**State of California** **Department of Consumer Affairs**

# Memorandum

**To:** **Board Members** **Date: July 8, 2003**

**From:** **Organizational Development Committee**

**Subject:** **Action Items and Report on the Meeting of June 30, 2003**

The Organizational Development Committee met on June 30, 2003, in a teleconferenced meeting. Minutes of this meeting are provided in this tab section as Attachment A (following the numbered attachments referenced below).

## Issue 1:

### Final review and action on the board's Strategic Plan for 2003-05 (The Strategic Plan is provided as Attachment 1)

Background: At the April Board Meeting, the board devoted a portion of one day to revise its strategic plan. The changes made during this process have been incorporated into the plan. In the last quarter, each committee has reviewed the final objectives and tasks for that committee.

**The Organizational Development Committee recommends board approval.**

## Issue 2:

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

**10 Percent Reduction in Personnel Services is Ordered for 2003/04**

The state is facing a huge budget deficit now estimated as $38 billion.

A number of additional cost containment controls have been placed on state agencies besides hiring freezes and the elimination of vacant positions. In the last year:

- The board lost four positions and $185,000 in associated funding for these positions (June 2002)
- By February 2003, all out-of-state travel requested was denied

- Also in February, all agencies were required to cut their in-state travel budgets by 35 percent (in the case of the board, this was $52,100)
- All training requests, contracts and purchases underwent additional review by the department as a means to reduce expenses, and approval was significantly harder to attain
- On April 1, the Administration directed all agencies to cut their personnel services budgets by 10 percent for 2003/04, and to prepare a list of surplus employees to lay off.

  This was a $347,000 reduction for the board, and will be met by:
  1. the elimination of all vacant positions (six positions)
  2. the elimination of overtime payments
  3. and a substantial reduction in board member honoraria.

  However, the board did not have to lay off any staff; although it will have to continue to redirect work and stop performing some functions in order to complete the most important tasks

- On June 30, the board lost the six additional positions that were vacant

**Board Member Compensation**

**PROPOSAL:** Given that the board must redirect approximately $20,000 from board member reimbursement for the year to make the 10 percent cut in personnel services, the Organizational Development Committee proposes that the board alter its compensation policy for board members to:

1. Members will be compensated only for attendance at board meetings, which is $100 per day of the board meeting. Travel expenses will not be affected and will continue to be paid by the board, and are funded from other areas of the board's budget (this was not part of the 10 percent cut ordered in personnel services).

2. Members who work additional time on board business may still submit these hours for reimbursement but the hours will be held until the end of fiscal year 2003/04. If sufficient funds remain, the board members will be reimbursed for eight-hour increments, just as they are now. If funding is not available for this purpose, no additional compensation will be provided.

**The Organizational Development Committee recommends board approval of this change in board member compensation.**

In 2001/02, board members received $27,100 from a budget of $36,200 for board member compensation. A distribution of hours spent performing board business (which excludes travel time) that has been submitted in 2003/03 by board members is included in Attachment 2.

**New Budget Reductions Ordered for 2003/04 and 2004/05:**

On July 8, the Governor's Office issued new budget instructions for 2003/04 and 2004/05 (a copy is attached as Attachment 3). These directions include:

- No augmentations for 2003/04 will be approved except in extraordinary circumstances; instead agencies must absorb all costs.
- For 2004/05, there will be no funding for program expansion or new programs. Should new legislative mandates occur, agencies will not receive additional funding and must identify commensurate proposed reductions in existing programs to pay for the new requirements.
- No information technology projects will be funded
- Expenditure reduction plans similar to last year will likely be required (this would include another 10 percent reduction in personnel services may be established for 2004/05, along with 35 percent cuts in travel, plus other cuts)
- Agencies should target repeal of statutorily required activities or programs that they cannot fund, eliminate discretionary programs or consolidate programs. Some agencies may be combined with other agencies.

***Transfer of Board's Reserve and Repayment Status***

The board loaned $6 million from its fund to the state's General Fund one year ago. As a result, by June 2004, the board will have only a projected $75,000 remaining. By June 2005, the board's fund is projected to have a deficit of $2.7 million deficit (or 4.2 months of expenditures). As such, repayment of the loan needs to begin late this fiscal year (perhaps May or June 2004), or clearly early in the next fiscal year (July or August 2004).

The Internal Audits Office of the department noted in its sunset review audit of the board, that the board's fiscal condition will require repayment of the loan to begin late in 2003/04. The board has worked with the department and the Department of Finance to assure this repayment occurs before a deficit in the board's financial operations occurs. However, the Department of Finance declined to establish a repayment schedule for the loan for 2003/04, but did agree to reevaluate the board's financial position in November 2003 and reconsider initiating repayment.

- **2002/03 Budget**

Final figures for the last fiscal year will not be available until September. However the following are approximations.

**Estimated Revenue: $5,726,319**

The board's estimated revenue is comprised of $4,629,890 in fees, $541,000 in interest, $193,454 in cost recovery actually collected and $361,975 in fines collected through the fiscal year.

**Estimated Expenditures: $7,386,597**

The board spent approximately 48 percent of its budget on personnel costs. AG expenditures were 13.5 percent of the board's total budget.

Over the last few years the board's budget has been declining:

- The 2001/02 budget was $7,514,523
- The 2002/03 initial budget (Sept. 2002 when the state's budget was enacted) was $7,481,000
- The 2002/03 revised budget was reduced to $7,386,597 (due to the loss of funding for four positions).

**Fund Condition: $2,595,256 (or 4.2 months of operating expenses)**

The board estimates that it ended the year with a reserve of $2.6 million. If the fiscal year estimates are close to actual figures for the year, the board will outspend its revenue generation for the year by $1.66 million.

**Future Budget Change Proposals**

The board had planned on preparing two budget change proposals for this year and for future fiscal years. However, any augmentation requests will be denied according the most recent directions from the Department of Finance. The board had planned on seeking an AG augmentation of $300,000 annually, since the board has overspent its AG budget this amount the last three years, and to seek $25,000 for an occupational analysis for the examination for 2004/05 (this is required even if NAPLEX is approved).

## Issue 3:

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

Background: The committee notes that it is again time for all board members and designated staff to take state-mandated ethics training. This training must be completed during 2003. Since the last meeting, three board members have completed the training (Dr. Hiura, Dr. Fong and Mr. Powers).

The training can be taken online or via a video. It will require approximately 1.5 hours to complete. Upon completion, please send your completion certificate to Virginia Herold.

The Web site is http://caag.state.ca.us/ethics/index.htm.

## Issue 4:

### Status Update on the Joint Legislative Sunset Review – Recommendations of the JLSR Committee and Department of Consumer Affairs

Background: A number of recommendations for the board or board operations have been made as part of the sunset review process. The Joint Legislative Sunset Review Committee (JLSRC) and Department of Consumer Affairs issued a number of joint recommendations, and then each made several individual recommendations for the board. The Organizational Development Committee has been tracking these recommendations. Attachment 4 contains the recommendations and the status of these recommendations.

Nearly all the recommendations that are law changes to implement have been inserted into SB 361.

## Issue 5:

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

Background: The Department of Consumer Affairs' Internal Audits Office released the report of its operational audit of the board in March 2003. This audit started October 1, 2002, and was completed in February 2003. The audit looked at the board's internal controls, compliance with all state requirements, the licensing of pharmacists and technicians, enforcement matters and cashiering. (The department typically audits every agency undergoing sunset review.)

Again, the Organizational Development Committee has been tracking these recommendations to review board progress. Attachment 5 provides the recommendations and the board's activities to achieve them. Progress reports to the department on the board's actions to incorporate these changes will be prepared every six months. Copies of these status reports will be shared with the board.

## Issue 6:

### Personnel Update

As discussed earlier, all vacant positions on June 30th were eliminated.

In the case of the board we lost the following positions:

- Three inspectors (one new position for compounding, one from the promotion of Dennis Ming, and one “technical” inspector position that last year was reclassified from an analyst position to an inspector position while the board sought approval for a 4th supervising inspector position – which when we filled the supervising inspector position, left another inspector position vacant)
- One associate analyst (licensing of sites, created by the retirement of Sandi Moeckly at the beginning of 2003)
- One office technician (licensing of sites, created by the promotion of Suelynn Yee for licensing compounding pharmacies)
- One office technician (receptionist who resigned in February)

All board managers will effectively receive a 5 percent reduction in their state compensation stating in July to cover retirement contributions that were made by the state for the past few years. In addition managers will not receive a 5 percent raise negotiated several years ago for union-represented employees (all other board employees).

The board was able to secure training for new inspectors from the National Crime Investigation and Training (NCIT) in investigating and writing. All board inspectors and complaint handlers now have completed this training.

# Attachment 1

# California State Board of Pharmacy

# STRATEGIC PLAN

# 2003-2005

**Members:**
**John Jones, President**
**Don Gubbins, Vice President**
**John Tilley, Treasurer**
**David Fong**
**Stanley Goldenberg**
**Clarence Hiura**
**William Powers**
**Andrea Zinder**

Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer

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April 2003

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# PRESIDENT'S MESSAGE

The strategic planning process of the California State Board of Pharmacy is an annual effort of the board members, staff and the public to anticipate and plan for events and issues for the coming year. Although the board considers its current strategic plan when going through the planning exercise, the board also attempts to predict upcoming changes in pharmacy practice, consumer needs and demands and health care trends. After a lengthy discussion of potential and existing issues, the participants go through a process to categorize, consolidate and finally prioritize the issues and then set the goals for the coming year. The resulting strategic plan keeps the board focused on established goals while allowing the flexibility of handling new questions and challenges as they arise.

Each board committee considers its individual strategic plan goals at every meeting and the progress on the goals are reviewed at each of the quarterly full board meetings. The careful planning and continuous monitoring of the strategic plan assures that the board achieves its stated objectives and performs with optimal efficiency.

The pharmacy board publishes advance notice for each strategic planning meeting and encourages participation and contribution by all interested citizens of California who attend. Involvement of the board, its staff and the public results in a strategic plan that truly represents the public interest and serves the consumers of this state.

# CALIFORNIA STATE BOARD OF PHARMACY

Picture/Logo

## Vision Statement

Healthy Californians through quality pharmacist's care.

## Mission Statement

The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacist's care through education, communication, licensing, legislation, regulation, and enforcement.

# SHARED VALUES/CORE PRINCIPLES

The Board of Pharmacy will exhibit:

- Vision
- Integrity
- Flexibility
- Commitment
- Loyalty to its mission
- Relevance to important issues
- Compassion, and
- Open-mindedness

These values will be exhibited when considering all matters before the board affecting the consumers of California and the profession of pharmacy.

# About the California State Board of Pharmacy

The California State Board of Pharmacy (board) was established in 1891 to protect consumers by licensing and regulating those responsible for dispensing medications to the public. Today the board oversees all aspects of the practice of pharmacy in California: the practitioner (the pharmacists), the practice site (the pharmacies), and the product (drugs and devices). Additionally the board regulates drug manufacturers and wholesalers. With an annual budget of over $7 million and a staff of 50, the board licenses over 76,000 individuals and firms, and enforces 12 complex and varied regulatory programs.

The board has five policy development committees to fulfill its charge. The five committees are: Enforcement, Communication and Public Education, Licensing, Legislation and Regulation, and Organizational Development. Each of these committees corresponds to a board mission-related goal.

The board supports an active Web site, www.pharmacy.ca.gov/, that provides application material for licensing and information for ensuring compliance for pharmacists and pharmacies. The Web site also provides times and information on board meetings as well as other critical forums vital to pharmacy services.

# SCANNING ASSESSMENT

In assessing the critical data that will influence the board's ability to fulfill its vision and mission, the strategic planning team completed several scanning activities in 2002. The two primary scanning activities that were completed included STEP and SWOT analyses. Board members, all staff and key stakeholders participated in completing a survey questionnaire that was submitted to the strategic planning team for synthesis and analysis. A "STEP" analysis is an acronym for Socio-Cultural, Technologic, Economic, and Political-Legal issues that will impact the board over the next 3-5 years. All responses were aggregated for generalizations. All issues were further reviewed and prioritized at a board meeting held in April 2002. These issues are presented in "**Strategic Issues to be Addressed."**

A "SWOT" analysis is an acronym for Strengths, Weaknesses, Opportunities, and Threats. The SWOT data were collected during the survey activity in April 2002 as part of the scanning assessment. Similar to the STEP analysis, the SWOT data were aggregated for generalizations. The final SWOT analysis was completed by the board and is contained in the "**Internal/External Assessment"** section.

The STEP and SWOT analyses were reviewed in April 2003 as part of the annual strategic plan update.

# METHODOLOGY

In developing its strategic plan, the board relied upon the full participation of its entire staff, its board members and its stakeholders. After each group performed the SWOT and STEP analyses described above, the board identified the strategic issues to be addressed during the April 2002 Meeting. Additionally, the board developed a new mission and vision statements, shared values, and refocused the objectives of its committees into an outcome-oriented strategic plan, with refined objectives and tasks.

At the April 2003 Board Meeting, as part of the annual strategic plan update, the board prioritized board objectives for each committee and goal area, and modified the plan's objectives and tasks. These modifications followed comments from board staff and the public obtained during committee meetings in early 2003. The final prioritization is reflected in the objectives listed for each committee.

Thus at least two iterations by board staff, board members and stakeholders have gone into producing this strategic plan. The participation of each group has provided important information necessary for a dynamic strategic plan, capable of guiding the board in fulfilling its mission for several years.

# STRATEGIC ISSUES TO BE ADDRESSED*

## 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. Also, spiraling medical care and prescription costs may influence people to take short cuts on their drug therapy. Expanded patient rights will lead to higher costs to everyone. Consequently, tier or bid pricing strategies may evolve by manufacturers. Regardless it is anticipated that the cost of prescriptions and medical services will rise.

## 2. Aging population

There are increasingly more senior citizens, and that population is living longer. Many senior citizens are without the benefit of prescription drug insurance coverage and the ability to purchase medications. Also, aging consumers often have decreased cognitive skills, eyesight and mobility. Consequently as the senior population increases so will the volume of prescriptions and the impact on pharmacists and pharmacy personnel to meet the demand.

## 3. Pharmacists' ability to provide care

The ability of pharmacy to provide optimal care for patients with chronic conditions is being challenged. Drugs are becoming more powerful and it is anticipated that more intervention by pharmacists will be required. The challenge is even greater when consumers fill multiple prescriptions at different pharmacies. The pharmacist shortage, increased consumer demand for prescription drugs, patient compliance in taking medications and polypharmacy are issues which will impact pharmacists' ability to provide care.

## 4. Changing demographics of California patients

The diversity of California's population is growing with respect to race, ethnicity and linguistic skills, as is the segment that seeks drugs and products from foreign countries. This requires greater knowledge, understanding and skills from health care practitioners. The increasing diversity of patients is coupled with culturally-based beliefs that

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* Revised in April 2003. Developed in April 2002 following STEP and SWOT analyses by Board of Pharmacy members, staff and stakeholders

undervalue the need for licensed pharmacists and pharmacies, and instead encourage purchase of prescription drugs from nontraditional locations and providers.

There also is widespread belief that there must be a medication solution for every condition or disease state.

## 5. Laws governing pharmacists

New laws enhancing the pharmacists role as a health care provider are needed. The laws must address several key issues including: expansion of the scope of pharmacy practice, the ratio of personnel overseen by pharmacists, delineation of the role of pharmacists relative to selling versus nonselling duties of personnel, and the responsibility for legal and regulatory compliance of the pharmacist-in-charge.

## 6. Legislative issues for pharmacies

There are several legislative trends that will impact pharmacies. The federal government has demonstrated an increasing interest in regulating health care to safeguard consumer interests. New legislation and regulation may be created in response to the September 11 disaster. It is expected that the outcome of the 2004 elections will affect whether legislation to provide medical and pharmaceutical care to the indigent, elderly and non-citizen population is introduced and passed.

## 7. Electronic prescribing/automation

Technology will greatly impact the processing and dispensing of medication. Electronic prescribing and 'channeling' to locations other than a traditional pharmacy may become the business model. Automated pharmacy systems and electronic prescribing will impact pharmacy. New methods of dispensing medications raise additional liability issues.

## 8. Internet issues

The availability of prescription drugs over the Internet is on the rise. Multiple and easy access of drugs without pharmacist participation is dangerous. Entities promoting illegal drug distribution schemes have taken advantage of the Internet. Monitoring and protecting the public from improper drug distribution from these Internet pharmacies is severely handicapped with continued resource challenges by both the federal and state agencies with jurisdiction.

## 9. Disaster planning and response

Pharmacists need to be ready to be positioned to provide emergency care and medication in response to natural disasters and terrorism. This requires specialized knowledge, advance planning and integration of local, state and federal resources that can be quickly mobilized.

Additionally, regulatory adjustments to the September 11 terrorism may affect persons' rights to privacy.

## 10. Qualified staff

The state's fiscal crisis will affect the board's ability to investigate customer complaints or hire staff. The duration of the state hiring freeze is unknown. If wages are also frozen, the retention of current employees could be impacted.

# INTERNAL/EXTERNAL ASSESSMENT

The critical data stemming from the SWOT analysis is reflected below. The information represents a deliberative process of multiple iterations conducted with the board members, staff and stakeholders.

| Strengths | Weaknesses |
|---|---|
| 1. Staff/Inspectors: Staff's teamwork, dedication, diversity, and knowledge. Pharmacist inspectors provide necessary, specialized knowledge.<br><br>2. Leadership: Support and communication provided by management, diversity and experience of board members. | 1. Resources: Budget constraints and insufficient resources to meet mandated duties at desired levels<br><br>2. Staffing Shortages: Insufficient staff to perform, manage, and review consumer protection activities of licensing, enforcement, and education programs. |

| Opportunities | Threats |
|---|---|
| 1. Pharmacist's Role: Pharmacy profession has large potential role in healthcare delivery. Pharmacists have opportunities in roles associated with patient care and not exclusively dispensing.<br><br>2. Technology/Automation: Promoting legislation and regulations to foster the use of technological advances by pharmacies, attainment of operational efficiencies, decreased administrative burdens, and enhanced patient care services.<br><br>3. Consumer Safety/Privacy: Promoting a nonpunitive learning environment approach to improving pharmacy patient safety. Continuing emphasis on patient safety by involving | 1. Board of Pharmacy staffing is insufficient to perform mandated duties at desired levels.<br><br>2. Board funding: Lack of funding for new programs; lack of fiscal control of board over much of its budget; budget constraints and deficits; hiring freeze.<br><br>3. Cost of pharmaceuticals: Impacts of the increasing costs of pharmaceuticals cannot be managed or controlled by the consumer or the board. |

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| the pharmacist in patient care.<br>4. Public education: Increasingly informed consumers means the profession must be able to deliver public education on drug use safety and healthcare issues. | 4. Pharmacy personnel shortage:<br>Lack of licensees impedes the ability of patients to receive quality pharmacists care. |

# SUMMARY OF GOALS

## Goal One
Exercise oversight on all pharmacy activities.

## Goal Two
Ensure the professional qualifications of licensees.

## Goal Three
Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

## Goal Four
Provide relevant information to consumers and licensees.

## Goal Five
Achieve the board's mission and goals.

# Goals, Outcomes, Objectives, and Measures

## Enforcement Committee

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| **Goal 1:** | **Exercise oversight on all pharmacy activities.** |
| **Outcome:** | **Improve consumer protection.** |

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| **Objective 1.1:** | **To achieve 100 percent closure or referral on all cases within 6 months by June 30, 2005:** |
| **Measure:** | **Percentage of cases closed or referred within 6 months** |
| **Tasks:** | 1. Mediate all consumer complaints within 90 days.<br>2. Investigate all other cases within 120 days.<br>3. Close (e.g. issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.<br>4. Seek legislation to grant authority to the executive officer to issue a 30-day Cease and Decease Order to any board-licensed facility when the operations of the facility poses an immediate threat to the public.<br>5. Integrate data obtained from computerized reports into drug diversion prevention programs and investigations (CURES, 1782 reports, DEA 106 loss reports).<br>6. Re-establish the CURES workgroup that includes other regulatory and law enforcement agencies to identify potential controlled substance violations and coordinate investigations.<br>7. Secure sufficient staffing for a complaint mediation team and to support an 800 number for the public.<br>8. Improve public service of the Consumer Inquiry and Complaint Unit.<br>9. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. |

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| **Objective 1.2:**<br><br>**Measure:** | **To achieve 100 percent closure on all administrative cases within one year by June 30, 2005.**<br><br>**Percentage closure on administrative cases within 1 year** |
| **Tasks:** | 1. Pursue permanent funding to increase Attorney General expenditures for the prosecution of board administrative cases.<br>2. Aggressively manage cases, draft accusations and stipulations and monitor AG billings and case costs.<br>3. Establish a disciplinary cause of action for fraud convictions similar to current cash compromise provisions related to controlled substances.<br>4. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.<br>5. Review and update disciplinary guidelines. |

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| **Objective 1.3:**<br><br>**Measure:** | **Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2004.**<br><br>**Percentage of licensed facilities inspected once every 3 years** |
| **Tasks:** | 1. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.<br>2. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.<br>3. Seek legislation to mandate that periodic inspections are done of all board-licensed facilities. |

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| **Objective 1.4:**<br><br>**Measure:** | **Develop 4 communication venues in addition to the inspection program to educate board licensees by June 30, 2005.**<br><br>**Number of communication venues (excluding inspection program)** |
| **Tasks:** | 1. Develop the board's website as the primary board-to-licensee source of information.<br>2. Prepare two annual *The Scripts* to advise licensee of pharmacy law and interpretations.<br>3. Update pharmacy self-assessment annually.<br>4. Develop board-sponsored continuing education programs for pharmacists in the area of pharmacy law and the expectations of the pharmacist-in-charge and coordinate presentations at local and annual professional association meetings throughout California. |

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| **Objective 1.5:**<br><br>**Measure:** | **To monitor alternative enforcement programs for 100 percent compliance with program requirements by June 30, 2005.**<br><br>**Percentage compliance with program requirements** |
| **Tasks:** | 1. Administer effective alternative enforcement programs to ensure public protection (Pharmacists Recovery Program, probation monitoring program, citation and fine program).<br>2. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. |

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| **Objective 1.6:**<br><br>**Measure:** | **Respond to 95 percent of all public information requests within 10 days by June 30, 2005.**<br><br>**Percentage response to public information requests within 10 days** |
| **Tasks:** | 1. Activate public inquiry screens to expand public information. Establish web look-up for disciplinary and administrative (citation) actions.<br>2. Establish on-line address of record information on all board licensees.<br>3. Respond to specialized information requests from other agencies about board programs, licensees (e.g. subpoenas) and Public Record Act requests. |

# Licensing Committee

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| **Goal 2:** | **Ensure the professional qualifications of licensees.** |
| **Outcome:** | **Qualified licensees** |

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| **Objective 2.1:** | **Issue licenses within three working days of a completed application by June 30, 2005.** |
| **Measures:** | **Percentage of licenses issued within 3 work days** |
| **Tasks:** | 1. Review 100 percent of all applications within 7 work days of receipt.<br>2. Process 100 percent of all deficiency documents within 3 work days of receipt.<br>3. Make a licensing decision within 3 work days after all deficiencies are corrected.<br>4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.<br>• Pharmacists<br>• Intern pharmacists<br>• Pharmacy technicians<br>• Foreign educated pharmacists (evaluations)<br>• Pharmacies<br>• Non-resident pharmacies<br>• Wholesaler drug facilities<br>• Veterinary food animal drug retailers<br>• Exemptees (the non-pharmacists who may operate sites other than pharmacies)<br>• Out-of-state distributors<br>• Clinics<br>• Hypodermic needle and syringe distributors<br>5. Deny licenses to applicants not meeting board requirements. |

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| **Objective 2.2:**<br><br>**Measure:** | **Implement at least 50 changes to improve licensing decisions by June 30, 2005.**<br><br>**Number of implemented changes** |
| **Tasks:** | 1. Review Pharmacist Intern Program.<br>2. Implement changes to the Pharmacy Technician Program.<br>  a. Use PTCB as a qualifying method for registration.<br>  b. Eliminate clerk-typist from pharmacist supervisory ratio.<br>  c. Change education qualifications from A.A. degree in health science to A.A. degree in Pharmacy Technology.<br>3. Administer a pharmacist licensure exam more than twice a year.<br>4. Assist applicants in preparing to take the California pharmacist licensure examination by developing (or fostering the development of) educational programs and information on how to prepare for the pharmacist exam and by requesting that outside agencies (schools of pharmacy and private educational organizations) develop exam workshops that prepare applicants for the California Pharmacist Exam.<br>5. Develop statutory language to give the Board of Pharmacy the authority to grant waivers for innovative, technological and other practices to enhance the practice of pharmacy and patient care that would have oversight by an independent reviewing body during the study.<br>6. Continuously review and develop written exams to ensure they fairly and effectively test the knowledge, skills and abilities of importance to the practice of pharmacy in California.<br>7. Implement the sterile compounding pharmacy licensing requirements by July 1, 2003.<br>8. Issue temporary permits whenever change of ownership occurs.<br>9. Establish means for licensee to renew permits on line. |

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| **Objective 2.3:**<br><br>**Measure:** | **Evaluate five emerging public policy initiatives affecting pharmacists' care or public safety by June 30, 2005.**<br><br>**Number of public policy initiatives evaluated** |
| **Tasks:** | 1. Explore the need to regulate pharmacy benefit managers.<br>2. Explore the need to regulate drugs labeled for "veterinary use only."<br>3. Explore the importation of drugs from foreign countries.<br>4. Develop language and pursue a regulation change to allow the central fill of medication orders for inpatient hospital pharmacies. |

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| **Objective 2.4:**<br><br>**Measure:** | **Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2005.**<br><br>**Percentage of cashiered application and renewal fees within 2 working days** |
| **Tasks:** | 1. Cashier application fees.<br>2. Cashier renewal fees<br>3. Secure online renewal of licenses |

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| **Objective 2.5:**<br><br>**Measure:** | **Respond to 95 percent of all requests for verification of licensing information within 5 working days by June 30, 2005.**<br><br>**Percentage response for verifying licensing information within 5 working days** |
| **Tasks:** | 1. Respond to requests for licensing verification |

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| **Objective 2.6:**<br><br>**Measure:** | **Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2005.**<br><br>**Percentage of licensing records changes within 5 working days** |
| **Tasks:** | 1. Make address and name changes.<br>2. Process discontinuance of businesses forms and related components.<br>3. Process changes in pharmacist-in-charge and exemptee-in-charge.<br>4. Process off-site storage applications. |

# Legislation and Regulation Committee

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| **Goal 3:** | **Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.** |
| **Outcome:** | **Improve the health and safety of Californians.** |

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| **Objective 3.1:** | **Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.** |
| **Measure:** | **100 percent successful enactment of promoted legislative changes** |
| **Tasks:** | 1. Secure extension of board's sunset date.<br>2. Sponsor legislation to strengthen and update licensing requirements for pharmacy technicians.<br>3. Sponsor legislation to add enforcement options for non-compliance issues.<br>4. Sponsor legislation to update pharmacy law to standardize terminology regarding cancellation of licenses, waiving pharmacy law requirements during declared emergencies.<br>5. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices.<br>6. Sponsor clean-up language to B & P Code section 4312.<br>7. Sponsor public meetings 4 times a year to solicit comments on areas needing legislative changes. |

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| **Objective 3.2:**<br><br>**Measure:** | **Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.**<br><br>**Percentage successful enactment of promoted regulatory changes** |
| **Tasks:** | 1. Strengthen standards for compounding sterile injectable drug products.<br>2. Authorize the executive officer the authority to issue citations and fines.<br>3. Eliminate the clerk typist ratio.<br>4. Allow pharmacists to be pharmacist-in-charge of two locations simultaneously.<br>5. Update pharmacy Self-Assessment document.<br>6. Allow central filling by hospital pharmacies.<br>7. Revise regulations concerning electronic prescribing to conform to AB 2245, and require that the pharmacist confirm the authenticity of any electronic prescription in which there is an uncertainty or ambiguity. |

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| **Objective 3.3:**<br><br>**Measure:** | **Review 5 areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2005.**<br><br>**Number of areas of pharmacy law reviewed** |
| **Tasks:** | 1. Evaluate electronic prescribing laws involving controlled substances.<br>2. Evaluate the prescribing and dispensing of veterinary drugs.<br>3. Evaluate group dispensing by prescribers. |

# Communication and Public Education Committee

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| **Goal: 4:** | **Provide relevant information to consumers and licensees.** |
| **Outcome:** | **Improved consumer awareness and licensee knowledge.** |

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| **Objective 4.1:**<br><br>**Measure:** | **Develop 10 communication venues to the public by June 30, 2005.**<br><br>**Number of communication venues developed to the public** |
| **Tasks:** | 1. Convert *Health Notes* articles into consumer columns or fact sheets for wide-dissemination to the public.<br>2. Develop and update public education materials.<br>3. Maintain a vigorous, informative Web site.<br>4. Sponsor "Hot Topics" seminars to the public. |

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|---|---|
| **Objective 4.2:**<br><br>**Measure:** | **Develop 10 communication venues to licensees by June 30, 2005.**<br><br>**Number of communication venues developed to licensees** |
| **Tasks:** | 1. Publish *The Script* two times annually.<br>2. Publish one *Health Notes* annually.<br>3. Develop board-sponsored continuing education programs in pharmacy law and coordinate presentation at local and annual professional association meetings throughout California.<br>4. Maintain important and timely licensee information on Web site. |
| **Objective 4.3:**<br><br>**Measure:** | **Participate in 20 forums, conferences and public education events by June 30, 2005.**<br><br>**Number of forums participated** |
| **Tasks:** | 1. Participate in forums, conferences and educational fairs. |

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| **Objective 4.4:**<br><br>**Measure:** | **Respond to 100 percent of information requests from governmental agencies regarding board programs and activities.**<br><br>**Percentage response to information requests from governmental agencies** |
| **Tasks:** | 1. By June 1, 2004, submit report to Legislature on statutory requirements for remedial education after four failed attempts on the California pharmacist exam.<br>2. Provide information to legislators regarding board implementation of statutory requirements.<br>3. Provide agency statistical data information to the department. |

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| **Objective 4.5**<br><br>**Measure:** | **Respond to 100 percent of public information requests regarding board programs and activities.**<br><br>**Percentage response to information requests from the public** |
| **Tasks:** | 1. Respond to public information requests. |

# Organizational Development Committee

| | |
|---|---|
| **Goal 5:** | **Achieve the board's mission and goals.** |
| **Outcome:** | **An effective organization** |

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|---|---|
| **Objective 5.1:**<br><br>**Measure:** | **Obtain 100 percent approval for identified program needs by June 30, 2005.**<br><br>**Percentage approved for identified program needs** |
| **Tasks:** | 1. Review workload and resources to streamline operations, target backlogs and maximize services.<br>2. Develop budget change proposals to secure funding for needed resources.<br>3. Perform strategic management of the board through all committees and board activities.<br>4. Manage the board's financial resources to ensure fiscal viability and program integrity. |

| | |
|---|---|
| **Objective 5.2:**<br><br>**Measure:** | **Maintain 100 percent staffing of all board positions.**<br><br>**Percentage staffing of board positions** |
| **Tasks:** | 1. Continue active recruitment of pharmacists for inspector positions.<br>2. Vigorously recruit for any vacant positions.<br>3. Perform annual performance and training assessments of all staff. |

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|---|---|
| **Objective 5.3:**<br><br>**Measure:** | **Implement 10 strategic initiatives to automate board processes by June 30, 2005.**<br><br>**Number of strategic initiatives implemented to automate board processes** |
| **Tasks:** | 1. Perform a feasibility study to establish the board's own computer system to track licensees and enforcement activities.<br>2. Continue to work with the Department on the development and implementation of Professional Licensing and Enforcement Management System (PLEMS). |

| | |
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| **Objective 5.4:**<br><br>**Measure:** | **Provide for communication venues to communicate within the board by June 30, 2005.**<br><br>**Number of communication venues to communicate within the board** |
| **Tasks:** | 1. Continue the Communication Team to improve communication among staff and host quarterly staff meetings.<br>2. Continue Enforcement Team meetings with board members and enforcement staff.<br>3. Convene inspector meetings to develop standardized investigation and inspection processes and earn continuing education. |

| | |
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| **Objective 5.5:**<br><br>**Measure:** | **Annually conduct at least 2 outreach programs where public policy issues on health care are being discussed.**<br><br>**Number of outreach programs conducted in one year** |
| **Tasks:** | 1. Attend outreach programs. |

# Attachment 2

## Board Member Travel and Hour Summary
## 2002/2003 Fiscal Year

| Board Member | Total Per Diem & Expense* | Total Hours* |
|---|---|---|
| D. Gubbins | $2,804.74 | 126.5 |
| J. Jones | $4,388.34 | 236.7 |
| S. Litsey | $3,907.05 | 158.5 |
| W. Powers | $1,633.63 | 81.5 |
| C. Zia | $3,546.72 | 200.0 |
| A. Zinder | $1,800.73 | 82.5 |
| C. Huira | $3,402.90 | 176.5 |
| S. Goldenberg | $6,984.38 | 327.8 |
| D. Fong | $1,782.35 | 95.0 |
| S. Tilley | $756.25 | 60.5 |
| **TOTAL** | **$30,250.84** | **1,545.5** |

*Reflects per diem and travel claim expenses submitted to date; does not include rental car, cab or air travel expenses.

# Attachment 3

# BUDGET LETTER

| | |
|---|---|
| **NUMBER:** 03-18 | |
| **SUBJECT:** 2004-05 BUDGET POLICY | **DATE ISSUED:** July 8, 2003 |
| **REFERENCES:** BL 03-05 | **SUPERSEDES:** BL 02-20 |

TO: Agency Secretaries
Department Directors
Departmental Budget Officers
Departmental Accounting Officers
Department of Finance Budget Staff

FROM: DEPARTMENT OF FINANCE

This Budget Letter (BL) sets forth the Governor's policy direction for preparation of his 2004-05 Budget. As a reminder, BL 03-05, issued March 26, 2003, outlines the technical and procedural requirements for preparation of the 2004-05 Budget. BL 03-05 describes the framework for the completion and submission of proposed baseline/current services departmental budgets.

**Current Year Deficiencies**

Despite the major reductions to programs proposed for the 2003-04 Budget, given the current fiscal environment, departments are advised that current year State Operations' deficiencies will not be approved. Departments must absorb any increased costs. The Department of Finance (Finance) will only consider deficiencies for extraordinary circumstances. Consult with your Finance Program Budget Manager before submitting any deficiency requests.

**Budget Change Proposals**

Unless legislative steps are taken to address the budget's structural imbalance, currently authorized expenditures and statutorily required expenditure adjustments will exceed available resources in 2004-05. Therefore, there will be no discretionary funds available from any fund source for new initiatives or program expansion.

Agencies and departments should not submit requests for new programs or for expansion of existing programs. This includes information technology (IT) activities. During this time, the State needs to focus on only its most essential IT projects as well as the security of IT operations. Budget Change Proposals (BCPs) to fund new initiatives or program expansions will not be reviewed (unless they include revenue-generating proposals that would make them cost-beneficial), and will be returned to the requesting department or Agency. BCPs to fund workload increases or costs of legislation must be accompanied by commensurate proposed reductions in other existing programs. To avoid unnecessary workload, agencies are encouraged to discuss departments' budget change concepts with the appropriate Finance Program Budget Manager, prior to fully developing BCPs.

**Addressing the 2004-05 Funding Gap**

After Budget enactment, the Legislature has been asked to spend the balance of the legislative session to address the structural issues that, if left unresolved, will put future budgets out of balance and threaten the future prosperity of our State's citizens. Based on the May Revision projections, absent legislative

corrective actions, the 2004-05 General Fund funding gap is estimated at $7.9 billion. The ultimate funding gap will change depending on the final Budget and the legislative actions to address the structural gap. Some measures may require Constitutional or statutory changes that could be placed before the electorate.

Since the timing and final outcome of such actions are currently unknown, the Administration must collectively make further spending reductions in 2004-05 to bring ongoing expenditures in line with ongoing resources. **Consequently, Agencies and departments must be prepared to submit expenditure reduction plans similar to last year for both state operations and local assistance.** These reduction plans apply to General Fund and selected non-General funds (departments affected by these non-General funds will be separately notified by your Finance analyst).

Reductions for the 2004-05 Budget will continue to be complex, require the elimination of programs or layoff of employees, and require certain level of lead time both for development and implementation. Acknowledging that significant programmatic impacts have been incurred pursuant to position reductions, prior unallocated reductions, and other budget reductions, Agencies and departments must propose specific reductions that incorporate one or more of the following: (1) the repeal of statutorily required activities or programs; (2) the elimination of discretionary programs; (3) program consolidation; (4) the reorganization of Agencies, departments, boards, commissions, and offices (proposed reorganizations that cross Agency jurisdictions must be submitted jointly by the affected Agencies); and (5) restructuring program responsibilities between the State and local governmental entities. Detailed instructions will be issued later to formalize the reduction plan submission process.

**Proposed Statutory Changes**

Pursuant to Government Code Section 13308, Finance must provide to the Legislature on or before February 1 of each year, all proposed statutory changes, as prepared by the Legislative Counsel, necessary to implement the Governor's Budget. Therefore, all Budget Change or Reduction Proposals that require statutory changes also must include a copy of the proposed legislation. Finance will submit the approved language to the Legislative Counsel.

**Comprehensive Budget Development Process**

The Government Code and Budget Act require the Governor's Budget development process to be as comprehensive as possible, and any subsequent adjustments may only be made to meet critical and unanticipated needs. Further, the January Budget is to include all policy proposals being made for the ensuing fiscal year. Spring Finance Letters, due to the Legislature no later than April 1, should be used only for (a) updating those proposals made in January or (b) submitting any new critical proposals that cannot be delayed until the upcoming fall budget process without serious consequences. The May Revision changes to the Governor's Budget are due to the Legislature no later than May 14 and will encompass only traditional enrollment, caseload, and population adjustments and any necessary budget balancing proposals.

If you have any questions, please contact your Finance budget analyst.

STEVE PEACE
Director

# Attachment 4

# Status Update 7/1/03

# Recommendations of the Department of Consumer Affairs and the Joint Legislative Sunset Review Committee

**Informal Recommendations of the Joint Legislative Sunset Review Committee for the Board of Pharmacy (November 2002):**

1. Add two public members to the board.
   ✓*This provision is contained in SB 361 (Figueroa)*
2. Define "actively engaged" as provided for in the Business and Professions Code specification of the composition of the board's professional members.
   ✓*Legislative Counsel's opinion received.*
2. Make all committee meetings public meetings.
   *The board supports this – a proposed legislative change to require this of all boards is being developed by the department.*
3. Modify board regulations so that the executive officer issues citations and fines.
   ✓*Board adopts regulation change in April 2003; rulemaking file undergoing Administration review.*
4. Use staff other than exclusively pharmacist inspectors to investigate and inspect licensees.
   ✓ *Board currently uses non-pharmacist staff to perform certain investigation duties; statutory language to amend Business & Professions Code section 4008 (that requires board inspectors performing specific duties to be pharmacists) is contained in SB 361.*

**Draft Recommendations of the Department of Consumer Affairs (March 2003):**

1. The licensing and regulation of the pharmacy profession should be continued and a board structure should be maintained.
   ✓ *Provisions to extend the board's sunset date four years are contained in SB361 (Figueroa).*
2. Add two public members to the board.
   ✓ *Provisions to add two public members are contained in SB361 (Figueroa).*
3. Make all committee meetings of the board be public meetings.
   ✓ *Department may seek statutory provisions to require this of all boards. Meanwhile each year, all Enforcement & Licensing Committee meetings are public, two Legislation and Regulation Committee meetings are public, and at least one meeting of the Public Education and Organizational Development Committees is public.*
4. The board should adopt the NAPLEX.
   ✓ *Provisions to use the NAPLEX exam are contained in SB361 (Figueroa).*
5. Modify the citation and fine program to exclude the involvement of board members and

delegate to the executive officer the authority to issue citations and fines.

- ✓ *Board adopts regulation change in April 2003; rulemaking file undergoing Administration review.*

6. The board should not require all its investigators to be pharmacists.
   - ✓ *Board currently uses non-pharmacist staff to perform certain investigation duties; SB 361 (Figueroa) would amend Business & Professions Code section 4008 to eliminate requirements that board inspectors performing specific duties be pharmacists.*
7. The board should use the department's online consumer complaint form.
   - ✓ T*he board has added this feature to its Web site.*
8. The board should expand its consumer outreach and education, and work with the department to develop additional materials.
   - ✓ *Staff has met with the department's Communications and Education Division and a plan to mutually produce materials developed for the board's Communication and Public Education Committee.*
9. The board should establish a reliable method of communicating and surveying those who have filed complaints, and revise its survey instrument to provide meaningful data.
   - ✓ *The board actually has substantial information from consumers after and has sent over 2,000 complainants a survey form over the last few years. (The department misunderstood the board's Sunset Report.) At the department's insistence, telephone surveys of consumers, which were to begin in July 2003 will not occur, instead written surveys will continue*
10. The board should work with the department's Office of Privacy Protection on ensuring patient privacy.
    - ✓ *The board will work with the Office of Privacy Protection to assure the privacy of patients' records is continued. The board has promulgated a regulation to permit it to cite and fine pharmacies and pharmacists for up to $250,000 for failure to maintain the privacy of these records.*

Also, as observations:

11. The board is implementing the recommendations of its Pharmacy Manpower Task Force.
12. The board has expanded its consumer complaint disclosure policy.

**Recommendations of the Staff of the Joint Legislative Sunset Review Committee (April 2003):**

1. Items 1-10 above, plus:

11. Support the board's proposal to revise registration and program requirements for pharmacy technicians – specifically:
    a. accept PTCB certification
       - ✓*This provision is sponsored by board and contained in SB 361 (Figueroa)*

    b, accept the associate degree in pharmacy technology and eliminate the other associate degrees
       - ✓*This provision is sponsored by board and contained in SB 361 (Figueroa)*

    c. revise the specificity of the theoretical and practical requirements of the training curriculum

✓*This provision is contained in SB 361 (Figueroa)*

d. accept graduation from a school of pharmacy

✓*This provision is sponsored by board and contained in SB 361 (Figueroa)*

e. eliminate the equivalent experience provision for the clerk typist and hospital pharmacy technician.

✓*The specific provision for this is a regulation; however, the underlying authority for this would be repealed by provisions in SB 361 (Figueroa)*

12. The board should continue to ensure that pharmacists offer oral consultation on new prescriptions. Consumers should not be charged a separate fee for such consultations.

✓*No action required on the board's part*

# Attachment 5

# Status Update 7/1/03

# Recommendations of the Internal Audits Office, Department of Consumer Affairs

The findings and recommendations for the board arising from the Department of Consumer Affairs, Internal Audits Office operational audit (March 2003) are:

1. The loan of $6 million from the Pharmacy Board Contingency Fund to the State's General Fund will negatively impact on the board's future operations if not repaid in a timely manner.
   - ✓ *The board is working with the department and the Department of Finance to assure the loan is repaid before a deficit in board's fund occurs, carefully monitoring the board's finances. The DoF declined to begin repayment in 2003/04, but will reexamine the board's financial condition in November 2003 for possible reconsideration..*

2. Although the board's evidence room access controls are adequate, management could strengthen inventory controls and safety awareness.
   - ✓ *Staff has developed additional procedures for evidence, and destruction contracts to destroy evidence from closed cases will be secured in FY 2003/04.*

3. The board's licensing activities are adequate but could benefit from improvements.
   - ✓ *The auditors examined the board's pharmacist licensure and technician application processing functions, two desks that have been impacted by hiring freezes and staff vacancies. The board stopped providing status updates to applicants with applications pending less than two months old (technicians), relieving the technician to perform processing duties. Meanwhile the board processed and scheduled more than 1,340 applications for the June pharmacist examination, and was able to allow applicants who completed deficiencies as late as the day before the exam to take the examination.*

4. The board's enforcement program allows it to address consumer complaints, but continued improvements are needed to strengthen its operations.
   - ✓ *The board modified its tracking program to allow the date a complaint is received to be entered into the system, and not use the date the entry was made into the computer system as the initiation date for the complaint. This was the issue for the auditors. Additionally, the four new supervisors will aid the board in assigning complaints to inspectors and in reviewing completed investigation reports.*

# Attachment A
# Minutes of the Organizational Development Committee

June 30, 2003

**California State Board of Pharmacy**
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308

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

# ORGANIZATIONAL DEVELOPMENT COMMITTEE

## Minutes of the June 30, 2003 Meeting
## Via Teleconference

**Present:** **Don Gubbins, Vice President of the Board and Committee Chair**
**John Tilley, Board Member**
**Patricia Harris, Executive Officer**
**Virginia Herold, Assistant Executive Officer**

Call to Order

Chair Don Gubbins called the meeting to order at 9:30 a.m.

Status of Pending Legal Issues

Ms. Harris updated the committee on the status of Doumit v. the Board of Pharmacy, which has been appealed by Mr. Doumit. She also provided an update on Tain, et al. v Board of Chiropractic Examiners, et al.

Status of Strategic Plan Revision for 2003/05

Ms. Herold stated that comments made about the strategic plan during the April Board Meeting have been incorporated into a new draft of the strategic plan. At the July Board Meeting the board needs to take final action on the plan.

She added that during each of the committee meetings leading up to the board meeting, the committee will review the final objectives and activities for that committee.

The committee stated that the plan looked finalized, and was ready for board action.

Motion by Dr. Gubbins, seconded by Mr. Tilley: Recommend board approval of the board's revised strategic plan.

2-0

Update on the Board's Strategic Goals 2002/03

The committee reviewed the 4th quarter's status report on the strategic plan; this report from the committee will be provided in the board's packet for the July meeting.

Status Report on the Board's Sunset Review

The committee reviewed a status report detailing all sunset review recommendations and the status/action to date on each recommendation.

Amendments to SB 361 (Figueroa) contain a number of Board of Pharmacy sunset recommendations. This includes addition of two public members to the board, extension of the board's sunset date by four years, clarification that board investigations may be performed by pharmacist inspectors as well as non-pharmacist inspectors, modifications to the pharmacy technician program and use of the North American Pharmacist Licensure Examination in place of the board's licensure exam for pharmacists.

Meanwhile the board has pursued implementation of other recommendations, including adopting regulation changes to permit the executive officer to issue citations and fines, notifying the Department of Finance that repayment of the General Fund loan in 2003/04 is necessary to prevent a deficit in the board's fund early in 2004/03, and providing Web site access to the department's online complaint form.

Budget Update/Report

- **2002/03 and 2003/04 State Budgets and Deficit Reduction Items**

  Ms. Herold stated that the state's budget deficit has increased to a staggering $38 billion. A number of additional cost containment controls have been placed on state agencies besides hiring freezes and the elimination of vacant position (for the board this was four positions in June 2002 and an associated $185,000 for salaries):
  - In February, the board learned that any out-of-state travel would not likely be approved, allowing the board to redirect about $20,000 to the board's AG program line item
  - All agencies were required to cut their in-state travel budgets by 35 percent (in the case of the board, this is $52,100)
  - All training requests, contracts and purchases now undergo additional review by the department as a means to reduce expenses, and approval is much harder to attain
  - On April 1, the Administration directed all agencies to identify cut their personnel services budgets for 2003/04 by 10 percent, and to prepare a list of employees to lay off to assure 10 percent reduction in personnel services. In the case of the board, this will amount to a $347,000 reduction, and the loss of all vacant

positions as well as elimination of overtime salaries and board member honoraria.

- **Transfer of Board's Reserve and Proposed Fee Increases**

  The board "loaned" $6 million from its fund to the state's General Fund this budget year. This has left the board with a projected $75,000 remaining at the end of 2003/04, which will grow to a projected $2.7 million deficit (or 4.2 months of expenditures) by June 30, 2005.

  The Internal Audits Office of the department noted in its sunset review audit of the board, that the board's fiscal condition will require repayment of the loan to begin late in 2003/04. The board is working with the department and the Department of Finance to assure this repayment occurs before a deficit in the board's financial operations occurs. Ms. Herold added that the Department of Finance declined to establish a repayment schedule for the loan for 2003/04. However, the DOF agreed in November 2003 to reexamine the board's revenue and expenditure levels and reconsider repayment at that time.

- **2002/03 Budget Reductions**

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

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

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

- **Budget Change Proposals**

  Ms. Herold stated that the board will soon submit two budget change proposals for the 2003/04 and future fiscal years. Ms. Herold noted that seeking any augmentation requests in this fiscal climate will not likely be successful. However, staff believe that it is important that the board document its fiscal needs. The most necessary augmentations are:

  1. The board will continue to have problems with funding in its AG budget next year. The board has spent nearly $1 million the last three years for AG services, and to reduce spending to the amount allocated by the board's budget ($777,000) would result in a 25 percent reduction in spending from prior years. This year, the board withdrew some aging AG cases and reduced the number of AG cases referred as cost containment strategies required by the budget condition, and still the budget is estimated at $1

million. Nevertheless, the importance of the AG services to the board's consumer protection mandate require that a BCP be prepared to augment funding to historical levels of spending.

2. Additionally, the board will need to do a job analysis in 2004 for the pharmacist exam or if NAPLEX is approved, for the CA specific portion of the exam. The costs for this will be approximately $25,000.

The committee discussed the most recent budget reduction ordered, the 10 percent cut in personnel services. Ms. Harris noted that the board is fortunate in that it was able to identify the $347,000 in personnel cuts required by the Department of Finance by eliminating all six unfilled positions and by eliminating overtime payments and most of the board member compensation – instead of laying off staff. Other boards and departments have begun the process to lay-off staff. The committee discussed the impact on operations that would be caused by not filling these positions.

The committee suggested that to reduce board member compensation for the year by $20,000, that members should be compensated only for attendance at board meetings, which is $100 per day of the board meeting. Travel expenses will continue to be paid by the board, and are funded from other areas of the board's budget.

Last year (2001/02) board members received $27,100 from a budget of $36,200 for this board member compensation.

The committee recommended that any additional time worked on board business and submitted for reimbursement be held until the end of fiscal year 2003/04. If sufficient funds remain, the board members will be reimbursed for eight-hour increments, just as they are now. If funding is not available for this purpose, no additional compensation will be provided.

Motion by Chairperson Gubbins, seconded by Mr. Tilley: recommend board member compensation be limited to time spent at board meetings only. Additional hours spent performing board business (excluding travel time) during 2003/04 will be compensated at the end of fiscal year only if funds are available for this purpose.

2-0

Personnel Update and Report

The board's two newest supervising inspectors have begun their new positions. Dr. Ming has done considerable work in establishing the licensure of pharmacies performing compounding of sterile injectables, including the training of all inspectors in performing these inspections and the development of a self-assessment form for pharmacies. Dr. Coyne has fully assumed the supervisory oversight of the probations

and PRP programs. Over the next few months, the duties of the supervising inspectors and the workflow within the enforcement and licensing units will be altered to accommodate the much-needed additional supervisors.

The board has the following vacancies:

- Three inspectors (one new position for compounding, one from the promotion of Dennis Ming, and one "technical" position that was reclassified from an analyst position to an inspector position to allow for reclassifying one the new supervising inspectors – which when we filled the supervising inspector position, left an inspector position vacant)
- One associate analyst (licensing of sites, created by the retirement of Sandi Moeckly at the beginning of 2003)
- One office technician (licensing of sites, created by the promotion of Suelynn Yee for licensing compounding pharmacies)
- One office technician (receptionist)

To fill these positions, the board needs freeze exemptions. Two freeze exemptions were approved for the two inspector positions; however, because all six of these positions have been targeted for elimination to make the 10 percent reduction in personnel services expenditures, none of the positions can be filled at this time.

Additionally all board managers will effectively receive a 5 percent reduction in their state compensation starting in July to cover retirement contributions that were made by the state for the past few years. In addition managers will not likely receive a 5 percent raise that will be provided to union-represented employees (all other employees) that was negotiated years ago through collective bargaining.

The next Labor/Management Meeting with the union representing board inspectors is set for mid-July. The contract with the state requires that the board and the union convene meetings to discuss workload and management issues of concern (to the union). Two board inspectors are participating for the union (they are union stewards) as is one pharmacist from the Department of Mental Health.

Ethics Training Required

Chairperson Gubbins asked how many board members have taken the state-mandated ethics training, which must be completed by January 1, 2004. Only three members have.

The committee requested that all board members be again reminded of their obligation to complete this training. The committee determined that it would be best if each individual required to take this training either take it from the Web site (http://caag.state.ca.us/ethics/index.htm) or via a video.

Adjournment

There being no additional business, Chairperson Gubbins adjourned the meeting at 10:10 a.m.

# Organizational Development

## Goal

Achieve the board's mission and goals.

## Implementation Responsibility

Organizational Development Committee, The Communications Team and Management

| Strategic Objectives | | Timeline |
|---|---|---|
| 1. Pursue budget change proposals to meet identified program needs. | | July 2002 |
| *August 2002:* | *Due to deteriorating fiscal conditions of state budget, Dept. of Finance directs that all but most essential BCPs be withheld. Board scales back BCPs to request funding for 2002/03 and future budget years for $302,000 for AG services and $52,000 for postage.* | |
| *October 2002:* | *Budget change proposal for $353,000 denied for current and future years.* | |
| *November 2002:* | *Estimated shortfall in AG funding for the year remains at $300,000. At department's request – board requests restoration of $185,000 targeted for elimination from the board's budget as part of elimination of vacant positions on June 30, 2002 – so that this funding could be retained by the board and redirected to the AG line item. Meanwhile board begins to reevaluate oldest cases at AG and implements steps to reduce AG services.* | |
| *January 2003:* | *Estimated shortfall in AG funding still projected. Board must submit deficiency augmentation request and scale back AG expenditures to prevent overspending.* | |
| *February 2003:* | *Board redirects $230,000 from printing and out of state travel to redirect to AG program budget, preventing a need to submit deficiency augmentation request.* | |

| | | |
|---|---|---|
| | *June 2003:* *Board begins development of 2 BCPs to augment AG services in 2003/04 and future years by at least $250,000, and $25,000 for a pharmacist job analysis (need for the exam) in 2004/05.* | |
| 2. | Reorganize the board's management structure to oversee board programs and staff. | January 2003 |
| | *September 2002:* *State budget contains two supervising inspector positions. Senior management prepares questions for civil service ranking interviews for this classification. One position is new but the other is a reclassification of an existing position and must be approved by the Department of Personnel Administration. Board submits request to Department.* | |
| | *December 2002:* *Senior management participates in civil service interviews required to develop a list for those qualified for supervising inspector. Board receives approval to reclassify one position to that of supervising inspector.* | |
| | *February 2003:* *Supervising inspector positions filled by promotion of board inspectors.* | |
| | *June 2003:* *Board's supervisory structure established for enforcement staff to accommodate 4 supervising inspectors.* | |
| 3. | Pursue regulatory changes to require inspectors to file annual conflict of interest statements with the Fair Political Practices Commission. | July 2003 |
| | *December 2002:* *Department of Consumer Affairs releases regulatory notice that it is ready to modify its regulations specifying departmental staff that must file annual conflict of interest statements. Board inspectors are added to this list.* | |
| | *April 2003:* *Department of Consumer Affairs holds regulation hearing on proposed change to amend filing requirements for DCA staff; board inspectors are added.* | |
| 4. | Manage the board's financial resources to ensure fiscal viability and program integrity. | July 2003 |
| | *July 2002:* *Board agrees to move forward with regulation to increase fees to statutory maximums if transfer of $6 million from board's fund to General Fund occurs as part of the 2002/03 budget.* | |

| | |
|---|---|
| *September 2002:* | *Committee considers need for future fee increases and raising of statutory fee caps to assure ongoing future revenue matches board expenditures.* |
| | *State Budget loans $6 million from the board's reserve to the state's General Fund.* |
| *October 2002:* | *If the board's loan of $6 million is not repaid, the board's reserve will be near a deficit by the end of 2003/04. Board votes to increase fees to statutory maximums via regulation change effective July 1, 2003.* |
| | *Board votes to pursue increase in statutory fees via legislation. Fee caps would be increased to levels of the 1980s when adjusted for inflation.* |
| | *Director advises board that the board will not need to proceed with a fee increase; the loan will be repaid first.* |
| *January 2003:* | *Governor's budget for 2003/04 released. Indicates fund condition at end of 2003/04 of only 3 three days ($75,000). Board needs to secure repayment schedule for loan or initiate steps for fee increase.* |
| *February 2003:* | *Staff works with department and the Department of Finance to assure repayment of the loan begins before the board has a deficit - - sometime late in 2003/04.* |
| *March 2003:* | *Department's Internal Audit office's review of the board identifies repayment of the general fund and as a necessity to prevent a future fund deficit for the board.* |
| *April 2003:* | *Board identifies $360,000 in personnel services reductions, eliminating all vacant positions, in response to the Administration's directive to target 10 percent reductions in personnel services for 2003/04.* |
| *May 2003:* | *Department of Finance determines repayment of General Fund loan not needed by board in 2003/04. The Department of Finance agrees to reevaluate this position in Nov. 2003.* |

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| 5. | Perform a feasibility study to establish the board's own computer system to track licensees and enforcement activities. | June 2003 |

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| *November 2002:* | *Board staff works with DCA contractor to identify systems elements needed in a new computer system for the department (integrating applications, cashiering, licensing and enforcement systems) to replace existing system.*<br><br>*Board staff also initiates discussions with e-government program to establish means for online renewals and submission of applications. Program cannot be expanded to include the board at this time, future use of such technology for renewals seems feasible.* | |
| *January 2002:* | *Department prepares feasibility study for new computer system called Professional Licensing Enforcement System (PLEMS). If approved, the board's costs are estimated at $550,000 and will be installed in 2007/08.* | |
| *June 2003:* | *The Department of Finance reviews feasibility study for PLEMS. Meanwhile procurement activities are initiated to begin this phase.* | |
| 6. | Redesign and reformat the board's strategic plan into the new strategic management plan structure. | June 2003 |
| *July 2002:* | *Contract solicited for facilitator for board's strategic plan.* | |
| *December 2002:* | *Executive staff begins work with consultant to reformat existing strategic plan into new structure.* | |
| *February 2003:* | *Executive staff reformats goals and objectives of each committee into new strategic plan structure. During committee meetings, each committee reviews and approves reformatted goals.* | |
| *April 2003:* | *Board revises and updates strategic plan during public meeting of the Organizational Development Committee.* | |
| *May & June 2003:* | *Final plan modification integrated into 2003-05 plan.* | |

## Ongoing Objectives

7. Ensure management systems provide adequate staff compensation, regular performance monitoring and enhancements, optimize implementation of the strategic plan and improve decision-making.

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| *September 2002:* | *New 2002/03 state budget eliminates four vacant positions at the board, and removes $185,000 in annual expenditure authority linked to these positions.* |
| | *Sunset Report submitted to Legislature, as required.* |
| *December 2002:* | *Board participates in Joint Labor-Management Task Force with the union representing inspectors; a required contract term. These meetings will occur over a period of months to discuss workload and other issues* |
| *March 2003:* | *Second meeting of Joint Labor-Management Task Force occurs.* |

8. Continue the Communications Team (TCT) to facilitate and improve communications within the board.

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| *Sept. 11, 2002:* | *TCT hosts quarterly staff meeting. TCT also coordinates sales of board logo shirts.* |
| *December 2002:* | *TCT hosts quarterly staff meeting.* |
| *March 2003:* | *TCT hosts quarterly staff meeting.* |
| *July 2003:* | *TCT hosts quarterly staff meeting.* |

9. Link policy, strategic plan, and budgeting and develop a reporting strategy.

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| *October 2002:* | *All committees provide quarterly updates during October Board Meeting.* |
| *December 2002:* | *Strategic plan begins conversion into new structure to facilitate strategic management of the board.* |
| *January 2003:* | *All committees provide quarterly updates during January Board Meeting.* |
| *April 2003:* | *Board revises and updates strategic plan onto new format during public meeting of Organizational Development Committee. All committees provide quarterly updates during April Board Meeting.* |
| *June 2003:* | *Final plan for 2003-05 completed.* |
| *July 2003:* | *All committees provide quarterly updates during July Board Meeting.* |

10. Improve procedures to support quality improvement efforts, implement strategic objectives, create team approaches and improve decision-making.

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| *September 2002:* | *Restructuring of board's enforcement reports is facilitated by training staff in new procedures and a specialized writing course for inspectors. Group of staff begin integration of CURES data into proactive investigations.* |
| *December 2002 – June 2003:* | *Citation and fine committees expand to include additional board members. Reports and processes continue to evolve to better meet enforcement priorities and efficiencies.* |
| | *Board uses team approaches to respond to the workload needs for processing of applications in light of staff vacancies. Diverse staff assigned to assist with such work.* |

11. Ensure that staff development and resource management support organizational effectiveness.

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| *September 2002:* | *Sunset Report submitted to Legislature.* |
| *October 2002:* | *DCA initiates internal operational audit of board as part of Sunset Review process.* |
| *November 2002:* | *DCA executive office briefing on the board's Sunset Review Report.* |
| | *Board responds to 31 focused issues requested by the Joint Legislative Sunset Review Committee.* |
| | *Board's legislative hearing on its Sunset Review Report.* |
| *January 2003:* | *Board reviews and takes positions on five draft recommendations of the Joint Legislative Sunset Review Committee.* |
| | *Annual assessments of staff begins; targeted training for enhanced performance of each employee is one area of evaluation.* |
| *February 2003:* | *Board senior management participates in Joint Labor Management Task Force required by the Unit 19 Collective Bargaining Agreement, regarding inspector workload.* |
| *March 2003:* | *Department's Internal Audit office releases audit findings of board. Status reports will be submitted by the board every six months.* |
| *April 2003:* | *Department and Joint Legislative Sunset Review Committee provide recommendation following sunset review of the board. These findings include continued existence of the board to regulate the profession, the addition of two public members to the board, the use of NAPLEX to license pharmacists, the option to use non-pharmacy inspectors and implementation of changes to the pharmacy technician program.* |
| *June 2003:* | *Committee monitors board activities to implement sunset recommendations.* |

12. Maintain and upgrade automated systems to keep the board current with evolving technology.

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| *September 2002:* | *All application forms on Web site are revised as board initiates program to save postage by requiring applicants to download applications instead of requesting these from the board.* |
| *October 2002:* | *Board initiates discussions with Department of Justice to obtain board specific analyses of CURES data and to initiate modifications to the CURES system implemented by 2002-enacted legislation.* |
| *November 2002:* | *Additional staff receive training in data management software to facilitate monitoring of board programs.* |
| | *Board staff works with DCA contractor to identify systems elements needed in a new computer system for the department (integrating applications, cashiering, licensing and enforcement systems) to replace existing system.* |
| | *Board staff initiates discussions with e-government program to establish means for online renewals and submission of applications. Program cannot be expanded to include the board at this time, future use of such technology for renewals seems feasible.* |
| *January 2003:* | *Department prepares feasibility study report to implement Professional Licensing and Enforcement Management System (PLEMS) in the future. Discussions are ongoing with the Department of Finance.* |
| *April 2003:* | *Board continues work with the Department of Justice to access CURES data.* |
| *May 2003:* | *Board develops new tracking systems for pharmacies compounding sterile injectable drugs, and for citation and fine activities.* |
| *June 2003:* | *New staff trained in Web site development; staff will begin revamping board Web site in the future.* |

13. Activate and integrate data collection and analysis to support strategic planning, including performance measurement and process improvement studies.

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| *September 2002:* | *Compilation of Sunset Report results in availability of data for management review.* |
| *December 2002:* | *Board compiles and provides massive data to DCA in response to request for all sunset review data. This will become part of an annual submission to DCA.* |
| | *Board initiates reformatting of strategic plan to improve performance measure monitoring and reporting of board activities.* |

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| *March 2003:* | *Modifications and enhancements made to the board's automated activity tracker and inspection program systems. Also, new case management and licensing data tracking systems developed.* |
| *April 2003:* | *Board restructures strategic plan during board meeting and public meeting of the Organizational Development Committee.* |
| *May & June 2003:* | *New strategic plan will integrate performance measures as part of reporting system for objectives.* |

14. Form task-specific process review teams to improve operations.

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| *December 2002:* | *Board site licensing staff redesign processing functions to enable the board to continue existing site licensing duties in light of two staff vacancies that may not be filled and implementation of the compounding pharmacy license program.* |
| *April 2003:* | *All inspectors will undergo training to implement Sterile Injectable Compounding Pharmacy License program.* |
| *May 2003:* | *All inspectors undergo training to perform inspections for sterile injectable compounding pharmacies.* |

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

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

**DATE & TIME:** April 29 and 30, 2003

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

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

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

**Tuesday, April 29, 2003**

## CALL TO ORDER

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

## ANNOUNCEMENTS

- **Supervising Inspectors**

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

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

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

  This is the first meeting where CE has been offered.

- **Pharmacists Recovery Program**

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

- **Board Packets**

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

- **Fred T. Mahaffey Award**

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

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

- **Board Member Terms Expired**

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

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

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

## COMMITTEE REPORTS AND ACTION

### LICENSING COMMITTEE

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

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

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

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

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

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

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

MSC: POWERS/GOLDENBERG

SUPPORT: 9 OPPOSE: 0

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

  Chairperson Fong stated that in order to meet the requirements of the new law empowering the board with the ability to approve accreditation agencies, the Licensing Committee requested that criteria be developed under which to evaluate the agencies. The

board's approval should be based on the accreditation agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards. The following factors were developed for board consideration when evaluating an agency: periodic inspections, documented accreditation standards, evaluation of surveyors' qualifications, acceptance of the accreditation by major payors, unannounced inspections of sites, board access to an accreditor's report on pharmacies, length of time in operation, ability to accredit in other states, length of accreditation and process for reaccredidation.

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

SUPPORT: 9 OPPOSE: 0

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

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

- **Report from the Ad Hoc Committee on Pharmaceutical Benefit Managers (PBM) Regulation**

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

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

**ENFORCEMENT COMMITTEE**

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

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

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

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

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

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

MSC: TILLEY/HIURA

SUPPORT: 9 OPPOSE: 0

- **Enforcement Options Regarding the Importation of Prescription Drugs from Canada through Storefront Facilities**

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

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

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

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

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

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

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

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

Mr. Goldenberg requested public comment.

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

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

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

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

> On behalf of the Greenlining Institute, a statewide nonprofit public policy advocacy coalition of thirty-nine church, business, consumer and civil rights organizations as well as Greenlining's health project, Bridges to Health, which strives to ensure that all Californians have access to affordable health care and access to affordable prescription drugs.
>
> We are shocked that the California Board of Pharmacy is considering a President Bush anti-consumer position that will prevent America's poor and senior citizens from obtaining life-saving medicines at prices afforded to Canadians.
>
> What this Board should do is recommend to Governor Davis, the Secretary of State and Consumer Services methods by which all Californians can obtain the same drugs at the same prices that Canadians pay. Californians could save $12 billion a year and our State's health programs could save two billion a year or more.

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

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

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

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

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

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

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

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

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

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

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

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

- **Morton Farina, Pharmacist**

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

- **Lucille Blasta**

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

- **Karen Rauch**

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

- **Don Sherral**

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

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

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

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

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

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

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

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

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

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

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

M/S/C: POWERS/ZINDER

SUPPORT: 9 OPPOSE: 0

- **Implementation of Federal HIPAA Requirements**

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

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

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

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

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

- **Task Force with Medical Board of California on Prescriber Dispensing**

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

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

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

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

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

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

## PUBLIC EDUCATION AND COMMUNICATIONS COMMITTEE

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

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

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

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

## LEGISLATION AND REGULATION COMMITTEE

- **Adoption of Amendments to CCR 1775 et seq. – Citation and Fine**

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

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

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

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

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

SUPPORT: 9 OPPOSE: 0

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

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

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

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

MOTION: Legislation and Regulation Committee: Seek to add section 4106 to the Business and Professions Code as follows:

4106: For purposes of license verification, a person may rely upon a printout from the board's Web site that includes the license issuance and expiration dates, of any board-issued license.

SUPPORT: 9 OPPOSE: 0

- **AB 103 (Reyes) – Drug Marketing**

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

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

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

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

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

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

M/S/C: POWERS/FONG

SUPOPORT 9 OPPOSE 0

- **AB 261 (Maddox) – Backroom Clinics**

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

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

SUPPORT: 9 OPPOSE: 0

- **AB 521 (Diaz) – Drug Information**

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

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

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

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

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

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

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

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

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

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

MOTION: Take no position support AB 521 (Diaz) as amended April 22, 2003.

M/S/C: ZINDER/POWERS

SUPPORT: 4 OPPOSE: 5

- **AB 746 (Matthews) – Medi-Cal Fraud**

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

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

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

SUPPORT: 9 OPPOSE: 0

- **AB 1363 (Berg) – Hypodermics**

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

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

SUPPORT: 9 OPPOSE: 0

- **AB 1460 – Nation) – Laboratory Directors**

Chairperson Litsey stated that this bill would permit pharmacists to act as a laboratory director if they receive training required of laboratory directors and the laboratory performs only waived tests.
Chairperson Litsey stated that the Legislation and Regulation Committee recommends a support position on this bill because it intends to provide pharmacists with greater ability to manage patient's drug therapy.

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

SUPPORT: 9 OPPOSE: 0

- **SB 151 (Burton) – Triplicate Prescriptions**

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

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

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

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

SUPPORT: 9 OPPOSE: 0

- **SB 175 (Kuehl) – Veterinary Drugs**

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

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

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

SUPPORT: 9 OPPOSE: 0

- **SB 361 (Figueroa)**

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

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

- **SB 393 – (Aanestead) – Technician Checking Technician**

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

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

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

SUPPORT: 7 OPPOSE: 0 ABSTAIN: 2

- **SB 545 (Speier) – Emergency Contraception**

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

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

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

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

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

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

MOTION: Legislation and Regulation Committee: Oppose unless amended on SB 545 (Speier) – Emergency Contraception

SUPPORT: 4 OPPOSE: 5

MOTION: That the Board of Pharmacy take no position on SB 545 (Speier) – Emergency Contraception

M/S/C: ZINDER/ZIA

SUPPORT: 3 OPPOSE: 6

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

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

MOTION: Oppose SB 545 (Speier) – Emergency Contraception

M/S/C: JONES/TILLEY

SUPPORT: 6 OPPOSE: 3

- **SB 774 (Vasconcellos) – Hypodermic Needles**

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

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

MOTION: Legislation and Regulation Committee: Support SB 774 (Vasconcellos) – Hypodermic Needles

SUPPORT: 5 OPPOSE: 5

MOTION: Support SB 774 (Vasconcellos) if amended to address the disposal problems and record keeping problems.

M/S/C: FONG/JONES

SUPPORT: 8 OPPOSE: 0 ABSTAIN: 1

- **SB 490 (Alpert) – Emergency Contraception**

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

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

MOTION: Legislation and Regulation Committee: Support SB 490 (Albert) – Emergency Contraception.

M/S/C: POWERS/JONES

SUPPORT: 9 OPPOSE: 0

- **SB 506 (Sher) – Animal Drugs**

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

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

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

MOTION: Oppose SB 506 (Sher)

M/S/C: TILLEY/JONES

SUPPORT: 9 OPPOSE: 0

- **Recently Approved**

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

**Section 1720.4 – Foreign Graduates**

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

**Section 1745 – Partial Filling of Schedule II Prescriptions**

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

- **Pending Regulations**

**Section 1732.05 – Continuing Education**

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

**Section 1751 – Sterile Compounding**

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

**Section 1775 – Citation and Fine**

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

- **Awaiting Notice**

**Section 1707.5 – Hospital Central Fill**

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

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

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

**Section 1715 – Pharmacy Self Assessment**

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

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

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

**Section 1717.4 – Authentication of Electronic Prescriptions**

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

**Section 1764 – Wholesaling**

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

- **Section 1793.3 – "Clerk-Typist" Ratio**

  This regulation will eliminate the clerk/typist ratio.

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

## ORGANIZATIONAL DEVELOPMENT COMMITTEE

### Board President's Report

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

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

- **Mandatory Ethics Training for Board Members and Designated Staff must be completed in 2003**

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

- **Status of Strategic Plan Revision for 2003/04**

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

- **Public Outreach Program**

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

- **Sunset Review Process**

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

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

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

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

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

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

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

- **Findings of the Operational Audit of the Board of Pharmacy by the Department of Consumer Affairs, Internal Audits Office**

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

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

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

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

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

- **Budget Update for 2002/03 and 2003/04**

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

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

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

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

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

All training requests, contracts and purchases now undergo additional review by the department as a means to reduce expenses, and approval is significantly harder to attain.

Ms. Herold reported that on April 1, the Administration directed all agencies to identify cuts in their personnel services budgets of 10 percent for 2003/04, and to prepare a list of surplus employees to lay off. This will amount to a $353,000 reduction for the board, the elimination of all vacant positions and the elimination of overtime and board member honoraria. However, the board should not have to lay off any staff; although it will have to continue to redirect work and stop performing some functions in order to complete the most important tasks.

- **Transfer of Board's Reserve and Proposed Fee Increases**

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

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

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

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

- **2002/03 Budget Reductions**

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

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

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

- ***Budget Change Augmentations for 2002/03***

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

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

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

- ***Budget Change Augmentations for 2003/04 and 2004/05***

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

1. The board will continue to have problems with funding in its AG budget next year. The board has spent $1 million the last three years for AG services, and to reduce the budget to the amount allocated ($777,000) would result in a 25 percent reduction from prior years' spending. This year, the board withdrew some aging AG cases and reduced the number of AG cases referred as cost containment strategies required by the board's budget condition, and still the budget will be $1 million. Nevertheless, the importance of the AG services to the board's consumer protection mandate require that a BCP be prepared to augment funding to historical levels of spending.

2. Additionally, the board will need to do a job analysis in 2004 for the pharmacist exam or if NAPLEX is approved, for the CA specific portion of the exam. The costs for this will be approximately $25,000.

- **Personnel Update**

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

Lynee Ritchie resigned from her receptionist position in February.

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

- Two inspectors (one new position for compounding, the other from the promotion of Dennis Ming)
- One staff analyst (enforcement)

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

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

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

- **Future Meeting Dates**

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

  **2003 Meeting Dates: (Currently scheduled):**

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

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

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

## APPROVAL OF MINUTES

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

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

MOTION: Approve the January 22 and 23, 2003, Board Meeting Minutes.

M/S/C: JONES/ZIA

SUPPORT: 9 OPPOSE: 0

## ELECTION OF OFFICERS

**President**

MOTION: Nominate Don Gubbins for president.

M/S/C: TILLEY/no second

MOTION: Nominate John Jones for president

M/S/C: POWERS/HIURA

SUPPORT: 9 OPPOSE: 0

**Vice President**

MOTION: Nominate Don Gubbins as vice president.

M/S/C: GOLDENBERG/HIURA

SUPPORT: 9 OPPOSE: 0

**Treasurer**

MOTION: Nominate John Tilley as treasurer

M/S/C: ZIA/GOLDENBERG

SUPPORT: 9 OPPOSE: 0

## ITEMS FOR PUBLIC COMMENT

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

MOTION: Support SB 361 (Figueroa) – Extends the board's sunset date; adopts NAPLEX; revises pharmacy technician qualifications; establishes new enforcement tools; contains board – submitted technical provisions.

M/S/C: ZIA/LITSEY

SUPPORT: 7 OPPOSE: 0 ABSTAIN: 2

## ADJOURNMENT

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

## CLOSED SESSION

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

**Wednesday, April 30, 2003**

## STRATEGIC PLANNING

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

The board worked to revise its strategic plan.

## REINSTATEMENT

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