requirements and when a motion passes or fails. The board's legal counsel suggested that the board develop its own policies.

The board generally follows Robert's Rules of Order when a parliamentary question arises; however, these rules were developed for the public sector. The committee discussed various quorum and voting issues and developed recommendations for the board.

Quorum

Under law, quorum is defined as seven members (California Business and Professions Code section 4200(b)).

The board will use the following criteria in counting votes on a given motion or decision (this includes motions during board meetings and mail votes on disciplinary matters).

The board must have a quorum of members present to take an action.

- There must be a least seven members voting for the board to take an action or position on an item.
- A motion passes if a majority of those voting votes for the measure.
- Abstentions count as votes for purposes of establishing a quorum, but do not count as votes for or against the measure. Abstentions simply mean that the abstaining board member will go along with the majority decision of the board.

Dr. Fong asked how this policy compares to what other boards use within the department.

Dana Winterrowd, DCA Legal Counsel, stated that the Legal Office's policy is to leave it to a board's discretion.

Mr. Powers asked if the proposed policy is consistent with Robert's Rules of Order.

Mr. Winterrowd stated that it was not.

Joshua Room, Deputy Attorney General, stated that the proposed format could make it easier to carry motions with less affirmative votes.

Mr. Jones stated that this format will help to remove the gridlock the board experienced at the January board meeting and it would not create an unfair situation if everyone understands the rules.

Dr. Schell expressed concern about the board president's role in voting. He added that the president's role is to break a tie.

Steve Gray, representing Kaiser Permanente, congratulated the committee on addressing the issue. He added that denying the board president's vote would deny input on important decisions. He added that the intent of this proposal is to clarify the voting rules.

Sam Shimomura, representing Western University, stated that the board should not establish criteria for allowing board members to abstain because it may result in the board abstaining on all difficult or controversial issues to avoid criticism or conflict. He added that the board should establish a policy that it can only abstain for a conflict of interest issue and not a controversial issue.

Mr. Cronin recommended that the board reject this proposal and remain with Robert's Rules of Order. He stated that under Robert's Rules, it is assumed that for mail votes there is a quorum with everyone voting.

MOTION: Organizational Development Committee: That the Board of Pharmacy adopt the following as voting parameters for public meetings and mail votes:

Quorum

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SUPPORT: 6 OPPOSE: 3

• **Budget Update for 2003/04 and 2004/05**

Workload Priorities Adjusted: The board has had to reprioritize workload to address staffing shortages. Changes enacted by SB 361 that took effect in January on pharmacy technician and pharmacist licensure examination processing functions have been implemented. A great deal of staff time is now being invested in education activities surrounding SB 151, which alters the requirements for prescribing and dispensing controlled substances.

The state hiring freeze, which has been in effect since 2001, expired July 1. The board will hire additional staff to perform some office functions. These will be temporary staff except for one inspector position, because the board has no other vacant positions. Money will be redirected principally from printing to fund these positions.

AG Office's Hourly Rates Increase: The AG's hourly rates for legal services increased April 1, and will increase again on July 1. These higher rates will increase the costs for legal services from the Ag's Office. For the next year the board has received a \$135,000 augmentation to permit the board to buy the same number of legal services hours (at the April 1 rate) as the board was budgeted for in 2003/04.

Rate	<u>Previously</u>	<u>April 1</u>	<u>July 1</u>
Attorneys in the L.A. Office	\$120/hr	\$132/hr	\$139
Attorneys in other AG Offices	\$112	\$132	\$139
Legal Assistants	\$ 53	\$ 91	\$91

Until this fiscal year, for the last five years, the board's AG budget has been under-funded. Despite budget change proposals seeking augmentation, the board's AG budget has not been adequately funded. However, in 2003/04, the board did not use its full AG budget of \$780,000, due to the new citation and fine program, case management and because the Board of Registered Nursing received extra funding so that the AG could work its cases. The work on the BRN cases reduced the number of attorneys available to work on board cases.

CURES Support from Board to Increase? Last year, in response to the board's omnibus legislation in 2001 to extend CURES, certain regulatory boards (Pharmacy, Medical Board, Nursing Board, Dental Board, Osteopathic Board) were tapped to (in legislation) fund CURES data collection costs because the state's General Fund could not support it. Last year, the board funded \$68,000 for CURES data collection and analysis contracts. For 2003/04, the board was notified in January that the DOJ was seeking \$92,000 from the board. The documentation for the additional expenses was inadequate to justify the expenditures, so the board approved funding for CURES at \$68,000. The DOJ was advised to attend this board meeting to seek the additional \$24,000 if it still wished to seek this funding.

DOI Repayment: The department owes the board about \$135,000 in overpayment collected for Division of Investigation Services the board did not use over the last four years. The department will repay this amount at the end of 2003/04.

Board Member Expenditures and Reimbursements: According to current estimates, board members will be reimbursed for time spent performing board business outside of board meetings at the end of the fiscal year. This policy was adopted as a cost-cutting measure last July, and the board agreed to withhold compensation for such hours until it could be determined if the board could pay these costs. Board members already were reimbursed for hours spent in board meetings.

- **Budget Update for 2003/04:**

The fiscal year ended June 30, 2004.

As a review, since July 1, 2003 (the beginning of this fiscal year), the board has:

- Lost six positions vacant on June 30, 2003.
 - Taken a 12 percent (or \$411,000) cut in Personnel Services. Most of this was linked to the loss of the six positions; additionally \$12,000 in board member compensation was lost as was all overtime and \$9,000 from operative expenses. No staff at the board was laid off to meet the 12 percent reduction.
1. **Revenue for 2003/04:** The board's projected revenue for the year is now \$6,397,387. This is comprised of \$5,399,034 in fee revenue (84.4 percent) and \$92,246 in interest and misc. fees (1.4 percent).
 - The board collected \$750,973 in citation revenue during the first 11 months of the year (11.7 percent).
 - Additionally \$155,135 has been collected as cost recovery through June 1 (2.4 percent).
 2. **Expenditures for 2003/04:** The most recent estimates prepared by the Department of Consumer Affairs (March 2004) now set estimated expenditures for the year at \$6,901,670. This figure includes the 12 percent reduction in personnel expenditures. The projected expenditures for the year are:

Personnel:	53.5 percent
Pro rata to DCA:	13.9 percent
Enforcement (AG,OAH):	11.8 percent
Facilities Operation:	4.9 percent
Contracts:	3.9 percent
Travel:	3.3 percent
General Expense:	3.2 percent
Exam:	2.3 percent
Postage:	1.3 percent
Communications:	1.0 percent
Printing:	1.0 percent
 3. **Update: Board Fund Condition:** Last year the board loaned \$6 million from its fund to the state's General Fund. Repayment of this loan is required if the board will enter a deficit situation. This year, the board is expected to spend at least \$500,000 more than it projects it will collect in revenue. As such, the amount of money in reserve in the board's fund is important. The board will not have a deficit in its fund until sometime in 2005/06. A new fund condition will be provided at the October Board Meeting that contains the final budget figures for 2003/04.

For 2004/05:

4. **2004/05 Board Budget Approved:** The board's budget contains no new spending proposals, and as such, the board will continue to operate in the same manner, and with the same resources, as in 2003/04.
5. **No Funding increases for New Programs:** The Governor's Office and the Department of Finance have stated in recent budget instructions that there will be "no

discretionary funds available from any fund source for new initiatives or program expansion.” As such, any new legislative mandates or program modifications must be funded within existing funding. The board has not sought additional funding for future years’ budgets due to this directive.

- **Personnel Update**

In January, Inspector Rosie Yongvanich resigned from the board to become a full-time parent. The board is recruiting to fill the vacancy.

Three board staff are on parental leave: Manager Anne Sodergren, Legislative Coordinator Paul Riches, and Inspector Cindy Drogichen Rich.

Inspector Bob Venegas recently completed a two-week training in Virginia, provided by the FBI. The Drug Enforcement Administration paid for this investigator training. This was an honor for both the board and Inspector Venegas.

Mr. Cronin stated there is a perception that the Board of Pharmacy is shifting its policy so that citations and fines become a major revenue source for the board and that the fine amount is at 11.7 percent. He asked if this compares to previous years.

Ms. Harris stated it is more than collected in prior years, and includes settlements for several large Internet cases.

President Goldenberg suggested that this issue be address at the Enforcement Committee portion of the board meeting.

Mr. Cronin stated that another perception is that the Board of Pharmacy has decreased its willingness and availability to provide legal advice to its licensees. He suggested that the 11.7 percent revenue from violations be used towards educational benefits to licensees.

President Goldenberg suggested that this be address at the during the Enforcement Committee portion of the board meeting.

- **Approval of Minutes**

**Full Board Minutes
(April 21, 2004)**

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

MOTION: Approve the April 21, 2004, Board Meeting Minutes

M/S/C: SCHELL/ACEVEDO

SUPPORT: 9 OPPOSE: 0

INTRODUCTION

Dr. Simonian introduced four faculty members from UCSD; Dr. Alex Dominguez, Dr. Deborah Duwe, Dr. Ed Tsu and Dr. Susan Wilson.

President Goldenberg asked visiting students to stand and introduce themselves.

President Goldenberg acknowledged William Powers as the newly appointed vice president of the board, and Dave Fong as the newly appointed treasurer.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

President Goldenberg announced the new committee members of the Communication and Public Education Committee: Andrea Zinder (Chair), Richard Benson, William Powers and Kenneth Schell.

- **Proposal to Join the California Health Communication Partnership**

Mr. Powers stated that the UCSF's Center for Consumer Self Care is forming an organization comprised of agencies that develop consumer health education programs and materials. Called the California Health Communication Partnership, this group would develop and promote consumer health education programs and activities developed by the member organizations in an integrated fashion. The board has been invited to join as a founding member.

The California Health Communication Partnership would identify health communication programs and recommend the timing for integrated activities by individual partners for the programs. The partnering organizations would decide if and how they would use their resources to promote the health communication themes suggested.

The board would have minimal cost for joining and one of the benefits would be the increased production and/or promotion of health education materials for the public.

R. William Soller, Ph.D., Director of the Center for Consumer Self Care, thanked the board for the opportunity to present the program concept to the board.

Dr. Soller added that the California Health Communications Partners would be comprised of statewide and national organizations and government agencies with interest and/or public programs in health communications. Through a Steering Committee, health communication programs would be identified and a recommendation made for timing activities. The partnering organizations would determine how to utilize their resources to promote the health communication themes suggested by the Steering Committee.

Dr. Soller explained the program mission and talked about the partnership members. He stated that the goal of this program is to target large groups to significantly impact communities in California. He added that this particular research approach would provide a means to track consumer behavior in health communications and would evaluate the impact of national health awareness months.

Mr. Tilley asked if this is a non-profit organization.

Dr. Soller stated that the school of pharmacy is non-profit. The administrators are faculty members on the Steering Committee and would take a principal role in the organization of the program. Faculty members are paid from direct salary from the school guaranteed to tenured professors or outside sources. He added that it would be very beneficial for a board member to also sit on the Steering Committee.

MOTION: Communication and Public Education Committee: Join the California Health Communication Partnerships as a founding member.

SUPPORT: 8 OPPOSE: 0 ABSTAIN: 1

- **Proposal to Join the California Tobacco Control Alliance to Endorse its “Smoking Cessation Benefits for Everyone” Campaign**

Mr. Powers stated that at the April Board Meeting, the board voted to work with the UCSF School of Pharmacy to produce a future *Health Notes* on smoking cessation. Before making this recommendation to the board, the committee reviewed materials produced by the California Tobacco Control Alliance for primary care practitioners, which they call a “Health Care Provider’s Tool Kit for Delivering Smoking Cessation Services.”

The board was recently asked to join the California Tobacco Control Alliance’s campaign to encourage managed care providers to cover uniform smoking cessation benefits in standard health care packages. This is part of the alliance’s mission to reduce the number of smokers.

MOTION: Communication and Public Education: That the Board of Pharmacy indorse the California Tobacco Control Alliance’s “Smoking Cessation Benefits Everyone” Campaign.

SUPPORT: 9 OPPOSE: 0

- **Update on Project with UCSF’s Center for Consumer Self Care on the Development of a Consumer Fact Sheet Series**

Mr. Powers stated that at the April Board Meeting, the board approved a proposal by the committee to integrate pharmacy students into public outreach activities. At the June

committee meeting, Dr. Soller of the UCSF Center for Consumer Self Care participated in a discussion on implementing this proposal.

The project will have students develop one-page fact sheets on diverse health care topics. The board will work with Dr. Soller to develop these fact sheets, using pharmacy students from UCSF and UCSD. A prototype format for a series of fact sheets will be developed. Each interested student will be acknowledged with a credit at the bottom of the fact sheet he or she develops. Review by professional staff at UCSF for content accuracy will occur as part of the process.

- **Update on *The Script***

Mr. Powers stated that the March 2004 issue of *The Script* was mailed to California pharmacies at the end of March. A copy is on the board's Web site. This issue focuses on the many substantial changes to pharmacy law that took effect in 2004 (e.g., changes in the prescribing and dispensing of controlled substances, new pharmacy technician requirements and new pharmacist licensure examinations).

The CPhA's Pharmacy Foundation of California mailed the issue to California pharmacists in early June.

The hiring freeze ended June 30, 2004. The board intends to hire former newsletter editor Hope Tamraz as a retired annuitant to produce the next issue of *The Script*, which should be published in September.

- **Update on *Health Notes***

Mr. Powers stated that *Health Notes* is a monograph, produced by the board that contains up-to-date drug therapy guidelines for a specific subject area. Because *the board produces Health Notes*, it conveys what the board believes is current drug treatment in a particular area. Pharmacists can earn continuing education credit by completing a test published at the back of the monograph. Thus the board provides information and actually is sponsoring CE in an area of importance to the board. Seven issues have been produced since 1996.

Pain Management Issue:

Mr. Powers stated that the board is currently developing a new issue on pain management, which should be published in September of 2004. The new issue will contain new pain management therapies and the new prescribing and dispensing requirements for controlled substances. It is planned as an interdisciplinary issue for pharmacists as well as physicians, dentists, and nurse practitioners. Prominent pain management authors have written the articles, and board staff and Board Member Schell are editing and coordinating the issue. The CSHP is seeking funding for production and mailing costs. Depending on how many grants the CSHP obtains for this issue, the board hopes to spend \$0 on this issue.

Smoking Cessation

Mr. Powers stated that at the April 2004, Board Meeting, the board agreed to work with the UCSF to develop a *Health Notes* on smoking cessation. The UCSF is seeking funding for this issue from manufacturers of smoking cessation products.

The board will be responsible for the layout and design of the issue. If funding permits, the board will print and mail the issue. If the board lacks funding for this (\$85,000), the issue will be placed on the board's Web site.

UCSF Monograph on Atrial Fibrillation

Mr. Powers stated that at the April 2004, Board Meeting, the board voted to become a cosponsor with the UCSF School of Pharmacy to produce a monograph on Atrial Fibrillation. The audience would be pharmacists and physicians. Funding for this issue would come from a drug manufacturer. Continuing education credit for those who complete the reading would be one outcome of this project.

The UCSF intends that in place of publishing this issue as a printed monograph (such as *Health Notes*), to instead place the issue on the Web site for downloading, possibly as a CE program. There would be no direct costs to the board.

- **Establishment of Internet Subscriber Lists for Board Materials**

Mr. Powers stated that staff is waiting for the Department of Consumer Affairs to install software to permit the board to set up a subscriber list on the board's Web site. This feature would send e-mails to interested parties announcing that the board's Web site has been updated. The interested parties would subscribe themselves to the board's Web site, and be responsible for keeping their e-mail addresses current.

This service has the potential to substantially reduce the board's mailing expenses as well as printing costs. Materials that the board currently publishes and mails could be sent without cost via e-mail. Such a notification system would allow the board to update licensees far more quickly about new information and laws.

After being contacted by the board, the Department of Consumer Affairs has recognized the value of such software, and is interested in pursuing this for the rest of the department. The board will be the first agency to use the software, and this should be implemented by the end of July.

- **Update on Public Outreach Activities**

Mr. Powers stated that the board implemented and provided a sizeable and significant public outreach and licensee education program this year. This is a dynamic area of board activities and relies heavily on the involvement of board members and senior board staff.

The board staffed booths at two public education fairs since the April Board Meeting, “Healthy Aging” in Sacramento and a senior health fair in Yreka.

The board also continued to present its revised Power Point presentation on the board that highlights key board policies and pharmacy law. This is a continuing education course, provided by a board member and a supervising inspector. Questions and answers typically result in a presentation of more than two hours; these presentations are well received by those in attendance.

Additionally, the board has had increasing interest in its Power Point presentations on SB 151 and the new requirements for prescribing and dispensing controlled substances in California. Some of these presentations have occurred via teleconferences with large numbers of practitioners. More than 20 separate presentations have occurred in the last three months.

Future Presentations

Dr. Hiura asked if the board has lended its name in the past for endorsing programs.

Ms. Herold stated that in the past the board has endorsed various programs. She added that the board held a health fair summit through CPhA, CSHP and other organizations where the board actually advocated that pharmacists’ care be specifically compensated for as a service rather than tied to a drug product. She added that most of the *Health Notes* published to date have been collaborations with other organizations that develop the issue and obtain the money to publish *Health Notes*. The board reviews the issues and determines its cost; either for layout or postage.

Ms. Harris added that the board is not paid for the outreach services it provides, and must pay for travel costs for all staff and board members who travel. Ms. Harris stated that because public outreach is a priority, the board uses its resources to achieve this priority.

Ms. Harris commended the efforts of Supervising Inspectors Bob Ratcliff, Judi Nurse, Dennis Ming and Joan Coyne and executive staff Virginia Herold and Paul Riches. She added that the work they perform on outreach efforts is in addition to the regular work load and often requires a great deal of travel.

Dr. Gray complemented the board on its public outreach efforts. He added that the public appreciates the information shared.

Dr. Gray expressed concern about the board participating in the Arial Fibrillation monograph because at the last board meeting, the UCSF was unwilling to disclose the sponsoring pharmaceutical organization. He added that this should be a matter of public information.

Dr. Soller stated that the contract has not been signed yet. Dr. Soller indicated that the manuscript developed by the University would undergo peer review, but not review by the funding source.

Dr. Fong referred to the audio conference on SB 151 that Supervising Inspector Judi Nurse participated on and asked about future audio conferences.

Ms. Nurse stated that there were approximately 20 participants at each of the three teleconferences that she participated in. She added that the audience in all presentations were very interested and asked many questions.

Ms. Herold stated that a Power Point presentation is on the board's Web site for downloading with speaker notes containing additional information. She added that Paul Riches participated in a teleconference that included 1,200 individuals.

Don Shaevel, pharmacist from Palm Springs, California, commended the board for developing smoking cessation materials.

ENFORCEMENT COMMITTEE

President Goldenberg welcomed the new members to the committee: William Powers (Chair), Stan Goldenberg and Dave Fong.

Mr. Jones stated that his service as a member of the Enforcement Committee during the last six years has been a rewarding and informative assignment. He commended the board's inspectors and staff on their professionalism. He added that although the nature of the work on this committee is intense, the work offers insight into a board member's role. He added that he would miss serving on this committee.

- **Recommendation to Amend Business and Professions Code Section 4115(f) to Allow Another Verification Process Other than Initials**

Mr. Jones stated that when a pharmacy technician assists in the filling of a prescription, Business and Professions Code section 4115(f) requires a pharmacist to initial a prescription to verify that he/she checked the prescription before the medication is provided to the patient. This requirement is also in regulation, CCR, Title 16, sec. 1793.7(b).

Mr. Jones stated that at the Enforcement Committee meeting, the Rite Aid Corporation requested a waiver of the requirements to accept Rite Aid's biometric fingerprint recognition technology as a means of complying with this requirement.

Rite Aid plans to use a biometric fingerprint authentication system in its approximately 3,400 pharmacies nationwide with implementation in California by November 2004. The purpose of the biometric system is to provide pharmacy staff with the secure access and authorization necessary to process prescriptions during the dispensing process. The biometric function includes the ability to register one or more of the user's fingers, and to use the biometric scan of the fingerprint(s) for secure authorization. Signing in with the biometric scan then permits Rite Aid to identify the pharmacy associate responsible for various phases of the dispensing process. This technology allows for a more secure authorization of a pending prescription order, including an order prepared by a pharmacy technician.

During the Enforcement Committee meeting, the committee discussed the use of biometric fingerprint technology as a viable alternative to the pharmacist's signature on the prescription label; however, a statutory change would be required. The board's inspectors were supportive of such a statutory change that would allow the use of this technology since it appears to be more reliable and legible than an initial on the label that is often written in haste.

The Enforcement Committee agreed to recommend to the Board of Pharmacy that it support a statutory change to Business and Professions Code section 4115(f) that would allow another verification process other than a signature as approved by board regulation.

Since there was significant support for this proposal, it was suggested that the amendment be placed in the board's omnibus bill this year if possible.

Mr. Jones asked the board to support the statutory change.

Dr. Fong stated that he supports this proposal and encouraged the board to move forward and support this new technology.

Dr. Schell stated that he also supports the recommendation but wanted to assure that the board could identify reliable technology.

Mr. Jones stated that the board is not endorsing a particular system. People using the systems are responsible for any failures.

Steve Gray, representing Kaiser Permanente, stated that Kaiser strongly recommends that the board move forward with this proposal. He stated that there are excellent examples of technology that actually improve accountability. He added that several other states are using this technology and California is a little behind in its use. He added that Kaiser implements systems now but certain features that are available in other states are not in use because it is not permitted in California. He added that Kaiser has a system that will be available for use in January 2005.

MOTION: Enforcement Committee: That the Board of Pharmacy support a statutory change to Business and Professions Code section 4115(f) that would allow for another verification process other than a signature on the prescription label as approved by board regulations.

SUPPORT: 9 OPPOSE: 0

- **Discussion on the Reimportation of Prescription Drugs from Canada**

Mr. Jones stated that the National Association of Boards of Pharmacy (NABP) held an Importation Enforcement Workshop and Task Force meeting on June 22-23, 2004, to address the issue of importation and the prosecution of entities involved in this activity. Information from this meeting was provided in the board packets. Also provided was the NABP's report on the most recent action by state boards of pharmacy against storefront, pharmacies, and other entities that assist in the illegal importation of prescription medication from Canada. These included: the Interim Findings from the Guiliani Partners, LLC, on the examination and assessment of prescription drug importation from foreign sources to the United States and a letter from McKesson Corporation to the Task Force on Importation.

Mr. Jones stated that at the last board meeting, it was reported that the Food and Drug Administration (FDA), on behalf of the U.S. Department of Health and Human Services' (HHS) Task Force on Drug Importation, announced that it established a docket to receive information and comments on certain issues related to the importation of prescription drugs. The FDA also announced a public meeting on April 14th so that individuals, organizations and other stakeholders could present information to the Task Force for a study on importation mandated by the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The Task Force is interested in information related to whether and under what circumstances drug importation could be conducted safely, and what its likely consequences would be for the health, medical costs, and development of new medicines for American patients. The public docket closed June 1, 2004. A transcript from the April 14th meeting was included in the board packet.

Mr. Jones stated that the Enforcement Committee also discussed the legality of importation and the various legislative proposals that have been introduced at the federal and state level that would allow for the safe importation of prescription drugs from Canada. Although the board did not take a position on the California bills, it is tracking the status of these bills.

One bill, AB 1957 (Frommer) would require the Department of Health Services (DHS) to establish a California Rx program to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices and would require the DHS to establish a Web site before July 1, 2005 to various drug benefit programs including Canadian pharmacies that meet certain standards. One of the standards is that the Canadian pharmacy meets the requirements of a nonresident pharmacy.

Another bill, SB 1149(Ortiz) would require the Board of Pharmacy to establish an interactive Internet Web site to identify licensed Canadian pharmacies that meet specified criteria for the safe acquisition, shipment, handling, and dispensing of prescription drugs to persons in California. One of the standards is that the Canadian pharmacy meets the requirements for licensure by the board.

Recently Senator Ortiz invited representatives from the Board of Pharmacy to participate in a fact-finding trip to meet with Canadian officials. The plan was for a delegation of legislators and administration representatives to travel to Canada in July to learn more about the Canadian prescription drug system. They would meet with key government and industry officials involved in the drug manufacturing, distribution and dispensing systems in Canada.

The board declined the invitation because such a trip would require an individual trip request approval that takes months to obtain because the request must be reviewed and approved by the Department of Consumer Affairs, State and Consumer Affairs Agency, the Department of Finance and the Governor's Office. Agency has advised the department that it will not begin this review process until the Governor signs the budget for 2004/05. Moreover, only those out-of-state/out-of-country trips that will be considered for approval are those trips that are mandated or are program-essential functions. Information sharing and fact-finding trips generally do not meet this requirement.

Mr. Tilley asked what the status of Canadian storefronts is in California.

Ms. Harris reported that the board has not taken any action against these storefronts. She added that the issue was discussed last year in a Closed Session meeting and should not be discussed in a public meeting.

Mr. Tilley expressed concern that this illegal activity continues.

Mr. Jones stated that several states have attempted to take a strong position on enforcement action against these storefronts without first getting support from their attorneys general and found that they had no enforcement capabilities at all.

Deputy Attorney General Joshua Room stated that among those in support of SB 1149 is the Attorney General's Office, indicating that the AG's Offices is not likely to take action against the storefronts.

Mr. Tilley again expressed concern that someone should enforce the law.

Mr. Room stated that there is some question of uncertainty about whether the current law will remain the law at the national level.

The board discussed the issue of counterfeit drugs and how the drugs are difficult to detect from legitimate drugs.

Steve Gray, representing Kaiser Permanente, stated that there now appears to be a market for empty pharmaceutical containers. He encouraged the board to have discussions with the medical industry, and suggested that staff contact Marv Sheppard from the University of Texas Pharmacy School, who specializes in counterfeiting issues.

Bruce Young, representing the California Retailers Association, stated that the board and the state should be cautious about facilitating consumer's ability to illegally buy medicine from outside the country. He added that there are ramifications about the financial exposure to the state if patients are injured.

Mr. Young stated that it is the CRA's belief that importation of drugs if authorized should come through a pharmacy where someone is more likely to spot a potential counterfeit drug. He added that the real problem and the culprit are manufacturers who price drugs for sale outside of America at lower prices.

Mr. Ratcliff stated that it is difficult for any pharmacist to identify counterfeit drugs given the sophistication of today's counterfeiters. Moreover, when the board learns about counterfeit drugs being discarded, the board has difficulty in identifying the pharmacies where the counterfeit drugs have been found because neither the pharmacist nor the drug manufacturer want to scare the public.

- **Disclosure of Citation and Fines to the Public**

Mr. Jones stated that at its last meeting, the Board of Pharmacy revised its disclosure policy. During the discussion, licensees expressed concern about the disclosure of administrative citations. Administrative citations are not considered discipline of a license. However, they do represent the resolution of an investigation or complaint that has been substantiated and as such, are disclosed to the public.

Mr. Jones stated that to address the concerns of licensees, the following language has been added to the citations to advise the licensee: "If a hearing is not requested to contest the citation(s), payment of fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure (Bus. & Prof. Code §§ 125.9, 4314; Cal. Code Reg., tit. 16, § 1775)."

For cases where no fine has been issued, the following statement will be provided:

"No fine has been assessed with this citation and no proof of abatement has been ordered. If no hearing is requested to contest the citation, the right to contest the citation has been waived. If no hearing is requested to contest the citation, the right to contest the citation has been waived. If the citation is not contested, the citation shall be represented as a satisfactory

resolution of the matter in any public disclosure (Bus. & Prof. Code §§ 125.9, 4314; Ca. Code Regs., tit. 16, § 1775).”

For disclosure to the public, the following language will be provided:

The issuance of a letter of admonishment and/or a citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The final administrative action including payment of a fine does not constitute an admission of the violation(s) charged and is considered satisfactory resolution of the matter. (Bus. & Prof. Code §§ 125.9, 4314; Cal. Code Regs., tit. 16§ 1775).”

- **Evaluation of Implementation of the Quality Assurance Program**

Mr. Jones stated that the National Association of Boards of Pharmacy (NABP) Foundation funded a study on medication errors in California. The purpose of the study was to chart the profession’s implementation of the Board of Pharmacy’s new regulation on quality assurance. The original intent of the study was to prospectively assess, through a board inspector questionnaire, which components of the quality assurance (QA) program were the most difficult for pharmacy to implement, over time. However, after the evaluation was implemented, additional limitations were imposed that caused a re-evaluation of the original objectives. The objectives were changed to the following: identify and compile deficiency data and citation/fine data for the new QA regulation, identify the board inspectors’ subjective interpretation of pharmacy’s compliance with various aspects of the regulation and identify and compile data on types of medication errors through a review of the board’s citation and fine data.

The conclusion of the evaluation found that the Board of Pharmacy and its inspectors have fully embraced the concept of quality assurance in an effort to protect consumers through analysis of medication errors. This was supported subjectively through the interview process and objectively through the number and frequency of correction orders (deficiencies) and citations/fines issued by the board during the review period.

The evaluation also compiled a list of medication errors by type in an effort to further medication error prevention. These errors types are similar to those reported by national patient safety programs. It was noted that further analysis would be necessary to determine if the implementation of quality assurance requirements actually impacts medication errors encountered by consumers.

The information regarding medication errors evaluated from the citation/fine data reports will be reported in the next board newsletter.

- **Retired Status of a Physician License**

The Medical Board of California advised that starting July 1, 2004, a physician who is in retired status would no longer be eligible to practice medicine. While the physician will be exempt from paying a renewal fee and continuing education requirements, a retired physician will no longer be allowed to engage in the practice of medicine. The practice of medicine, of course, includes prescribing.

- **Implementation of SB 151 – Changes to the Prescribing and Dispensing of Controlled Substances**

Mr. Jones stated that this bill repeals the triplicate prescription requirement for Schedule II controlled substance prescriptions and replaces it with a tamper-resistant prescription form that may be obtained from approved printers. Eleven printers have been approved. The Enforcement Committee discussed the implementation of SB 151 and the many questions that the board has received. A list of questions and answers on changes in the law were reviewed and will be added to the board's Web site.

- **Update on SB 1307 Regarding Wholesalers**

Mr. Jones stated that the Board of Pharmacy is sponsoring SB 1307 to strengthen the regulation of wholesalers by enacting comprehensive changes in the wholesale distribution system for prescription drugs. The Enforcement Committee recommended to the board that it sponsor this legislation after discussing the issue for at least two years. The language was carefully developed to directly address issues found during investigations of wholesalers in California. The bill contains the following major elements:

- Requires the development of a “pedigree” that tracks each drug through the distribution system beginning January 1, 2007, although the board may extend the implementation date for wholesalers to 2008 and pharmacies until 2009.
- Requires all out-of-state wholesalers shipping drugs into California to become licensed (This provision was placed in AB 2862, a companion bill containing similar provisions for nonresident wholesalers).
- Increases the board's ability to fine for more serious violations related to wholesaling.
- Requires wholesalers to post a \$100,000 bond to secure administrative fines and penalties
- Restricts wholesale transactions by pharmacies.
- Requires that drugs be purchased only from licensed entities
- Authorizes the board to embargo drugs when the board suspects or finds drugs that are adulterated or counterfeit.

A segment from “60 Minutes” that was broadcast in December 2002 was played for the board. The board originally viewed this tape in January 2003. This segment provides a good overview as to why the board is sponsoring SB 1307.

LICENSING COMMITTEE

President Goldenberg welcomed new members to the committee: Ruth Conroy (Chair), Richard Benson and Clarence Hiura.

- **Introductions**

Dr. Schell introduced Dr. Jennifer Rasmussen and Dr. Jennigrace Bautista, new licensees and residents at Kaiser Permanente in San Diego, who were in attendance at the meeting.

- **Report on the Meeting of June 9, 2004**

President Goldenberg reported that Dr. Conroy would report on the Licensing Committee Meeting of June 9.

Dr. Hiura welcomed Dr. Conroy as the new chair of the committee and thanked Patricia Harris and Virginia Herold for their support during his tenure as chair of the Licensing Committee.

- **Request from the Pharmacy Foundation of California**

Dr. Conroy stated that the California Pharmacists Association requested that the Board of Pharmacy consider amendments to the CE statute and regulations. One reason for this request was that in January 2004, the activities of the Accreditation Evaluation Service (AES) moved from the California Pharmacist Association (CPhA) to the CPhA Education Foundation. The following changes were requested:

1. Change the term “continuing pharmaceutical education” to “continuing pharmacy education”
2. Change AES from a “continuing education provider and coursework review component of the California Pharmacists Association” to “the accreditation agency for providers continuing pharmacy education in California”
3. Change the role of AES and ACPE from “approvers” to “accreditors”
4. Change the reference from AES to the CPhA Educational Foundation
5. Change the language from “organization” to “accreditation agency”
6. Change the review/audit requirement to a minimum of once a year from 10 percent
7. Change the term “certificates of completion” to “statements of credit”
8. Require the provider to furnish the “statement of credit” to participants who complete the requirements for course completion
9. Require that the material be current in order for it to be considered valid CE
10. Change continuing professional pharmaceutical education to continuing professional pharmacy education

The statutory modification to Business and Professions Code section 4232 will be sought in the next omnibus bill.

MOTION: Licensing Committee: That the Board of Pharmacy amend the continuing education statute and regulations as requested by the Pharmacy Foundation of California.

SUPPORT: 9 OPPOSE: 0

- **Report on the Implementation of North American Pharmacy Licensure Examination (NAPLEX) and California Pharmacy Jurisprudence Examination (CPJE)**

Dr. Conroy reported that the transition to the NABLEX and CPJE has been completed with the recent licensure of 248 pharmacists. Since January 1, 2004, (when the statute took effect), the board has processed 1,792 applications and 1,507 candidates have been determined eligible to take the examinations. As of the beginning of July, 654 candidates have taken the CPJE.

The transition to this new examination format has been challenging and staff will continue to work to streamline this new labor-intensive process. While the board has not been without its critics, tremendous efforts by staff to implement the program timely should not go unnoticed. This was a major change in program operations and this new change was done without additional staff. In fact, the board had lost staff in its licensing and enforcement programs. Moreover, the board was ready to implement the CPJE in December; however, contracts were not in place for the CPJE and NAPLEX until March. There was further delay when by mid-May only 266 candidates (out of the 1,000 eligible candidates) had taken the CPJE. This delayed the release of the CPJE results because 400 candidates were needed to take the examination in order to validate the questions.

Ms. Harris referred to the Competency Committee report provided in the board packet for the pass/fail information and other statistical data for both the NAPLEX and CPJE examinations.

Meanwhile, the licensing unit has experienced a substantial increase in telephone, faxed and in-person inquiries regarding the examination process. Many candidates are confused and want to be walked through the application process. Staff has been working hard to ensure timely processing and licensure of pharmacist applicants. Every effort is being made to assist applicants to the extent that the board can without impacting the application process. The application process for licensure examination has been updated and is on the board's Web site.

Mr. Tilley asked Dr. Rasmussen and Dr. Bautista and other new licensees in the audience to describe their exam experience to the board.

Comments were varied and included that the most stressful part was the new application process, and that no one was available to provide verbal instructions or status checks. Also for identification at the test site for CPJE applicants there was much confusion about exact name matching.

Additional comments included: testing sites varied in computer equipment and overall effectiveness as a testing site. Security was an issue because candidates could leave the room during the examination to go to the bathroom.

Dr. Fong asked the group if they felt the test was fair.

Comments included: The NAPLEX was not fair; the NAPLEX was not similar to the course work studied in school; the NAPLEX was not disease-based but rather random with mostly calculations, and the school's curriculum do not have compounding classes. The students added that the turn-around time for application processing was very fast and efficient and it was a nice surprise to receive a telephone call from the board stating that an item was missing from their application packet.

Mr. Tilley thanked the group for their input.

Dr. Fong commended Ms. Harris, Ms. Herold and staff for a very diligent and focused job on the new exam process and for their responsive approach to applicants.

Mr. Jones stated that the board has three members on the NABP test committee and that will have an impact on the way the exam reflects California standards.

- **Implementation of the Statewide Protocol for Pharmacists to Furnish Emergency Contraception**

Dr. Conroy reported SB 490 (Chapter 651, Statutes of 2003) permits pharmacists to furnish emergency contraception medication based on a statewide protocol adopted by the California State Board of Pharmacy and the Medical Board of California. The Medical Board of California approved the statewide protocol for pharmacists to furnish emergency contraception and the protocol is available on the board's Web site.

Bruce Young, representing the California Retailers Association, suggested that the protocol be provided to pharmacy owners and the associations that represent them.

- **Pharmacy Manpower Statistics**

Dr. Conroy referred the board to the manpower statistics for California provided in the board packet.

Dr. Conroy stated that as of December 2003, 5,624 pharmacies were licensed with the board. This is a 6.3 percent increase from January 2001.

As of December 2003, 37,756 pharmacy technicians were registered. This is a 41 percent increase from December 2001, where there were 26,706 registered pharmacy technicians.

In 2003, there were 24,256 licensed pharmacists with California addresses. This is a 16 percent increase from 2001, where 20,905 pharmacists were licensed.

- **Report on the Implementation of the Licensure and Inspection Program for Pharmacies that Compound Injectable Sterile Drug Products – One Year Evaluation**

Dr. Conroy stated that Supervising Inspector Dennis Ming presented to the Licensing Committee an overview and evaluation on the successful implementation of the sterile compounding licensing program. The program was implemented in July 2003, as the result of legislation.

Dr. Ming stated that when the board implemented the Sterile Compounding Licensing Program in July 2003, the board inspected pharmacies that intended to compound sterile injectable drugs. He added that the board now has one year of experience in working with these pharmacies and the inspection process.

Dr. Ming explained that in order for pharmacies to ship compounded sterile injectables to California they must first be licensed as a non-resident pharmacy. A compounding application is not required if the facility is licensed as a hospital, home health agency or skilled nursing facility and possesses current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, the Accreditation Commission on Healthcare or the Community Health Accreditation Program.

Dr. Ming reported that the board has received 249 applications for compounding pharmacies and has licensed approximately 190 pharmacies.

Dr. Ming stated that since the statute requires the board to inspect pharmacies once a year before renewal, the board began re-inspections in April 2004 of pharmacies that were previously issued a Sterile Compounding License and needed to renew their licenses. Re-inspections are assigned to inspectors who conducted the initial inspection.

Dr. Ming stated that the board held an in-service training session for all inspectors at the June 2004 Enforcement Team Meeting with the objective to review inspections of compounding pharmacies.

Dr. Ming stated that the inspector staff are focused on the equipment used in compounding pharmacies and how this equipment is maintained. He added that if an error occurs, it would start with the equipment. Inspectors are working with these pharmacies to ensure they understand the importance of well-maintained equipment. Dr. Ming stated that out of

approximately 50 re-inspections, the board has not issued any cease and desist orders and no pharmacy was found to jeopardize patients. However, inspectors have issued corrections or advisements.

Dr. Ming stated that this process has raised the bar on standards for pharmacies that compound sterile injectable drugs in California.

Dr. Ming added that an article would be written for *The Script* to help licensees understand the process and to better assist them in maintaining compliance over time and to standardize records.

Dr. Conroy announced that the next Licensing/Compounding Meeting is scheduled for September 22, 2004, in Oakland, California. She directed the board to meeting minutes from the June 9 Licensing Committee meeting and the Workgroup on Compounding meeting.

LEGISLATION AND REGULATION COMMITTEE

President Goldenberg welcomed new members to the committee: John Jones (Chair), Ken Schell, and James Acevedo.

Regulation Report and Action

- **Adoption of CCR, Title 16, Sec. 1746 – Statewide Protocol for Dispensing Emergency Contraception Products**

Ms. Zinder stated that this regulation would codify the statewide protocol for pharmacists dispensing emergency contraception. The protocol itself has previously been approved by the board and the Medical Board of California.

MOTION: Legislation and Regulation Committee: The Board of Pharmacy adopt CCR, title 16, sec. 1746 – Statewide Protocol for Dispensing Emergency Contraception Products

SUPPORT: 9 OPPOSE: 0

Ms. Zinder stated that the board would now compile the rulemaking file for submission to the Administration and the Office of Administrative Law for approval.

- **Adoption of Amendment to CCR, Title 16, Section 1751 et seq. – Sterile Compounding**

Ms. Zinder reported that the noticed changes remove provisions that were determined to be building standards and are not permitted to be adopted by the board. These provisions caused the Office of Administrative Law to disapprove the initial rulemaking. Instead the building

standards were removed from the regulation and inserted in SB 1913, the board's omnibus bill. If the regulation changes are approved by the board, the file will be resubmitted to the Office of Administrative Law and staff anticipates approval of the rulemaking file at that time.

MOTION: Legislation and Regulation Committee: The Board of Pharmacy adopt changes to Section 1751 et seq. of Title 16 of the California Code of Regulations to remove provisions determined to be building standards.

SUPPORT: 9 OPPOSE: 0

Regulation Update

Board Approved and Undergoing Administrative Approval

The board has adopted and compiled the rulemaking files and they are undergoing administrative review:

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

Ms. Zinder stated that this regulation would permit a pharmacist to serve as pharmacist-in charge at two locations.

- **Section 1710 – Hospital Central Fill**

Ms. Zinder stated that this regulation would permit central refill operations for hospitals.

- **Section 1711 – Patient Notification**

This regulation will clarify patient notification requirements in the event there is a medication error.

- **Section 1717.1 – Common Electronic Files**

This regulation will require pharmacies using common electronic files to adopt policies ensuring patient confidentiality.

- **Section 1717.4 – Authentication of Prescriptions**

This regulation will require pharmacists to ensure the authenticity of prescriptions.

- **Section 1720 – Pharmacist License Process**

This regulation will require qualified individuals to pay the pharmacist licensing fee in a shorter time frame and require applicants to take the licensure examinations within one year of applying to take the exams.

- **Section 1721 – Pharmacist Exam**

This regulation will clarify and increase the penalties for cheating on the pharmacist licensure examinations.

- **Section 1724 – Passing Score**

This regulation establishes the methodology of determining the passing score on the pharmacist licensure examination to comply with changes made by Senate Bill 361 (Figueroa, Chapter 539, Statutes of 2003).

- **Sections 1749 and 1793 et seq. – Pharmacy Technicians**

This regulation conforms and clarifies regulations relating to pharmacy technicians to reflect changes made by Senate Bill 361 (Figueroa, Chapter 539, Statutes of 2003).

- **Section 1793.3 – “Clerk-Typist” Ratio**

This regulation will eliminate the clerk/typist ratio in community pharmacies.

Awaiting Notice

- **Section 1715 – Pharmacy Self Assessment**

This regulation will update the pharmacy self-assessment form to reflect recent changes in pharmacy law. An informal hearing is required.

Legislation Report and Action

Board-Sponsored Legislation

- **AB 1960 (Pavley) – Pharmacy Benefit Manager**

Ms. Zinder stated that this bill requiring the board to regulate contract terms and disclosures by PBMs was recently amended to move away from California pharmacy law provisions as requested by the board in its previous position. The bill no longer requires the board to enforce its provisions.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy change its position on Assembly Bill 1960 (Pavley) from oppose unless amended to no position.

SUPPORT: 9 OPPOSE: 0

- **AB 746 (Matthews) – Drug Marketing**

Ms. Zinder stated that a previous version of this bill required the board to revoke a license after a second conviction for Medi-Cal fraud. This bill was recently amended to delete the prior version of the bill and add new provisions that do not directly impact the board.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy change its previous motion of support to no position on Assembly Bill 746 (Matthews).

SUPPORT: 9 OPPOSE: 0

Status Update for Bills with Board Position

- **AB 320 (Correa) – Gag Clauses**

Ms. Zinder stated that this bill prohibits “regulatory gag clauses” in malpractice settlements. The board has a support position on this bill. This bill is currently in the Senate Appropriations Committee.

- **AB 1826 (Bogh) – Fraudulent Use of a License**

Ms. Zinder stated that this bill adds the theft of professional license numbers to identity theft statutes. This bill failed passage in committee.

- **AB 2184 (Plescia) – Automated Dispensing Devices**

Ms. Zinder stated that this bill allows expanded use of automated dispensing machines in skilled nursing facilities. The board has a support position on this bill. This bill is currently on the Senate Floor.

- **AB 2660 (Leno) – Pharmacist DEA Registration**

Ms. Zinder stated that this bill allows pharmacists working under protocol to obtain DEA registration numbers, among other provisions. The board has a support position on this bill which is currently on the Senate Floor.

- **AB 2682 (Negrete McLeod) – Wholesalers**

Ms. Zinder stated that this bill requires all out-of-state distributors to be licensed by the board. Current law allows wholesalers shipping to another wholesaler in California to be exempt from being licensed as a California distributor; the bill requires all wholesalers in a distribution channel to be licensed unless the company is a manufacturer that distributes only its own products from licensed manufacturing premises. The board developed the language for this companion bill to SB 1307, and the board has a support position on this bill. The bill is in the Senate Appropriations Committee.

- **SB 1159 (Vasconcellos) – Hypodermic Needles**

Ms. Zinder stated that this bill repeals the prescription requirement for needles and syringes, and would allow pharmacists under specified conditions to sell 10 needles without a prescription. The board has a support position on this bill that is currently on the Assembly Floor.

- **SB 1427 (Ackerman) – Counterfeit Drugs**

Ms. Zinder stated that this bill would have imposed a felony for drug counterfeiting. The board has a support position on the bill. The bill failed in committee.

- **SB 1563 (Escutia) – 340B Drug Pricing**

Ms. Zinder stated that this bill would require wholesalers and manufacturers to extend 340B drug discounts to “safety net” providers. The board has an oppose unless amended position on the bill because the provisions are located in California Pharmacy Law, where they would become the board’s responsibility to enforce. This bill is in the Senate Appropriations Committee Suspense File.

- **SB 1735 (Figueroa) – Special Fund Agencies**

Ms. Zinder stated that this bill exempts Department of Consumer Affairs boards and bureaus from the state’s hiring freeze that ended June 30, 2004, and restores vacant positions recently eliminated over the last two years. The board has a support position on this bill and the bill is currently in the Senate Appropriations Committee Suspense File.

Status Update for Bills without Board Position

- **AB 1957 (Frommer et al) – Drug Importation**

Ms. Zinder stated that this bill requires the Department of Health Services Board to establish a Web site for approved Canadian pharmacies. This bill is currently in the Senate Appropriations Committee. The board has no position on this bill currently.

- **AB 2125 (Levine) – Prescription: Requisite Information**

This bill would have required prescribers and pharmacies to include the patient's diagnosis on the prescription unless instructed otherwise by the patient. This bill failed passage in committee.

- **SB 1149 (Ortiz) – Importation**

This bill requires the Board of Pharmacy to list Internet sites selling prescription drugs that have violated recognized standards for good practice. The board would also designate Canadian pharmacies that meet California's standards for pharmacy practice. The bill is currently in the Assembly Appropriations Committee. The board has no position on this bill currently.

Mr. Tilley expressed concern that importation is illegal. Since he was absent from the April Board Meeting, he asked why the board did not take a position on the bill.

Mr. Riches stated that during the April Board Meeting the board reached an impasse with either a clear majority for or against the bill. He added that the Legislature's bill analysis from June 22, identifies a number of changes. The most significant is to establish a process for Canadian pharmacies to apply to the board for approval and if approved to be placed on the board's Web site. The bill establishes a contracting process for these pharmacies to be placed on the board's Web site, and establishes a \$1,500 fee.

Mr. Riches stated that SB 1149 was amended to appropriate \$71,000 to the board in the 2004/05 budget year, which represents approximately half of the fiscal estimate that the board placed on the bill. Provisions in the bill also establish a special fund that would pay for all costs.

Bruce Young, representing the California Retailers Association, expressed concern about the board entering into a contract with a company to be listed on the board's Web site, that cannot legally import drugs into California,

Mr. Powers stated that many states are attempting to deal with this problem in many different ways. He added that pharmaceutical companies are responsible for the problem of the U.S. having the highest prices in the world for medication that is sold for substantially less elsewhere. But until the federal government acts to control pharmaceutical prices, states and local communities will continue to consider ways to deal with this issue.

Mr. Tilley encouraged the board to change its position on AB 1957 and SB 1149 to oppose.

Dr. Schell encouraged the board to remain with no position until more information is learned about how the federal government will act on pending legislation.

Dr. Fong stated that the board must first consider public protection and not communicate a message to the public that Canadian pharmacies are an exception to federal law that prohibits such importation of prescription drugs. He suggested a watch position on these bills.

Mr. Powers stated that the public will buy drugs from Canada or wherever possible in order to buy affordable drugs. These bills provide a limited way for consumers to gain some knowledge about the sites they are ordering drugs from. Other states have tried this and inspected the Canadian sites selling prescription drugs and found them to be safe with standards as good or better than those for pharmacies in the U.S.

Art Whitney suggested that the board consider its mission statement; the board's mission is to protect the public rather than to provide affordable health care.

Another comment made was that the board needs to consider the balance between the risk of getting medications from another country and an even greater risk of not taking the medication because it is not affordable.

Mr. Cronin, representing the California Pharmacists Association, encouraged the board to take an oppose position on these bills.

Mr. Riches stated that the bill contains a list of criteria that the Canadian pharmacy would have to meet to be eligible. The board would have latitude in judgment in assessing these individual pharmacies.

Mr. Tilley stated that it appears that the board is condoning this illegal activity. If the bill passes, Canadian pharmacies will be added to the board's Web site and the board would not have the ability to enforce the law on these pharmacies. Consequently, these pharmacies would not have to comply with the same rules as pharmacies in California do. He asked if these pharmacies would be inspected.

Mr. Riches explained that this would not be a licensing process and would not be subject to the enforcement functions the board normally takes. The federal government needs to act on this issue; the state lacks the authority.

MOTION: That the Board of Pharmacy oppose AB 1957 (Frommer et al) and SB 1149 (Ortiz)

M/S/C: TILLEY/FONG

SUPPORT: 6 OPPOSE: 2

- **SB 1307 (Figueroa) – Wholesalers and manufacturers of dangerous drugs and devices**

Ms. Zinder stated that this bill is sponsored by the Board of Pharmacy to improve the licensing of wholesalers and the safety of wholesale transactions. The bill is currently awaiting a hearing before the Assembly Appropriations Committee. Recent amendments have been made to address a range of issues raised by interested parties. Among the most notable are:

1. Deleting provisions establishing a separate designation for “closed door pharmacies.”
2. Permitting per occurrence fines for specified violations in pharmacies primarily serving long term care patients.
3. Shifting provisions relating to non-resident wholesalers to Assembly Bill 2682 (Negrete McLeod).
4. Permitting the board to delay implementation of the electronic pedigree in pharmacies to January 1, 2009.
5. Clarifying provisions requiring wholesalers to track furnishing to long-term care pharmacies.
6. Modifying the board requirement for wholesalers to accommodate small and start-up wholesalers.

Bruce Young, representing the California Retailers Association (CRA), thanked President Goldenberg for addressing the issue at a recent CRA Chamber Meeting. Mr. Young stated that the biggest objection is that no electronic tracking system exists. He suggested that the board convene a task force and review the FDA report from its 2003 nationwide task force.

Mr. Riches stated that this bill is currently in the Senate Appropriations Committee. He added that the board has worked extensively on this bill and made many changes.

President Goldenberg stated that the goal is to create a forum for the stakeholders, the public and board members to work this out prior to the legislative process. Moreover the 2009 implementation date for pharmacies to track pedigrees will assure that the technology is readily available at a low cost.

Collette Galvez, representing the Center for Public Interest Law, cautioned that the board’s number one priority is public protection. She stated that the board’s earlier discussions today focus on the need to embrace technology and regulating Canadian pharmacies. When there are convening priorities, the number one priority is public protection.

Mr. Jones referred to a recent drug scare involving counterfeit Viagra that could have been avoided if pharmacies could have tracked a lot number.

- **SB 1913 (Figueroa et al) – Professions**

Ms. Zinder stated that this bill contains numerous provisions sponsored by the board to make technical and non-controversial changes to pharmacy law. She highlighted several provisions.

Mr. Cronin stated that this bill allows certified nurse midwives, nurse practitioners and physician assistants to order drugs from a wholesaler and he asked where this provision originated.

Mr. Riches responded that the amendment came through Senator Figueroa's office from the Nurse Practitioners Association and Physician Assistants Association.

NEW BUSINESS/AGENDA ITEMS FOR FUTURE MEETINGS

John Cronin, representing California Pharmacists Association, suggested that the board's citation and fine funds be used solely for educational purposes for licensees. He added that he heard that the cite and fine funds are being used as a means to collect revenue instead of raising fees.

Joshua Room, DAG, explained that the money is not accessible to the board and the board would need specific Department of Finance authority in order to spend it.

Ms. Harris stated that at the same time that the cite and fine regulation went into effect the board lost \$6 million to the General Fund. The board also spent \$2 million more than it had for its operational budget last year. She added that the citation and fine program was not an attempt to deal with budget shortfalls but instead used to augment inspections.

Mr. Room stated that if the board's reserve falls below a certain level then the board must raise fees but if the reserve exceeds a certain level, then the board must reduce fees.

Mr. Cronin requested that the Enforcement Committee reevaluate the need for spending money on educational efforts for pharmacists.

Ms. Harris stated that the board's core function is licensing and enforcement, including, resolving consumer complaints timely. However, the board also acknowledges the importance of educating licensees. The board has developed a significant licensee education effort over the last year. Additional discussion should be placed with the Communication and Public Education Committee.

Also, various cite and fine scenarios will be placed in future newsletters as educational items for pharmacists.

CLOSED SESSION

The board held two petition hearings to consider early termination of probation for Herman Leo Kramer and Robert Stephen Olsen.

The board moved into Closed Session pursuant to Government Code Section 11126, sub. (a) regarding personnel matters to perform the evaluation of the Executive Officer.

The board moved into Closed Session pursuant to Government Code Section 11126, sub. (c)(3) to deliberate upon disciplinary cases.

Thursday, July 22, 2004

CLOSED SESSION

The board moved into Closed Session pursuant to Government Code Section 11126, sub. (c)(3) to deliberate upon the petitions for reinstatement.

ADJOURNMENT

There being no further business, President Goldenberg adjourned the meeting at 12:30 p.m.