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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 & TIME: January 21 and 22, 2004

LOCATION: **The Crowne Plaza Irvine**
17941 Von Karman Avenue
Irvine, CA 92614

BOARD MEMBERS PRESENT:
John Jones, President
James Acevedo (January 21, only)
Richard Benson
Ruth Conroy
David Fong
Stanley Goldenberg
Clarence Hiura
William Powers
Kenneth Schell
John Tilley (January 21, only)
Andrea Zinder (January 21, only)

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

Wednesday, January 21, 2004

CALL TO ORDER

President Jones called the meeting to order at 8:00 a.m. on Wednesday, January 21, 2004.

CLOSED SESSION

The board moved into Closed Session pursuant to Government Code Section 11126, subdivisions (e), (2), (c) to confer with and receive advice from its legal counsel regarding pending litigation.

The board ended Closed Session at 8:50 a.m.

ANNOUNCEMENTS

President Jones called the public meeting to order at 9:00 a.m. on Wednesday, January 21, 2004.

- **Continuing Education Credits Available for Attending the Board Meeting**

  President Jones stated that continuing education hours could be earned by pharmacists wanting to learn more about the issues and operation of the board by attending this 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 and no partial credit will be given for attendance at part of a meeting. President Jones added that three hours of continuing education credit could also be earned by pharmacists who attend the Enforcement Workshop scheduled during the board meeting on Thursday.

- **Recognition**

  President Jones acknowledged former Board Member and Board President Steve Litsey, who was present in the audience. He also welcomed pharmacy students from USC, Western University and UCSD who were in attendance.

COMMITTEE REPORTS AND ACTION

Organizational Development Committee

President's Report

- **Election of Vice President**

President Jones announced that former board vice president Don Gubbins' term ended in July 2003 creating a vacancy.

MOTION: Nominate Stan Goldenberg as vice president.

M/S/C: TILLEY/HIURA

MOTION: Close the vice president nominations.

M/S/C: HIURA/TILLEY

SUPPORT: 10 OPPOSE: 0

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

Chairperson Tilley reported on the Organizational Development Committee Meeting of January 9, 2004. He thanked Stan Goldenberg for his input on budget matters and he thanked Patricia Harris and Virginia Herold for their hard work.

- **Annual Update of the Board's Strategic Plan**

Chairperson Tilley reported that each year the board reviews and updates its strategic plan. This revision typically occurs during the April Board Meeting during the annual public meeting of the Organizational Development Committee.

Chairperson Tilley stated that last year, a major revision of the strategic plan was undertaken that substantially restructured the plan. Lindle Hatton, PhD, led the board in this process. At the time of the revision (which actually was initiated in 2002 and completed in 2003), the board's intent was to make minor updating changes to the strategic plan in 2004 and undertake a major revision in 2005. This is consistent with the direction provided by Dr. Hatton that generally strategic plans should endure for more than one year in their scope and vision, and should be focused on three to five years.

MOTION: Organizational Development Committee: That the board perform its annual update of its strategic plan this year by directing each committee to review its plan during the next quarterly meeting and bringing any changes to the April 2004 Board Meeting for discussion, modification and adoption into the strategic plan for 2004.

SUPPORT: 10 SUPPORT: 0

- **Proposed Technical Amendments to Clarify Renewal of a Permit and Scholarship Donations**

  Chairperson Tilley stated that several years ago, a California Pharmacist Scholarship and Loan Repayment Program was established whereby pharmacists and pharmacies could donate funding for scholarships for pharmacy students. This donation would be made at the time a pharmacist or pharmacy renews his/her/its license. The amount of this donation was established as $25 in the statute. In establishing cashiering parameters, the department concluded that contributions over $25 could not be accepted and the full amount of the donation would need to be returned.

  Chairperson Tilley stated that to permit pharmacists and pharmacies to donate more than $25, the statute needs to be amended.

  Dr. Fong asked how much the board has collected so far.

  Ms. Herold responded that the board has not collected very much because the renewal notice does not include a statement announcing that a donation to this fund can be made. The board requested that the department revise the renewal form to include this statement and it is anticipated that the new renewal notice will be ready by February or March 2004.

  Ms. Herold stated that once the board receives this donation, the money is transferred to the Office of Statewide Health Planning and Development, which is charged with handling the fund. This fund is designated for pharmacists in underserved areas, once the balance is sufficient to start the program. Ms. Herold added that the board could remind licensees about the scholarship fund in future newsletter articles.

  Dr. Fong asked for more information about how the Office of Statewide Health Planning and Development will administer the fund.

  MOTION: Organizational Development Committee: Add proposed amendments to Business and Professions Code section 4009 to permit pharmacists and pharmacies to donate more than $25 to a scholarship fund that would assist pharmacists and pharmacies serving underserved areas as follows:

  At the time a pharmacy license is renewed pursuant to subdivision (a) of Section 4410 or a pharmacist license is renewed pursuant to Section 4401, the pharmacy or pharmacist may make a ~~twenty-five dollar ($25)~~ contribution~~,~~ <u>of at least twenty-five dollars ($25)</u> to be submitted to the board, for the sole purpose of funding the California Pharmacist Scholarship and Loan Repayment Program established pursuant to Article 5

(commencing with Section 128050) of Chapter 2 of Part 3 of Division 107 of the Health and Safety Code. The contribution submitted pursuant to this section shall be plaid into the State Treasury and credited to the California Pharmacist Scholarship and Loan Repayment Program Fund established pursuant to Section 128051 of the Health and Safety Code.

SUPPORT: 10 OPPOSE: 0

Chairperson Tilley stated that technical amendment is needed to section 4403 to conform the language to current usage. The board generally "renews" rather than "reissues" licenses.

MOTION: Organizational Development Committee: Add a technical amendment to Business and Professions Code section 4403 as follows:

4403: The board shall not reissue or renew any license without the payment of the fees required by this chapter and the payment of all fees that are delinquent at the time that the application is made.

SUPPORT: 10 OPPOSE: 0

- **NABP Staff Recommendation that the Board Become a Full Member of NABP**

Chairperson Tilley stated that staff of the National Association of Boards of Pharmacy has recommended that the board become a full member of the NABP because California is now using the NAPLEX to assess minimum competency in pharmacists as a condition for licensure, and accepting score transfers of NAPLEX exams for candidates who have taken the NAPLEX after January 1, 2004.

Chairperson Tilley stated that full membership in the NABP would allow the board to vote in matters before the NABP, a right the board does not currently have as an associate member. This would provide the board with a greater role in the development of national policies regarding pharmacists' care. This determination will be made by the vote of the NABP executive staff in the near future.

Chairperson Tilley stated that the Annual Meeting of the NABP is set for April 24 –28 in Chicago. The committee encouraged board members who can afford to go on their own to attend this meeting. Current budget restrictions will make it nearly impossible for the board to receive funding for any board member or the executive officer to attend. However, this national meeting will allow the board to participate in evolving

national policy of state boards of pharmacy on such key areas as importation of drugs and the regulation of wholesalers.

Dr. Fong stated that he plans to attend the NABP annual meeting. His expectation is that California will take an active role within the group.

Mr. Cronin asked what the status of the board's inclusion on the NABP exam committee is.

President Jones stated that California has three members out of 30 on the NABP exam committee who are knowledgeable about the California exam and are former members of the board's Competency Committee. He added that the California members are valued for their input.

- **Budget Update for 2003/04**

Chairperson Tilley reported that the state continues to face a huge budget deficit this year and projections continue to forecast deficits for the future. The Davis Administration issued several cost containment requirements that have impacted the board's budget this year. Since July 1, 2003 (the beginning of this fiscal year), the board has:

- Lost six positions vacant on June 30, 2003.
- Identified a 12 percent (or $420,000) 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 operating expenses. No staff at the board was laid off to meet the 12 percent reduction.
- Been advised that it cannot purchase three vehicles to replace existing vehicles assigned to inspectors (these vehicles were scheduled for replacement last year).

The Governor has issued two executive orders regarding the budget – one extends the hiring freeze through June 2004, the other directs agencies not to contract for goods or services or to undertake unnecessary travel.

Mr. Powers referred to the $12,000 the board lost in board compensation and $9,000 lost from operating expenses and stated that the board is self funded and questioned why this money was lost, and where it went.

Ms. Herold responded that the board has lost its ability to spend the money – the board's spending authority for the years was reduced this much. The money has been returned to the board's special fund.

Ms. Herold reported that Board Inspector Rosemarie Yongvanich, who was on parental leave, recently decided not to return to work. The board will seek a freeze exemption to hire someone to fill the vacancy.

Dr. Fong asked how these reductions affect the board's ability to respond to the public about application status and general licensing questions.

Ms. Harris referred to the Licensing Committee report for the implications of these reductions. She added that because of the change in law for technicians, the board received over 1000 applications in December, and with only one technician to process the applications, the board had to creatively manage this workload by turning off the phones and by scheduling other office staff to answer the phones. This resulted in staying on top of the application process. However, because the board will begin using the NAPLEX examination and has already received many applications, the board must once again redirect the workload. The goal is for the entire process to run more smoothly, once the programs are up and running.

Ms. Harris explained that because so few staff are assigned to process applications, the board is unable to handle all of the application status calls it receives. Answering these calls reduces the amount of applications that can be processed on any day, which delays application processing overall, which further leads to increased status calls. She added that during the next few months as the board transitions through the new exam structure, the board would continue to keep the Web site updated with new exam information as well as application processes and timelines for status calls to the board.

Ms. Harris stated that in spite of these difficult working conditions staff work hard to keep on top of the process. She commended the Licensing Unit staff on their efforts.

Revenue for 2003/04

The board's projected revenue for the year is $5,640,544. This is comprised of $5,420,423 in fee revenue and $220,121 in interest.

Actual fee revenue is likely to be approximately 10 percent higher than the $5.4 million, but interest revenue will be substantially less (this figure is calculated by the Department of Finance, and is $100,000 more than last year's actual interest income, which was collected on a larger balance in our fund).

Not included in the projections is revenue from citations, which as of early December was $470,000.

Expenditures for 2003/04

The most recent estimates prepared by the Department of Consumer Affairs (December 2003) now set maximum expenditures for the year at $7,000,486. This figure includes the 12 percent reduction in personnel expenditures.

Budget detail:

- Personnel is still the largest component in the budget, comprising 49 percent of board expenditures.
- Enforcement expenses (excluding enforcement staff salaries) are 14.9 percent.
- Pro rata charges for DCA and the state are 13.7 percent of our budget (by comparison, in 1998/99 pro rata was 11.2 percent of our budget).
- Travel is budgeted for $167,011 (2.4 percent), which is nearly equal to last year's actual travel expenses of $165,294, but nearly $20,000 less than the board spent for travel in 2001/02. (In fact, travel has been steadily decreasing since 1998/99, when it was $228,235.)

Board Member Expenditures and Reimbursements

Update: Board Fund Condition

Last year the board loaned $6 million from its fund (the board's "savings account") 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 $1.3 million more than it projects it will collect in revenue. As such, the amount of money in reserve in the board's fund is important.

Current projections are that the board will not have a deficit in its fund until early in 2005/06.

Budget Change Augmentations for 2003/04 and 2004/05

The board must prepare a "budget change proposal" to increase its budget for resources and staff. The board is not seeking any augmentations for 2003/04 or 2004/05 due to the state's budget crisis.

The board will have to continue to provide services to a growing licensee population with existing staff and existing resources. However, workload priorities will continue to result in changes in how the board performs duties. For example, the board has changed its telephone system to provide callers with more automated answers to their questions, and restrict the immediate access of callers to the board's receptionists. Additionally, all staff is being assigned to answer the phones for four hours at least once per month as a means to respond to the calls that we do receive in light of staffing reductions.

- **Status Update on Department of Consumer Affairs Internal Audit on the Board**

  Chairperson Tilley reported that a number of recommendations for the board were made as part of the board's sunset review process during 2002/03. The Joint Legislative Sunset Review Committee (JLSRC) and Department of Consumer Affairs issued a number of joint recommendations, and then each made several additional recommendations for the board. The Organizational Development Committee has been tracking these recommendations, and the board has initiated the work and completed most of it.

  Several of the initiated recommendations deal with public education and outreach, and work is now underway on these items. Another recommendation, making all committee meetings of the board public, will be partially implemented. All committee meetings of the Enforcement, Licensing and Communication and Public Education Committees will be public. At least two meetings of the Legislative and Regulation Committee will be public meetings. At this time, plans are that only one meeting each year of Organizational Development Committee will be noticed as a public meeting.

- **DCA's Internal Audits Office – Assessment of the Board's 180-Day Post Audit Status Report**

  Chairperson Tilley stated that as part of the sunset review, the department's Internal Audit Office reviewed the board's operations from October 2002 to 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. (The department typically audits every agency undergoing sunset review.)

  The Organizational Development Committee also has been tracking these recommendations to review board progress. In October 2003, the committee prepared a copy of the board's status report 180 days after the audit. Progress reports to the department on the board's actions to incorporate the recommendations are required at six months and 12 months.

  Since the October Board Meeting, the Internal Audits Office has audited our 180-day status report. In early December the office issued its assessment. Of the four initial findings, the auditors indicate that the board has:

  1. Ongoing assessment and evaluation of its fund condition is in place to prevent a deficit in the fund.
  2. Partially completed inventory controls for destroying outdated evidence and posting signs regarding the board's evidence storage.

3. Tracking systems in place for monitoring processing of applications, but the board would benefit if a single, integrated tracking system existed for all of its 12 programs (the board is relying on the department to provide such a system).
4. Fully implemented changes to the automated complaint tracking system.

The auditors also stated their intent to audit all the board's activities when assessing its 360-day progress report.

- **Transition to the New Administration**

Chairperson Tilley stated that the Schwarzenegger Administration began November 17, 2003. A few new appointments have made thus far changing key administrators – Medical Board Executive Director Ron Joseph has been appointed interim director, replacing Kathi Hamilton. Former legislator Fred Aguiar began work as Secretary of the State and Consumer Services Agency on January 5. A new press officer has been appointed to replace former Deputy Director Mike Luery, who left state service.

Several executive orders have been issued dealing with budget matters and regulations.

1. **Executive Order S-2-03 – Regulations**

   This executive order suspends all pending rulemaking proceedings for six months. The order requires a list of all regulations adopted during the Davis Administration, and each agency to prepare a list of any "underground" regulations.

   The board's Legislation and Regulation Committee will discuss this executive order more fully during its report at this meeting.

   Mr. Powers expressed concern that an exemption to submit sterile compounding regulations were denied by the agency, which will require the whole rulemaking to start over with a 45-day initial notice. He stated that this could cause considerable harm to patients. He added that the board should speak to those responsible regarding this type of irresponsibility.

   Chairperson Tilley stated that the board's staff is working with the department's legal counsel to rework the exemption request.

2. **Executive Order S-3-03 -- Hiring Freeze**

   The Governor continued the hiring freeze established by Governor Davis in 2001. In the case of the board, this means that the board could not fill

vacancies by hiring anyone who is not already a board employee, nor could the board promote staff into any vacant position at the board without a freeze exemption issued by the Department of Finance. Currently the board has no vacancies, should one occur, the board could not fill the position unless a freeze exemption was issued, and then the board would have to hire employees on the state layoff list. All positions vacant for six months are eliminated. The order will expire in June 2004.

3. **Executive Order S-4-03 – Contracts and Nonessential Travel**

   This executive order prohibits state agencies from contracting for goods and services without an exemption unless the contract is for legal services or expert testimony in pending litigation. The Department of Consumer Affairs recently secured an exemption for special fund agencies in the department from this order – agencies such as the board. As such the board can continue to enter into contracts, which is fortunate because without an exemption, the board would not have been able to obtain signed contracts to administer the NAPLEX or the California jurisprudence examination.

   However, the board still must make certain it does not undertake unnecessary or nonessential travel. Currently the only definition provided for this is travel to conferences, training or seminars.

- **Loss of Professional Licensing and Enforcement Management System**

  The Department of Finance suspended financing to continue work on implementing the department's proposed Professional Licensing and Enforcement Management System (PLEMS), a new computer system to replace the primary computer system CAS, which had been created in the early 1980s. The Department of Finance was not convinced that the proposed project was an essential information technology activity and had issues that require the Department of Consumer Affairs to conduct additional research. The department has suspended work on this new system, so the project is at least inactive, if not dead.

  Computer systems that provide licensing and enforcement data are essential. The board has requested that the department redirect staff from the PLEMS project to the programming unit of CAS to allow the existing system to be modified.

- **Personnel Update**

  As discussed earlier, all vacant positions on June 30th were eliminated. The board lost six positions, but currently has no vacancies.

- **Mandatory Ethics Training for Board Members and Designated Staff Must Be Completed in 2003**

  Chairperson Tilley commended all board members and designated staff that have completed the state-mandated ethics training as required before January 1, 2004.

  Everyone required to complete this training did complete it.

APPROVAL OF MINUTES

Full Board Minutes
(October 29 and 30, 2003

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

MOTION: Approve the October 29 and 30, 2003, Board Meeting Minutes

M/S/C: GOLDENBERG/HIURA

SUPPORT: 8 OPPOSE: 0

Communication and Public Education Committee

Chairperson Powers reported on the public meeting of January 8, 2004. He added that this was the first public meeting held independently from a board meeting. There were three public members present.

- **Web Site Redesign**

Chairperson Powers reported that at the October Board Meeting, the board approved a recommendation from the committee that the board sponsor a contest for pharmacy students to redesign the board's Web site. This was in recognition that the Web site needs to be updated and pharmacy students, who often have much creativity in designing Web sites, would greatly benefit by working so closely with the information the board places on the Web site. As a result both the board and pharmacy students would benefit and the board would have an attractive and redesigned Web site.

Chairperson Powers stated that the following the board meeting, staff researched requirements for California government Web design. There are at least 80 pages of requirements that provide little room for creativity. The goal is that the Web pages for each state agency be similar, and not contain fonts that are difficult to read, and graphics or other features that can slow the loading of a Web page by computers without fast modems or large memories.

Chairperson Powers stated that after reviewing about 25 of these pages of requirements, the committee determined that the Web design contest might not be the best way to go because the board is not likely to be able to install designs created by students.

He stated that as an alternative, the committee discussed other ways to integrate pharmacy students into public outreach activities so that students may share their knowledge and enthusiasm. One suggestion is to have students develop new public education materials on specific topics they learn about during their internships or classes, or topics that are emerging public policy matters (e.g., flu vaccines: inhalation forms vs. shots). If the board develops a prototype template/format for a series of fact sheets, each student could complete the information and be acknowledged with a credit at the bottom of the fact sheet. The board could check the accuracy of the information and assure it is written at an appropriate reading level.

Ms. Herold distributed a copy of such a prototype fat sheet. Those students who prepare the fact sheets would be acknowledged on each fact sheet, which would benefit their resumes. And via the availability of the information, the public and the board would benefit. The standardized format would make it easy for students and the board to develop and produce, and easy for the public to reference.

MOTION: Communications and Public Education Committee:
That the board discontinue its plans to sponsor a web design contest among pharmacy students, and instead identify another public outreach activity that would involve pharmacy students in the board's public education program.

SUPPORT: 10 OPPOSE: 0

- **Emergency Contraception Fact Sheet**

Chairperson Powers stated that at the last board meeting, the board approved a new Emergency Contraception Fact Sheet for use by pharmacists who provide emergency contraception under protocol. This new fact sheet has been placed on the board's Web site and will be published in the next issue of *The Script.*

Since the last meeting, the Pharmacy Access Partnership translated the fact sheet into nine languages – Cambodian, Chinese, Farsi, Hmong, Korean, Russian Spanish, Tagalog and Vietnamese. These versions will also be added to the board's Web site.

- **Update on *The Script***

Chairperson Powers stated that articles for the January 2004 issue of *The Script* have been written and are undergoing review. This issue should be published in late February. The articles will feature new laws (for example, new pharmacy technician requirements, new pharmacist licensure exam requirements, new requirements for prescribing and dispensing controlled drugs).

Chairperson Powers added that the Education Foundation of the CPhA printed and mailed the October 2003 *The Script* to pharmacists in November. The Education Foundation will also print and mail the January issue of *The Script* to pharmacists once it is available.

- **Update on *Health Notes***

  Chairperson Powers stated that staff is now working to publish a wholly new Pain Management issue early in 2004, probably April. This new issue will contain new pain management therapies and the new prescribing and dispensing requirements for controlled drugs enacted by SB 151 (Burton, Chapter 406), which will take effect in 2004 through 2005 in sequential stages.

  Chairperson Powers stated that staff is coordinating the development of this issue. Authors have been selected and have agreed to write specific articles, which are due at the end of January. After this, each article will be reviewed and edited by an appropriate expert, and then the edits reviewed by the authors. The board will also review the articles (Ken Schell has agreed to do this), as will the Legal Office. The same graphic designer who has designed all other *Health Notes* is available to design the issue.

  Chairperson Powers stated that the board is seeking outside funding sources for this issue. Because of the interest in pain management and in the new changes to prescribing of controlled substances, there is much interest and support for this issue.

  The issue also will be of interest to physicians, nurse practitioners, dentists and other prescribers.

  Mr. Goldenberg stated that he encourages a proactive approach while developing the *Health Notes* by addressing anticipated questions, possibly with a section for questions and answers in each issue. Also, to provide meaningful examples describing different types of pharmacy practices.

  Ms. Harris stated the board is also working with companies to develop interactive continuing education programs to get information out regarding new laws and procedures. The board has also met with other prescribing boards that have agreed to include some of the Board of Pharmacy's articles in their publications. She added that the board is working closely with the profession and the industry in getting the word out regarding the new enactments of SB 151.

  President Jones stated that support from commercial interest is also involved to assure that pharmacists, prescribers and others have an understanding of the new laws on the proper use of pain medication.

- **Development of New Public Education Materials**

  Chairperson Powers stated that during the Communication and Public Education Committee Meeting, the committee discussed patient medication compliance and the compliance problems caused when patients cannot read a prescription label because the patient cannot read English or perhaps see the label itself.

  Chairperson Powers stated that Pharmacist Robert Siedman, who deals with patient issues for a large health maintenance organization, was one of these active participants as was Daniel Temianka, M.D., of HealthCare Partners Ltd.

  Chairperson Powers stated that he invited Drs. Temianka and Seidman to the board meeting so that they could participate in a discussion with the board on ideas for improved patient compliance by improved prescription labels and more meaningful, useful labels for patient reference and use. Unfortunately, they were unable to attend the meeting.

  Chairperson Powers stated that Dr. Temianka and Dr. Seidman stated that certain patients could benefit by requesting specialized prescription labels on their medication containers so that those who cannot read English or those who are visually impaired can receive their medications in containers they can read. Whereas this is not a suggestion for a mandate for labeling in a patient's native language or to accommodate a patient's visual needs, in those cases where the pharmacy can readily provide such a label, the proposal is to educate patients that they should ask for such labels on their prescription medications. There are also concerns that endanger patient health that arise from a patient's low literacy, complicated or unclear language on prescription labels in general, and the legibility of the font size used on labels.

  Chairperson Powers stated that he strongly supports the introduction of legislation to require labels be printed in a patient's predominate language and in readable fonts.

  Chairperson Powers added that discussion also included whether there could be better containers to provide medication to patients in other than the prescription containers used so predominately today. Different types of containers or packages for prescription drugs could facilitate improved or more helpful labeling for patients.

  Dr. Fong referred to a two-year bill that would require every pharmacy to have an interpreter. He suggested that the board work with the sponsor of the bill on this.

  President Jones questioned whether licensees have the ability to effectively handle the public with their prescription needs in this multi-cultural society. He asked how it is addressed in pharmacy school admissions.

Sam Shimomura, representing Western University, stated that all California pharmacy schools have a very diverse student body where 55 percent of the students are foreign born and English is their second language.

Steve Gray, representing Kaiser Permanente, stated that the only solution is to have translation services available. He added that pharmacists participating in federally funded programs are already required by federal law to have translation services available to every patient. This specifically refers to Medicare programs.

- **Public Outreach**

  The board's continuing education course has been provided to eight local meetings of pharmacists since January 2003.

LICENSING COMMITTEE

Chairperson Hiura reported on the meeting of December 3, 2003.

- **Approve of Statewide Protocol for Pharmacists to Furnish Emergency Contraception (Implementation of SB 490 (Alpert) Chapter 651, Statutes of 2003)**

  Chairperson Hiura stated that Senate Bill 490 (Chapter 651, Statutes of 2003) permits pharmacists to furnish emergency contraception medications based on a statewide protocol adopted by the Board of Pharmacy and the Medical Board of California. Prior legislation (Senate Bill 1196, Chapter 900, Statutes of 2001) permits pharmacists to furnish emergency contraception medications to patients based on a protocol with a single licensed prescriber.

  Chairperson Hirua reported that the proposed draft protocol presented for board review synthesizes elements from protocols submitted by the Pharmacy Access Partnership and the American College of Obstetricians and Gynecologists. Staff also reviewed protocols from the states of New Mexico and Washington and a sample protocol used by pharmacists under the existing protocol requirements.

  The draft protocol was prepared with the intent to keep it simple and to comply with the statutory requirements established by Senate Bill 490. Both the Board of Pharmacy and the Medical Board of California must approve the protocol. The Medical Board of California is awaiting Board of Pharmacy action before considering the protocol at its next board meeting in several weeks at its next board meeting in several weeks.

  The draft protocol has the therapy as two doses administered 12 hours apart within 72 hours of engaging in unprotected sex. However, recent studies indicate that emergency contraception drug therapy remains substantially effective up to 120 hours after unprotected sex and one emergency contraceptive product (Plan B) can be administered in a single dose. While the efficacy of emergency contraception declines over time, it remains approximately

80 percent effective when taken within 120 hours. The newer timing and dosing regimens would expand access to emergency contraception that is important and the single dosing of Plan B would greatly aid in patient compliance with the therapy. The studies support no increased risk or side effects to the longer time period or the altered dosing regimen.

Language authorizing a pharmacist to dispense condoms was removed from the proposed; however, the consensus of the board was that this language should be added back in because many health plans would cover the cost of condoms with a prescription.

Shannon Smith-Crowley, representing the American College of Obstetricians and Gynecologists, referred to their concerns outlined in a letter dated January 13. She added that one objection to the standardized protocol is asking a woman for the date of her last menstrual period in order to rule out pregnancy. She stated that there are only two questions the pharmacist needs to ask patients to establish the appropriateness of the medication and that is whether the woman is allergic to any drug and whether she has had unprotected sexual intercourse within 72 hours.

Ms. Smith-Crowley stated that the EC Fact Sheet states that EC is most effective if taken within three days of unprotected sex and pharmacists should counsel clients that "EC effectiveness declines gradually over 5 days" (120 hours). She added that recent studies show that within the 5-day period EC may still be effective. She requested that the protocol reflect the 3-day period until all concerned parties agree on changing the timing to 5 days, at which time the fact sheet could also be changed.

Kathy Bessinque, representing Pharmacy Access Partnership, stated that as a pharmacist, she provides EC. She requested that the language asking the date of the last menstrual period be left in the protocol because it gives the pharmacist an opportunity to open a dialogue with the patient about if pregnancy is established, and to refer the patient as part of patient counseling.

Mr. Riches informed the board that Executive Director Jane Bogess of the California Access Partnership had unexpectedly passed away over the weekend. Mr. Riches recognized her efforts in this project and he stated that the California Access Partnership was a driving force in the emergency contraception law in California.

President Jones also recognized Ms. Bogess' extreme dedication to the coalition and added that she was very active in promoting pharmacy access throughout California. She will be missed.

MOTION: Licensing Committee: Approve the proposed statewide protocol for emergency contraception with the request that the board consider modifying the protocol to include the Plan B therapy of a single dose within 5 days.

SUPPORT: 1 OPPOSE: 9

MOTION: Approve a statewide protocol for emergency contraception to include the Plan B therapy of a single dose within 5 days and to include language authorizing the pharmacist to dispense condoms under a prescription to ensure payment by a health plan.

M/S/C: POWERS/BENSON

SUPPORT: 10 OPPOSE: 0

- **Proposed Statutory Changes To The Intern Program.**

Chairperson Hiura stated that the Licensing Committee reviewed the intern program during the last two meetings. Based on the committee's review and discussions, staff drafted modifications to the program. The modifications were drafted as a statute because current intern requirements are in regulation and should be in statute. The changes include the following: a ratio of two interns to one pharmacist (this is consistent with current board policy), the requirement that the pharmaceutical experience comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education and the elimination of the extension provision for the intern permit and the definition of a preceptor.

Chairperson Hiura stated that during the committee meeting, the public recommended proposed changes. The committee agreed with the recommended changes and directed staff to modify the language accordingly. The proposal was modified and shared with interested parties for comment. He added that staff received feedback and some additional language changes and some of the changes were added and reflected in the proposed language.

Mr. Goldenberg referred to the elimination of the extension provision for the intern permit and the definition of a preceptor and asked for clarification.

Ms. Harris stated that the intern provisions are in regulation. She stated that many years ago the board registered preceptors and when this role was eliminated, a statute provision replaced the regulation to allow for a pharmacist in good standing to supervise an intern.

Ms. Harris stated that the regulation on intern license extensions reads that the board can issue an intern permit up to five years; these longer permits are usually to first year students entering pharmacy school. Upon graduation, if the student does not take the exam right away or has trouble passing the exam, the board has the authority to extend the intern permit for another year or two. She added that the board is recommends a statute provision that the board can issue an intern permit from one to six years. Another is to add a provision that the board could issue an intern permit to a pharmacist who wants to reinstate a pharmacist license.

Steve Gray, representing Kaiser Permanente, referred to section 4209(b) of the Business and Professions Code and suggested changing the word "while" to "where" as follows: … pharmacist-in-charge at the pharmacy ~~while~~ where the pharmacist intern obtained the experience. This would allow a pharmacist-in-charge to sign an affidavit based on knowledge and a review of the training records of the facility.

MOTION: Licensing Committee: The Board of Pharmacy approve statutory changes regarding the intern program.

SUPPORT: 0 OPPOSE: 10

MOTION: The Board of Pharmacy approve the statutory changes regarding the intern program by adding proposed Section 4209 (b) of the Business and Professions Code as follows:

4209. (a) An intern pharmacist shall complete 1,500 hours of pharmaceutical experience before applying for the pharmacist licensure examination.
(1) This pharmaceutical experience must comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.
(b) An intern pharmacist is required to submit proof of his or her experience on board approved affidavits, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy where the pharmacist intern obtained the experience.
(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, shall be exempt from subdivision (a). Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

M/S/C: GOLDENBERG/BENSON

SUPPORT: 10 OPPOSE: 0

- **Approval of New School of Pharmacy at Lake Erie College of Osteopathic Medicine**

Chairperson Hiura stated that the board received an intern pharmacist application from a student at Lake Erie College of Osteopathic Medicine, School of Pharmacy. This is a new school, which provides an accelerated Pharm.D. program, which can be completed in three years. The first students admitted into this program are currently in their second year of instruction.

President Jones stated that this request was received by the board after the December 3, 2003, Licensing Committee Meeting and consequently does not have a recommendation from the committee. He anticipated similar requests as new schools are opened in the United States.

Ms. Herold stated that according to the Accreditation Council for Pharmacy Education (which until several months ago was known as the American Council on Pharmaceutical Education) or ACPE, this program was ranked by that agency as "Pre-candidate Status."

Pre-candidate status is the lowest of the ACPE provisional accreditations, and students who graduate from such a school would not be eligible for pharmacist licensure in most states. The ACPE states that pre-candidate schools have the concepts of an acceptable ACPE program committed to paper, but the program components have not yet been fully implemented.

"Candidate Status" is the next provisional level of ACPE accreditation, which would allow graduates from such a school to become licensed pharmacists. In order to be fully ACPE accredited, the school must have graduated one class of students, among other conditions.

Internship is an integral part of the pharmacy education of students, and students need intern permits to gain experience. Students could be at risk in new programs where state licensing agencies look for ACPE accreditation as a means to assure the students are receiving approved educational coursework as a condition of issuing an intern license. The public could be at risk if substandard training and education have been provided to interns.

California Code of Regulations sections 1719, 1727 and 1729 require that intern licenses may be issued only to those students who attend ACPE or board-approved schools of pharmacy, and admission to the pharmacist licensure examination to graduates from ACPE or board-approved schools.

Ms. Herold reported that over the weekend, the ACPE did provide "Candidate Status" to the Lake Erie College of Osteopathic Medicine. She added that this is still viewed as a provisional accreditation.

MOTION: Recognize the School of Pharmacy at Lake Erie College of Osteopathic Medicine for purposes of issuing intern licenses, accepting intern hours and accepting intern hours and accepting the degree granted by the school of pharmacy.

M/S/C: POWERS/TILLEY

SUPPORT: 10 OPPOSE: 0

- **Workgroup with the Department of Health Services – State Food and Drug Branch on Pharmacy Compounding**

Chairperson Hiura stated that last April, the Board of Pharmacy agreed to form a workgroup with the Department of Health Services, State Food and Drug Branch to address pharmacy-compounding issues, including criteria used by the board to determine when compounding falls outside the scope of pharmacy practice. Because the Food and Drug Branch licenses manufacturers in California, they communicated the importance of their understanding of how the board notifies individuals when pharmacy-compounding activities falls outside the scope of pharmacy practice.

Chairperson Hiura stated that it was agreed to establish this workgroup upon the conclusion of the committee's review of Pharmaceutical Benefit Management Companies (PBMs), and was added as a committee strategic objective.

The Licensing Committee has begun the formation of the workgroup and President Jones has appointed Board Members John Tilley and Ken Schell, and Supervising Inspector Dennis Ming, to the committee. The meeting will be public with all interested parties invited to attend.

- **Final Report on the Study on the Evaluation of Pharmacy Technicians in a Unit-Dose Drug Distribution System**

Chairperson Hiura stated that in May 1998, the Board of Pharmacy approved a study on the evaluation of pharmacy technicians in a unit-dose distribution system. The UCSF School of Pharmacy coordinated the study in conjunction with Long Beach Memorial Medical Center (LBMMC) and Cedars Sinai Medical Center (CSMC). The study ended on December 31, 2003.

The Board of Pharmacy originally granted a waiver for the study pursuant to CCR section 1706.5 and the study was approved until November 1, 2000. Because of the delay in starting the study, the board extended the waiver until February 2001, and requested that UCSF, LBMMC and CSMC present the final report at its January 2001 meeting. When the final report was presented, the board agreed to extend the study another two years so that the study could be made permanent either through regulation or legislation.

Peter Ambrose, Pharm.D., Associate Clinical Professor for UCSF, School of Pharmacy, presented the final report on the study on the evaluation of pharmacy technicians in a unit-dose drug distribution system.

Dr. Ambrose thanked the board for the opportunity to speak and stated that the study was published in the American Journal of Health System Pharmacy, following peer review.

Dr. Ambrose explained the process of technicians checking technicians as outlined in the final report.

Dr. Ambrose reported that during the study, all certified technicians at both institutions passed all of the quality assurance audits. Further, no medication errors were reported as a result of technicians checking unit dose medication cassettes.

Dr. Ambrose stated that as the primary investigator of the study, he concluded that medication technicians accurately checked the unit dose medication cassettes filled by other technicians, after they have been trained and certified in a closely supervised program that incorporated quality assurance audits. Freeing the pharmacists from this activity allowed them to devote their time to other activities such as managing drug therapies for better patient care. He added that Cedars Sinai Medical Center and Long Beach Memorial provided statistics on what the pharmacists actually do and what type of clinical services that they do. He added that the study ended in December 2003. Now the pharmacists have returned to the duties of checking unit dose medication cassettes.

Dr. Ambrose thanked the board for approving the waiver. He added that they hope that the data provided will be helpful to the board when it considers issues regarding technician-checking technicians.

John Cronin, representing the California Pharmacists Association, stated that when the technician-checking-technician concept was first proposed, it was proposed as a change in regulations. CPhA had two arguments against it as a regulatory change. One argument was concern for pharmacists in hospital settings where technicians were qualified to do this, which this study addresses. The second argument was that such a change would require statutory action rather than regulation change.

Ms. Harris clarified that the board has the authority to waive regulations under experimental studies to advance the profession under CCR 1706.5, as such. the board waived a regulation to permit the technician checking technician study.

Steve Gray, representing Kaiser Permanente, stated that because more data is available and the results favor patient safety and freeing up the pharmacists to do pharmacists' care functions; the board could reexamine this issue and consider if this could be a regulation change.

Sally Chong, representing Prescription Solutions, expressed concern that technicians may not be experienced enough to accurately screen for medication errors if they are the individuals who review prescription orders.

The board asked the Licensing.Committee to review the issue of technicians checking technicians and report back to the board.

- **Acknowledgment of Students**

President Jones welcomed the many students from three schools of pharmacy, who were attending the board meeting and asked them to introduce themselves and name the school they attend.

- **Implementation of NAPLEX and California Specific Examination**

  Chairperson Hiura stated that staff has worked diligently to assure that the new examination structure will be in place as soon as possible. The contracts for the NAPLEX and the California Pharmacist Jurisprudence Examination are in the final stages of completion. The goal is to be able to issue licenses to pharmacists who have taken (and passed) the new examinations by the end of March 2004. This would coincide when the board would have been able to license pharmacists had they taken the board's prior exam.

  Applicants who take the NAPLEX after January 1, 2004, will have their scores available to the board if they designate California as a score transfer state before they actually take the examination. Once the contract is signed with the NABP, the score will be transferred to the board.

  The board plans to administer the California Pharmacist Jurisprudence Examination via computer terminals in March 2004. The board will use the examination vendor under contract with the Department of Consumer Affairs for this portion of the examination instead of the NABP. The Competency Committee has developed a sufficient item bank of test questions for the new content outline for the examination, a significant task that required monthly meetings since August. The examination items are ready. Information about the examination is on the board's Web site and it is updated periodically. There is a question and answer section on the board's Web site to help candidates understand the process, and the new application forms are on the Web site as well.

  President Jones acknowledged Kathy Bessinque and Holly Strom, members of the Competency Committee, who were present.

  President Jones reported that the board has placed three members on a 30-member test committee who are actively involved in the NAPLEX development.

- **Update on the Changes to the Pharmacy Technician Program**

  Chairperson Hiura stated that beginning in January 2004, changes to the licensure requirements for applicants seeking registration as pharmacy technicians took effect. These changes were the result of SB 361 (Figueroa, Chapter 361, Statutes of 2003).

  Specifically, changes in Business and Professions Code section 4202 (a) alter the qualifying methods an applicant must satisfy to become registered. To be issued a technician registration, an applicant now must satisfy one of the following criteria:
  - Obtain an associate's degree in pharmacy technology;

- Complete a course of training specified by the board (this is 240 hours of theoretical and practical training provided by a technician training school or by an employer);
- Be a graduate of a school of pharmacy accredited by the ACPE; or
- Be certified by the Pharmacy Technician Certification Board (PTCB).

- **Future Meeting Dates of the Licensing Committee**

  Chairperson Hiura announced the Licensing Committee meeting dates for 2004:
  March 3, (in Oakland). Also, June 9, September 22 and December 1; these meetings will be held either in Oakland or Burbank.

ENFORCEMENT COMMITTEE

Mr. Powers reported on the Enforcement Committee Meeting of December 10, 2003.

- **Statutory Proposals Regarding Wholesale Licensure Requirements and Wholesale Drug Transactions**

  Mr. Powers stated that the Enforcement Committee is in the process of developing rules designed to strengthen the regulation of drug wholesalers. The committee considered a number of different proposals. Based on discussions at prior committee meetings and discussion at the October 2003 board meeting, staff developed a legislative proposal for the committee's consideration. The proposal includes elements that have been considered previously, particularly expanded citation and fine authority for certain violations, and elements drawn from recent legislation passed in Florida. The recent Florida legislation focused on preventing the introduction of counterfeit drugs into the system by implementing stricter licensing requirements for drug wholesalers, increasing the criminal sanctions for counterfeiting prescription drugs, and requiring pedigrees.

  Additionally, the National Association of Boards of Pharmacy (NABP) has issued a "draft" model rule for the licensure of wholesale distributors.

  Mr. Powers stated that the proposal is designed to address challenges presented by the existing distribution system for prescription drugs. The principal elements are:
  - Require pedigrees for all drug shipments beginning January 1, 2007.
  - Prohibit the wholesaling of prescription drugs by pharmacies.
  - Require wholesalers to obtain a $100,000 bond to secure payment of administrative fines and penalties.
  - Permit the board to issue fines on a per occurrence basis for specified violations (e.g., sale of counterfeit drugs, sale of outdated drugs, failure to preserve records, etc.)
  - Prohibits the owners of closed-door pharmacies (defined as pharmacies serving skilled nursing and intermediate care facilities) from owning a wholesale facility.

Mr. Riches stated that closed pharmacies serving limited patient populations who typically obtain preferentially priced drugs for serving these populations are a source of diversion in the marketplace.

The board's proposal includes a prohibition on co-ownership of the wholesaler and a closed pharmacy because of the diversion situations encountered by the board.

Mr. Riches stated that the pedigree requirement and moving the implementation date back one year to January 1, 2007 are the two most significant changes from the Enforcement Committee's draft language.

Mr. Riches reported that another significant inclusion was the proposed citation and fine authority for wholesale violations such as distribution of misbranded or adulterated drugs or counterfeits, failure to maintain documentation and failure to maintain the pedigree.

Every out-of-state wholesaler must have an exemptee-in-charge who has demonstrated training experience and is responsible for an individual wholesaler acting in accordance with the law.

Mr. Riches referred to the bonding requirement and stated that both Florida law and the NABP model rules include a $100,000 bond to secure administrative fines and other penalties. The requirement of a surety bond or equivalent security to be in place in advance of licensure would allow the board to enforce actions and continue to provide the disincentive for illegal activity.

Supervising Inspector Judi Nurse reported that since 1994, 91 board investigations were conducted and that 150 million doses of drugs were involved in these cases. Approximately 70 percent of the cases involved a pharmacy and a wholesaler with common ownership.

Ms. Nurse stated that board investigation efforts attempt to identify how and where drugs were originally sold and repeatedly resold on paper. Meanwhile the drugs themselves are shipped back and forth throughout the country, and travel as far as Puerto Rico before winding up at the final destination back in California. This turbulent activity becomes a good environment for introduction of counterfeits due to non-existent or sketchy paperwork.

Ms. Nurse stated that typically counterfeit drugs are life style drugs, or more expensive, newer drugs that do not have generic equivalents.

Ms. Nurse encouraged the board to address diversion issues and counterfeit drugs when considering this proposal.

Ms. Nurse stated that it is also a concern to the board when large quantities of drugs are returned to the manufacturer because of the potential for counterfeiting. Often when

counterfeit drugs are returned to a major wholesaler, they are returned to stock resulting in a legitimate pharmacy ending up with the counterfeit drugs.

Ms. Nurse stated while a pharmacist-in-charge (PIC) is required within these businesses typically the PICs are filled by semi-retired pharmacists or those looking for part-time work and often they are not aware of the type of business being run and that drugs were even purchased. The PIC is usually the only connection the board has to the illegal business and the PIC is often not the responsible party.

Ms. Nurse stated that another consideration that the board might want to address is the practice of wholesalers who sell far more drugs to a given pharmacy than the business warrants.

Ron Bone, senior vice president for distribution for McKesson, stated that McKesson has an unwavering commitment for the safety of the pharmaceutical products they distribute. As such, McKesson has implemented stringent processes and procedures with their suppliers throughout its distribution network to assure customers receive safe pharmaceutical products. Currently, McKesson purchases 95 percent of all pharmaceutical products directly from the manufacturer and 100 percent of high-risk drugs (i.e., HIV drugs, biotech and oncology products) directly from the manufacturer. McKesson purchases only about 5 percent from alternate source venders.

Mr. Bone explained that McKesson conducts a rigorous due diligence process of suppliers. The process includes a Dunn and Bradstreet report on the company and its owners, background and security checks and assurances of appropriate licensing and insurance. In addition, McKesson conducts a yearly site inspection to review company purchasing practices and a detailed check of their products.

Mr. Bone stated that McKesson encourages the board to create more stringent wholesaler licensing requirements. This should include a detailed physical site inspection, criminal and financial background checks and a comprehensive review of businesses and their products.

Mr. Bone stated that the lack of due diligence on these matters in Florida, as discovered, was a major reason rough operators were able to enter the system and compromise pharmaceutical products. McKesson supports the board's efforts to increase criminal penalties for those who knowingly counterfeit and distribute prescription drugs. He expressed concern that California laws are too lenient for such offenses.

Mr. Bone stated that McKesson opposes the proposal to require a paper pedigree on all products because a pedigree cannot be effectively transmitted through a distribution network and is also subject to counterfeit. He added that a paper pedigree would impose substantial costs and efficiencies to wholesalers and customers without providing any additional guarantee to the safety of the product.

President Jones stated that the pedigree provision would not take affect until January 2007, to allow time for the industry to comply.

Mr. Bone responded that counterfeit drugs are focused on high-risk drugs and he stated that manufacturers would be willing to work towards assuring a safe secure supply chain. He added that manufacturers are now testing return products.

Mr. Tilley stated that pharmacists must be assured that the medications they receive are the medications that were ordered.

Mr. Bone suggested that the board aggressively assure that wholesalers are conducting legitimate businesses.

Melinda Johnson, director of government affairs, representing AmeriSource Bergen Corp., stated that 99 percent of their products are purchased directly from the manufacturer and they have the same process in place to buy products from alternative source venders. She explained that manufacturers hold all the power with their products and earn as much as possible. Often they are the only source for the product. She added that it is not a typical sales/purchase relationship.

Ms. Johnson referred to the proposed requirement for a pedigree and stated that if a manufacturer has met the sales allotment for the month, they will refuse to sell their products and instead refer the wholesaler to another wholesaler. She stated that distributors would not be able to have a pedigree on all drug products and it would cause a drug shortage in the country. Customers would be forced to shop wholesaler to wholesaler and the potential for diversion becomes even greater.

Ms. Johnson stated that she worked with the FDA staff and asked specifically if a corporate use identification marker could be placed on the product, and the answer was no because it is a felony to change the label. She expressed concern that the board is not considering whether manufacturers will implement the program.

Ms. Johnson stated that the first step should be to increase regulatory stipulations and penalties on the illegal activity of wholesalers. She added that in light of the current budget crisis, they would not oppose an increase in licensing fees to add additional board inspectors to assure annual inspections.

Mr. Cronin stated that the board must consider the cost involved with this legislative proposal, and how it will solve the problem. He asked what the impact is on California consumers.

President Jones stated that the board must guarantee the safety of the distribution system in California.

A representative of PharMerica, Inc. expressed concern about limiting legitimate business sales.

Mr. Cronin suggested that the board pursue electronic pedigree and asked how central-fill pharmacies within a wholesaler enters into the equation. He added that it makes sense for the wholesaler to own the pharmacy. He expressed concern with the language and asked the board to allow pharmacies to look at innovative approaches to increase efficiency, lower cost, and save money.

Steve Gray, representing Kaiser Permanente, requested clarification of definitions. He added that closed pharmacies are not open for dispensing of dangerous drugs or devices to the general population. He stated a hospital pharmacy is not open to dispensing to the general population. He asked if all hospital pharmacies are considered closed pharmacies and does this include home infusion and Costco. He added that there are inconsistencies with section 4013.

Ron Resner, representing a small wholesaler business, cautioned the board not to react to the significant problems faced in Florida because they are dealing with damage control as the result of a very lax and inefficient regulatory and enforcement system. He added that there are many legitimate wholesalers who were punished and moved out of Florida because of the prohibited and unfair language. He added that the proposed language is reactionary.

MOTION: Enforcement Committee: That the Board of Pharmacy support the proposed citation and fine statute for wholesale violations and the proposed statutes regarding wholesale drug transactions.

SUPPORT: 3 OPPOSE: 0 ABSTAIN: 7

Additional discussion ensued, noting that additional changes could still be made to the legislative proposal before it was enacted.

MOTION: That the Board of Pharmacy support the proposed citation and fine statute for wholesale violations and the proposed statutes regarding wholesale drug transactions.

M/S/C: SCHELL/ACEVEDO

SUPPORT 9 OPPOSE: 0

- **Recommendation from the Joint Task Force on Prescriber Dispensing regarding dispensing by a medical group.**

Chairperson Powers stated that the Medical Board of California (MBC) and the Board of Pharmacy held a joint task force meeting on the issue of prescriber dispensing. The meeting

was held on May 27, 2003, and the task force reached consensus on the following: (1) Under current law, an individual prescriber can own his/her own prescription stock and dispense to his or her own patients and such practice should be allowed to continue with the goal of strengthening and educating prescribers regarding record keeping requirements; (2) Allow a medical group to dispense prescription medications pursuant to a special permit issued by the Board of Pharmacy and specified conditions that require one physician from the medical group to be responsible and accountable for the security of the prescription medications, record keeping requirements, and a consultant pharmacist reviews the dispensing process; (3) Establish the authority for a pharmacy to place an automated dispensing device in a prescriber's office; and (4) Provide for joint oversight by the appropriate licensing agencies.

Chairperson Powers stated that the task force agreed that staff from the two boards would work together to draft language for each board to consider as a possible joint legislative proposal for 2004.

Draft language was developed and the Medical Board task force members provided comments on the draft. The language was reworked to address their comments. The proposal would require a special clinic license for these group practices, which would have a significant fiscal impact to the board.

The language was first provided to the Enforcement Committee at its September meeting. However, it was requested that the committee postpone its discussion until the interested parties had more time to review the proposal and submit comments. The Enforcement Committee agreed to reschedule the issue to its December meeting.

Chairperson Powers stated that there was considerable discussion that the legislative proposal would authorize the Board of Pharmacy to issue a clinic permit to a medical group and this was not in the best interest of the public. Moreover, it was argued that it was contrary to current law that prohibits prescribers from owning pharmacies. There was also concern about the proposed amendment to Business and Professions Code section 4170(a), which would allow a registered nurse to hand to a patient the medication that is dispensed by the prescriber. There is an Attorney General Opinion (57 Op. Att'y Gen. 93 (1974)) that states that a nurse may assist, at the prescriber's direction in the dispensing of such drugs, including handing them to the patient, it was noted that this opinion was prior to the most recent amendments to this section.

The board took no action on the proposal from the Joint Task Force on Prescriber Dispensing.

- **Importation of Drugs from Canada**

Chairperson Powers stated that the board has discussed the issues and has sought comments on the issue of prescription drug importation from Canada and from other countries. This has been a sensitive and controversial issue. The board has been tasked with balancing consumer access to affordable prescriptions against the safety and effectiveness of drugs obtained from

foreign sources. The board has heard from many interested parties on this issue during its committee meetings and at its quarterly board meetings.

During its October meeting, the board decided to hold a summit on prescription drug importation in April 2004. The plan was to invite leaders representing all sides of the issue in an effort to fully discuss the health care policy concerns inherent with this topic.

Since the last board meeting, the United States District Court for the Northern District of Oklahoma ruled on November 6, 2003, that Rx Depot/Rx Canada violated federal law by causing the importation of prescriptions drugs from Canadian pharmacies. Rx Depot/Rx Canada assists individuals in procuring prescription medications from pharmacies in Canada. Each location has one or two employees who accept prescriptions from U.S. customers. Customers are asked to fill out a medical history form and other forms provided by Rx Depot/Rx Canada. Customers can deliver these documents to Rx Depot/Rx Canada's stores in person, or can mail or fax them to the nearest Rx Depot/Rx Canada store.

Once a Rx Depot/Rx Canada customer has submitted the required forms and prescriptions, the papers and the customer's credit card information or a certified check are transmitted to an operating pharmacy in Canada. A Canadian doctor rewrites the prescription, and the Canadian pharmacy fills the prescription, ships the prescription drugs directly to the U.S. customer, and bills the U.S customer's credit card. Rx Depot/Rx Canada receives a 10 to 12 percent commission for each sale they facilitate for the Canadian pharmacies. They also receive commissions for refill orders, which generally are arranged directly between customers and the Canadian pharmacies. It was noted in the decision that Rx Depot/Rx Canada stores are essentially commissioned sales agents for Canadian pharmacies.

The decision called for immediate closing of the 88 nationwide Rx Depot/Rx Canada affiliates, including 17 California locations. Rx Depot/Rx Canada appealed the decision. On November 21st, the 10th Circuit Court of Appeals decision denied the motion from Rx Depot to stay the District Courts ruling.

President Jones stated that the Administration has conveyed the message that due to the considerable public interest and publicity, time is needed to consider this issue more carefully.

MOTION: That the Board of Pharmacy withholds its plan for a summit on the importation of prescription drugs from Canada to allow more time for the administration to consider all of the issues.

M/S/C: POWERS/GOLDENBERG

SUPPORT: 9 OPPOSE: 0

- **Implementation of Enforcement Provisions from SB 361**

Mr. Powers stated that SB 361 (Figueroa) was the legislative vehicle for the Board of

Pharmacy's sunset extension and contained statutory recommendations approved by the Joint Legislative Sunset Review Committee. The following compliance provisions were added to California Pharmacy Law effective January 1, 2004.

- **Section 4083 – Order of Correction**

  Mr. Powers stated that section 4083 allows an inspector to issue an order of correction to a licensee directing the licensee to comply with pharmacy law within 30 days by submitting a corrective action plan to the inspector, or the licensee can contest the order of correction to the executive officer for an office conference. If an office conference is not requested, compliance with the order does not constitute an admission of the violation noted in the order of correction and the order of correction is not considered a public record for purposes of disclosure. A copy of the order of correction and corrective action plan must be maintained on the license premises for at least three years from the date the order was issued.

- **Section 4315 – Letter of Admonishment**

  Mr. Powers stated that this authorizes the executive officer to issue a letter of admonishment to a licensee for failure to comply with pharmacy law and directs the licensee to come into compliance within 30 days by submitting a corrective action plan to the executive officer documenting compliance, or the licensee can contest the letter of admonishment to the executive office for an office conference. If an office conference is not requested, compliance with the letter of admonishment does not constitute an admission of the violation noted in the letter of admonishment. The licensee must maintain on the licensed premises a copy of the letter of admonishment and corrective action plan for at least three years from the date the letter was issued. The letter of admonishment will be considered a public record for purposes of disclosure.

- **Section 4314 – Issuance of Citations**

  Mr. Powers stated that this section allows the board to issue an order of abatement that will require a person or entity to whom a citation has been issued to demonstrate how future compliance with the pharmacy law will be accomplished and provides that such demonstration may include, but not be limited to, submission of a corrective action plan as well as completion of up to six hours of continuing education courses in subject matter specified in the order of abatement.

- **Implementation of SB 151**

  Mr. Powers noted the board's activities to implement and educate about SB 151.

  Senate Bill 151 (Burton) repeals triplicate prescription requirement for Schedule II controlled drugs and revises requirements for prescribing and dispensing all controlled substances by January 1, 2005. All written controlled substances prescriptions must be written on special

security paper that is printed by approved printers. The board and the Department of Justice must approve the printers. An application form and procedures for these security printers will be on the board's Web site by the end of January.

The next issue of The Script will contain many articles about the phased-in requirements for prescribing and dispensing controlled substances. Additionally the board's public outreach activities will highlight these changes as well.

LEGISLATION AND REGULATION COMMITTEE

Dr. Fong stated that he would report on the committee meeting held January 8, 2004, in Chairperson Andrea Zinder's absence.

- **Proposed Changes to Pharmacy Law – Omnibus Provisions for 2004**

1. Correct usage errors in Section 4101.

Dr. Fong stated that the proposed changes reflect the requirement that wholesalers designate an "exemptee-in-charge" and correct the name of veterinary food-animal drug retailers in this section.

MOTION: Legislation and Regulation Committee: The Board of Pharmacy sponsor a provision in the 2004 omnibus bill to correct usage errors in Section 4101

Amend Section 4101 of the Business and Professions Code, to read:

4101. (a) Any pharmacist who takes charge of, or acts as pharmacist-in-charge of a pharmacy or other entity licensed by the board, who terminates his or her employment at the pharmacy or other entity, shall notify the board within 30 days of the termination of employment.
(b) ~~Any exemptee who takes charge of, or acts as manager of,~~ An exemptee-in-charge of a wholesaler or veterinary ~~food-drug animal~~ food-animal drug retailer, who terminates his or her employment at that entity shall notify the board within 30 days of the termination of employment.
~~(c) This section shall become operative on July 1, 2001.~~

SUPPORT: 9 OPPOSE: 0

2. Make a technical correction to Section 11155 of the Health and Safety Code.

Dr. Fong stated that the proposed change would replace "physician" with "prescriber." This change reflects the reality that practitioners other than physicians are authorized to prescribe controlled substances.

MOTION: Legislation and Regulation Committee: The Board of Pharmacy sponsor a provision in the 2004 omnibus bill to correct a usage error in Section 11155 of the Health and Safety Code

Amend Section 11155 of the Health and Safety Code, to read:

11155. Any prescriber ~~physician~~, who by court order or order of any state or governmental agency, or who voluntarily surrenders his controlled substance privileges, shall not possess, administer, dispense, or prescribe a controlled substance unless and until such privileges have been restored, and he has obtained current registration from the appropriate federal agency as provided by law.

SUPPORT: 9 OPPOSE: 0

3. Correct an erroneous code section reference in Section 11159.1 of the Health and Safety Code.

Dr. Fong Stated that this proposed change is technical.

MOTION: Legislation and Regulation Committee: The Board of Pharmacy sponsor a provision in the 2004 omnibus bill to correct an erroneous code section reference in Section 11159.1 of the Health and Safety Code.

Amend Section 11159.1 of the Health and Safety Code, to read:

11159.1. An order for controlled substances furnished to a patient in a clinic which has a permit issued pursuant to Article 13 ~~3.5~~ (commencing with Section 4180 ~~4063~~) of Chapter 9 of Division 2 of the Business and Professions Code, except an order for a Schedule II controlled substance, shall be exempt from the prescription requirements of this article ~~but~~ and shall be in writing on the patient's record, signed by the prescriber, dated, and shall state the name and quantity of the controlled substance ordered and the quantity actually furnished. The record of the order shall be maintained as a clinic record for a minimum of seven years. This section shall apply only to a clinic that has obtained a permit under the provisions of Article

13 ~~3.5~~ (commencing with Section 4180 ~~4063~~) of Chapter 9 of Division 2 of the Business and Professions Code. Clinics that furnish controlled substances shall be required to keep a separate record of the furnishing of those drugs which shall be available for review and inspection by all properly authorized personnel.

SUPPORT: 9 OPPOSE: 0

4 Correct errors in Section 11207 of the Health and Safety Code and clarify that a pharmacy technician may assist a pharmacist in filling controlled substance prescriptions.

Dr. Fong stated that these changes are also technical.

MOTION: Legislation and Regulation Committee: Board of Pharmacy sponsor a provision in the 2004 omnibus bill to correct errors in Section 11207 of the Health and Safety Code and to clarify that a pharmacy technician may assist a pharmacist in filling controlled substance prescriptions.

Amend Section 11207 of the Health and Safety Code, to read:

11207. (a) No person other than a ~~registered~~ pharmacist as defined in Section 4036 of the Business and Professions Code ~~under the laws of this state~~ or an intern pharmacist, as defined in Section 4030 ~~4038.1~~ of the Business and Professions Code, who is under the personal supervision of a pharmacist, shall compound, prepare, fill or dispense a prescription for a controlled substance.
(b) Notwithstanding subdivision (a), a pharmacy technician may perform those tasks permitted by Section 4115 of the Business and Professions Code when assisting a pharmacist dispensing a prescription for a controlled substance.

SUPPORT: 9 OPPOSE: 0

- **Moratorium on Pending Regulations Imposed by Executive Order S-2-03**

Mr. Riches reported that Executive Order S-2-03 requires state agencies to take several actions related to rulemaking activity.

1. **Regulatory Review –**The board is required to review all rulemakings adopted since January 6, 1999, based on existing statutory criteria to assure their compliance with those

criteria. This review is required to be completed by February 17, 2004, and be submitted to the Governor's legal affairs secretary.

Mr. Riches stated that the board adopted 19 regulation packages adopted during this time period. He reported that the board also conducted a review of ongoing board practices to assure there were no underground regulations and the board conducted an additional fiscal evaluation on the sterile compounding regulations.

Mr. Riches stated that the moratorium on adopting new regulations until mid May does not preclude the board from noticing new regulations. The board had a substantial number of regulations prepared to go to notice when the executive order was issued. These regulations will be noticed in February and the regulation packages will be brought to the April Board Meeting for a vote to clear the backlog.

2. **Rulemaking Moratorium –** As stated earlier, all state agencies must suspend rulemaking activity for 180 days to provide the Administration with time to review pending proposals. The only immediate effect of this moratorium for the board is delaying the recently approved rulemaking on sterile compounding standards. This proposal must be submitted to the Office of Administrative Law for review by February 20, 2004 or it expires, unless a review waiver is also sought to permit the Department of Consumer Affairs 90 extra days to review the rulemaking.

   The board requested an exemption to the moratorium for this rulemaking because of its impact on the public health and safety, but the administration denied the initial request. The board is requesting reconsideration and is seeking a waiver. If not approved, the board will have to begin this process again.

   The USP has recently published its revised chapter on sterile compounding and that document should be considered before initiating a new rulemaking process.

3. **Review of Existing Board Standards –** All state agencies must review existing standards of practice to identify any potential "underground" regulations. An "underground" regulation exists when a state agency applies a general standard to all affected persons without adopting that general standard through a formal rulemaking procedure. With the assistance of counsel, board staff reviewed existing standards and practices. The review did not uncover any potential "underground" regulations.

   During the review process, counsel advised the board that several of the guidance documents the board has published in the past required revisions and updates. Those guidance documents have been removed from the board's Web site pending the completion of the revision process.

   Mr. Riches stated that the proposed text of those proposed regulations for action at the April 2004 Meeting have had the required information hearings. Notices for these

regulations will be published as soon as possible within the restrictions established by Executive Order S-2-03.

Regulations Awaiting Notice for Action at the April 2004 Board Meeting

1. Section 1707.5 – Hospital Central Fill

This regulation will permit central refill operations for hospitals.

2. Section 1709.1 - Pharmacist-in-Charge at Two Locations

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

3. Section 1711 – Patient Notification

This regulation will modify the patient notification provisions of the board's quality assurance regulation to require notification to the patient if the drug was actually taken or if it resulting in a clinically significant delay in therapy.

4. Section 1717.4 and 1717.2 – Electronic Prescriptions & Electronic Records

This regulation will make any needed changes to board regulations to conform to changes in patient privacy laws.

5. Section 1717.4 – Authentication of Electronic Prescriptions

This regulation will require pharmacists to authenticate electronic prescriptions.

6. Section 1719 et seq. – Pharmacist Examination

This regulation will update existing requirements for the pharmacist examination and make those changes necessary to conform to the provisions of Senate Bill 361.

7. Section 1793.3 – "Clerk-Typist" Ratio

This regulation will eliminate the clerk/typist ratio.
An informational hearing was held and action deferred until January 2004 board meeting to accommodate staff workload and ongoing negotiations regarding a statutory revision to ancillary staff ratios.

MOTION: That the Board of Pharmacy move the proposed amendment to section 1793.3 "Clerk Typist" Ration to a regulation hearing on April 21, 2004.

M/S/C: FONG/SCHELL

SUPPORT: 7 OPPOSE: 0 ABSTAIN: 2

Awaiting Notice and an Information Hearing

1. **Section 1715 – Pharmacy Self Assessment**

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

2. **Section 100 Filing**

   This filing will conform existing board regulations to the numerous changes in Pharmacy Law made by 2003 legislation. This regulation is awaiting compilation (a informational hearing is not required).

Status of Bills with a Board Position

Mr. Riches updated the board on several bills introduced last year on which the board has a position.

AB 261 (Maddox)

This bill would increase penalties for operating a "backroom pharmacy."
The board has a support position on the bill, which died in committee.

AB 746 (Matthews)

This bill would require the board to revoke a license after a second conviction for Medi-Cal fraud. The board has a support position on this bill that is currently before the Senate Rules Committee.

AB 1363 (Berg)

This bill would establish requirements for needle exchange programs. The board has a support position on this two-year bill.

AB 1460 (Nation)

This bill would permit pharmacists to perform CLIA waived tests to monitor drug therapy.
The board has a support position on this two-year bill.

SB 393 (Aanestad)

This bill would permit "tech-check-tech" in hospitals. The board has a support if amended position on this two-year bill.

SB 506 (Sher)

This bill would require the board to track wholesale distribution of antibiotic drugs. The board has an oppose position on this two-year bill.

Bills of Interest

Mr. Riches noted several additional bills of interest to the board.

AB 57 (Bates)

This bill would place MDMA into Schedule II. And is currently in the Assembly inactive file.

AB 521 (Diaz)

This bill would require pharmacists to notify patients of harmful drug interactions and it is a two-year bill.

Staff does not anticipate significant activity on any of the remaining two-year bills.

Dr. Fong stated that the next Legislation and Regulation Committee meeting is scheduled for April 5, 2004, at 10:30 a.m. in Sacramento.

NEW BUSINESS/AGENDA ITEMS FOR FUTURE MEETINGS

Mr. Tilley reminded the board that the yearly dues for members is $120, and is now due.

Dr. Fong referred to record keeping requirements in pharmacies and stated that his pharmacies are inundated with lots of paperwork. Ms. Harris suggested that a written proposal be submitted for review by the Legislation and Regulation Committee.

ADJOURNMENT

There being no further business, President Jones adjourned the meeting at 5:35 p.m.

Thursday, January 22, 2004

ENFORCEMENT WORKSHOP

President Jones called the Enforcement Workshop meeting to order at 8:30 a.m. on January 22, 2004.

Staff provided an overview of the Board of Pharmacy Enforcement Unit.

The meeting was adjourned at 12:15 p.m.