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

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

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

**DATE & TIME:** January 22 and 23, 2003

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

**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
Ron Diedrich, Deputy Attorney General
Dana Winterrowd, Department Legal Counsel

**Wednesday, January 22, 2003**

## CALL TO ORDER

President Jones called the meeting to order at 9:00 a.m. on Wednesday, January 22, 2003.

## COMMITTEE REPORTS AND ACTION

### LICENSING COMMITTEE

Chairperson David Fong reported on the Licensing Committee Meeting of December 5, 2002.

- **Approval of Two New Schools of Pharmacy – Loma Linda University and UC San Diego**

Chairperson Fong reported that the Licensing Committee acknowledged the opening of two new schools of pharmacy in California; Loma Linda University and UC San Diego. Currently, both schools are moving forward with the applications for accreditation with the ACPE; however, final accreditation is not granted until the first class graduates in 2006. According to California Code of Regulations, title 16, section 1719 (A); either the board or the ACPE must approve or accredit a school before its graduates can take the California pharmacist licensure exam.

President John Jones stated that he would be participating on the ACPE evaluation team for the initial accreditation of UC San Diego School of Pharmacy on January 28-30, 2003.

Avis Ericson, Executive Associate Dean of Loma Linda University, stated that it was her understanding that the Board of Pharmacy needs to recognize the school of pharmacy before students from the first graduating class are eligible to take the California licensure exam.

MOTION: Licensing Committee: That the Board of Pharmacy recognize the new schools of pharmacy at Loma Linda University and at the University of California San Diego pending final accreditation by the American Council of Pharmaceutical Education (ACPE) in 2006.

SUPPORT: 9 OPPOSE: 0

- **Licensure of Pharmacy Benefit Managers (PBMs)**

Chairperson Fong stated that during the December 5, 2002, meeting the committee discussed whether PBMs should be licensed, and if so, what the purpose the licensure should be. Considerations included:

1. Should PBMs be licensed under a financial regulation to prevent disruption and access to service?
2. Should PBMs be a regulation of prescription drug benefits?
3. Is formulary development professional practice?

The committee determined that if the board considered licensing PBMs, it must be consistent with the mandate to protect the public.

Chairperson Fong stated that the Board of Pharmacy has authority over pharmacists when they fail to practice safely regardless of whether they work in a PBM environment or pharmacy environment. The committee did not conclude that the Board of Pharmacy should specifically regulate and license PBMs as an entity, but should have continued discussions on this topic.

Mr. Hiura suggested that the board establish a committee to address the issue, spearheaded by the board's public members.

Mr. Goldenberg stated that the board should carefully consider this important issue because there may come a time when California consumers get their prescriptions without ever seeing a pharmacist.

Mr. Tilley stated that from his experience as a pharmacist, there is a place for PBMs. However, it is the pharmacist who must be the advocate for the patient when the patient's drug therapy has changed. Mr. Tilley added that these recurrent daily disruptions could lead to prescription errors.

Mr. Fong stated that there is considerable controversy and discussion about the role of PBMs in patient care and the board has a responsibility to monitor the impact it has.

John Cronin, representing the California Pharmacists Association, stated that although the Board of Pharmacy may not be the best entity to regulate PBMs, the board should be a driving force in any regulation passed. He suggested that the public also be involved in future discussions. Mr. Cronin recommended that the board move forward with a review of regulating PBMs with a committee of public members. He noted that the California Pharmacists Association has asked the Department of Managed Health Care to regulate PBMs.

Joseph Grasela, owner of Medical Center Pharmacies and University Compounding Pharmacy, stated that currently, there is no control over PBMs and they should be licensed. He added that under the current fee structure established by PBMs, pharmacists would not financially break even and inadequate reimbursement would force pharmacists to fill more prescriptions, causing more stress and placing the public at risk. Mr. Grasela added that PBMs expect pharmacies to dispense medication for $4 or to compound injectable medications for only $25, which is insufficient reimbursement.

David Robinson, representing Medco Health, recommended that the board invite representatives from PBMs to be included in these meetings. He discussed Georgia's efforts to regulate PBMs and stated that the regulation was probably not effective nor did it accomplish what was intended.

Steve Gray, representing Kaiser Permanente, suggested that the board plan a complete discussion and invite organizations that hire PBMs such as health plans, employers with self-managed groups, government and those who perform the functions of the PBMs independently. Mr. Gray also suggested that an invitation be extended to the Pharmaceutical Care Management Association (AMCP), as representatives of PBMs to share their knowledge.

Mr. Gray stated that 11 states considered legislation last year to regulate PBMs and after discussions decided against it because it is a complicated issue.

Patricia Harris suggested that the Medical Board also be included in discussions.

MOTION: The Board of Pharmacy create a subcommittee of the Licensing Committee comprised of three public board members and the chair of the Licensing Committee and invite comment and testimony from stakeholders and interested parties to review PBM issues and make a recommendation through the Licensing Committee to the board whether regulation or legislation is needed to protect California consumers.

M/S/C: POWERS/ZIA

SUPPORT: 9 OPPOSE: 0

- **Proposed Amendments to 16 CCR 1751 – Standards for Compounding Sterile Injectable Drug Products**

Chairperson Fong reported that at the last board meeting, the board held a regulation hearing to amend California Code of Regulations, title 16, section 1751, to establish minimum standards for pharmacies that compound medications. The proposed standards also included minimum requirements for pharmacies that compound injectable sterile drug products. Based on the comments received and testimony heard during the regulation hearing, the board deferred action on the proposed amendments pending further review and discussion by the interested parties at the Licensing Committee meeting in December. The board also voted to implement the new licensing requirements for pharmacies that compound injectable sterile drug products based on existing section 1751, pending adoption of the amended regulations. Pharmacies that compound medication after July 1, 2003, must be specially licensed by the board as compounding pharmacies.

Following this action at the October board meeting, the proposed amendments to section 1751 were redrafted during a public meeting in December.

Mr. Riches stated that the board initially took the existing regulations for sterile compounding and modified them to reflect changes relating to compounding drugs from non-sterile products, and at the same time, keep the existing rules intact. The most notable facility requirement in the proposed regulation is that this type of compounding should occur in a laminar flow hood in a clean room.

Mr. Litsey stated that during the process of developing the proposed language, a number of professional associations were represented in State and out. The goal was to develop guidelines that would protect the public while developing a workable regulation for practitioners and the board's enforcement team. Mr. Listey stated that considerable time and effort was involved in this process and he acknowledged Mr. Riches' and Mr. Ratcliff's efforts in responding to all of the comments. He also acknowledged Chairperson Fong's efforts to move this proposed regulation forward.

Mr. Riches stated that legislation requires that compounding pharmacies have a license effective July 1, 2003, and requires the license to be issued after the board finds them in compliance with board regulations relating to sterile compounding. Pharmacies located outside California shipping sterile injectable compounded medications into California must also meet these standards.

Steve Feldman, owner of California Pharmacy and Compounding Center, referred to costs he incurred to comply with the regulations such as installation of an 8 x 12 clean room at a cost of $19,000 and maintenance and cleaning service at $500 per month. Mr. Feldman stated that the least expensive barrier isolator he found was $9,500 (without outside instruction) and upwards of $25,000 (with instruction). Mr. Feldman added that these costs are considerable for pharmacies that want to compound medications.

John Cronin, representing the California Pharmacists Association, asked how the board would enforce these regulations to out-of-state pharmacies. He suggested that the board include a "frequently asked questions" section within the regulatory package. Mr. Cronin added that many pharmacies are interested in this regulation and want to know exactly what the requirements are. He commended the board for its work to improve the process to develop the regulation.

Mr. Gray referred to a letter from Michael A. Pastrick (dated January 22, 2003) regarding the proposed revisions to section 1751.

Mr. Gray reported that Mr. Pastrick is a former president of CPhA, a hospital pharmacist and the Mayor of the City of Concord.

Mr. Gray referred to the concept of partial sampling of products and Mr. Pastrick's recommendation that testing on sampling be required for Category III drugs and not a major requirement for Categories I and II because it gives a false sense of safety when the product is released before the sample is returned from testing. He added that it is better to place the emphasis on the process validation.

Mr. Gray stated that Kaiser Permanente supports the amendments submitted by Mr. Pastrick.

Teri Miller, representing the California Society of Hospital Pharmacists (CSHP), commended Paul Riches and the board on their efforts to develop a workable practical framework for protecting consumers.

Ms. Miller referred to the technical modifications submitted by the CSHP. Ms. Miller stated that the USP is in the process of rewriting its guidelines for compounding sterile products and discussion included reclassifying that chapter within the USP so that it would have the force of federal law. Ms. Miller added that the ASHP is waiting to revise its guidelines pending the USP decision. Ms. Miller stated that the CSHP supports moving forward with the board's regulation as written with minor modifications.

Bill Blair, Pharmacy Director representing McGuff Compounding Pharmacy, commended the board's efforts on the proposed regulations but he referred to a problem with the record-keeping requirements. He provided proposed changes to the existing requirements in board regulations.

Mike Cook, representing Central Admixture Pharmacy Services, thanked the board for the opportunity to participate in the December meeting. Mr. Cook stated that he supports the draft regulation submitted by Bill Blair that addresses the record-keeping requirement. Mr. Cook added that the requirement creates a hardship in obtaining all of the records because the majority of their patients are already in a hospital institution.

Mr. Grasela, University Compounding Pharmacy, stated that the record-keeping requirement will be difficult to comply with and may have been designed for in-home care or hospitals, but does not appear to be practical for the type of medications he uses.

Steve Feldman stated that the language should be revised to allow more flexibility for those practicing to collect the data that is truly essential in providing the right medication to patients.

Hank Rohe, Containment Technologies Group, congratulated the board on the proposed regulations. Mr. Rohe asked the board to consider equipment issues, specifically, that equipment must be verified that it meets loads. Mr. Rohe referred to the incident with Doc's Pharmacy and stated that it was the operation of the autoclave that caused problems.

MOTION: Licensing Committee: The Board of Pharmacy notice a new regulation hearing with proposed amendments to California Code of Regulations (CCR), title 16, section 1751 standards for compounding sterile injectable drug products.

SUPPORT: 9 OPPOSE: 0

**Notification from National Association of Boards of Pharmacy Regarding Security Breach and Halt of the Administration of the Foreign Pharmacy Graduate Equivalency Examination (FPGEE)**

Chairperson Fong stated that Business and Professions Code section 4200(a)(2)(B) requires an applicant who graduates from a foreign pharmacy school to receive a grade satisfactory to the board on an examination designed to measure the equivalency of foreign pharmacy education with that of domestic graduates.

To meet this requirement, the board relies on the Foreign Pharmacists Graduate Equivalency Exam (FPGEE) developed and administered by the National Association of Boards of Pharmacy (NABP).

Chairperson Fong reported that on November 18, 2002, the NABP issued notification that it halted the examination due to a security breach. Further, NABP advised that it had taken steps to ensure the integrity of the examination: scores affected by the breach will be invalidated and those applicants must retake the examination. If certificates have been awarded to candidates who passed the exam affected by the compromise, these certificates will be invalidated and the applicants must retake the examination. Further, all FPGEE examinations have been cancelled until a new examination can be developed, likely by June 2003.

This action by NABP will affect applicants from foreign pharmacy schools that apply to be licensed in California. A review of board records indicate that there are over 100 foreign graduates who are waiting for their intern permits that could be affected and at least one candidate who cannot take the board licensure examination until the NABP completes its investigation.

- **Competency Committee Report on the January 2003 Pharmacist Licensure Examination**

Ms. Herold reported that on January 14 and 15, 2003; the board administered its January 2003 pharmacist licensure examination at the Hyatt Regency San Francisco Airport Hotel. She reported that the board had 674 candidates complete the exam.

Ms. Herold stated that the board would need board members to assist with grading on February 19, 2003, in Sacramento.

Ms. Herold stated that on June 17 and 18, 2003, the board will administer its June 2003 pharmacist licensure examination at the San Jose Convention and Cultural Facilities Center.

**ENFORCEMENT COMMITTEE**

- **Proposed Revisions to the Citation and fine Process – Delegation to the Executive Officer to Issue Citations**

  Chairperson Goldenberg reported that during the Joint Legislative Sunset Review Committee hearing in November, Committee Chair Senator Liz Figueroa requested that the Board of Pharmacy evaluate its current citation and fine process and consider delegating the authority to issue citations and fines to the executive officer. The reason for this request is that all other DCA agencies delegate their authority to the executive officer, it would remove board members from the investigation process, it would improve the overall timeliness of issuing a citation and it would reduce costs.

  In both oral and written comment, the Center for Public Interest Law (CPIL) supported the request from the Joint Legislative Sunset Review Committee. While CPIL commented that the board's process has improved tremendously over the years, it still departs substantially from (1) the way almost every other DCA board has implemented the cite and fine statute, (2) the intent of the citation and fine statute (which was to provide an alternative to long, drawn-out disciplinary proceeding which must be reviewed by board members) and (3) the existing Administrative Procedure Act (which requires board members to review a proposed ALJ decision based upon the evidence presented in that proceeding, and in that proceeding alone). They also commented that the board's process is lengthy, overly complex, and is not required under current law.

  It was noted that it takes 82 days from the date a case is reviewed by the executive officer to the issuance of a citation. (It took the Compliance Committees 210 days.) The cost for the current process is $164,000 (almost double the cost for the Compliance Committees). The Enforcement Committee also projects the issuance of 1,200 citations (a 500 percent increase from the number of citations issued the previous year).

  It was also encouraged that the board continue the informal appeal process whereby the licensee can contest the citation and fine to the executive officer.

  President Jones stated that this was a recommendation of the Sunset Review process.

  President Jones stated that the Enforcement Committee would continue to review enforcement statistics regarding the inspector's activity and the disposition of the cases. In addition, the committee would review staff activity regarding cite and fine action.

President Jones added that this action would considerably improve overall efficiencies and ultimately benefit consumers. This is the same process used by other boards within the department.

Mr. Fong expressed concern regarding the number of cases the board handles and the additional workload placed on the executive officer. Mr. Fong requested guidelines to objectively review the board's workload.

President Jones stated that the executive staff is under financial pressure and faced with increased workload due to the current budget crises and the difficulty in filling vacant positions within the board.

Ms. Harris stated that in working closely with the supervising inspectors during the last 6-8 months, the tremendous workload they are under is evident. However, the board is in the process of hiring two additional supervising inspectors to assist with this review process.

Collette Galvez representing the CPIL thanked the board for considering these options and for working to improve the cite and fine and enforcement processes during the last year. She added that this would serve the board to manage its workload and achieve its objectives. She agreed that it is important to consider what other boards are doing and to use this information as a model for improvement.

Mr. Powers thanked Ms. Galvez for the letter dated December 9, 2002, submitted on behalf of the Center for Public Interest Law.

Chairperson Goldenberg stated that the executive officer as well as staff has demonstrated a passion for the profession of pharmacy equal to any pharmacy member that he has known. Mr. Goldenberg added that consistency and fairness that the board continues to strive for will not be compromised by this change and removing a board member from the active process does not remove the board from overseeing the process.

Mr. Gubbins expressed confidence in the executive officer's and staff's ability to handle these matters and added that the enforcement committee would continue its review in this process.

Mr. Tilley recommended that the board first take action on the committee's recommendation to sponsor legislation to add additional enforcement options.

- **Proposed Legislative Changes – Add sections 4083 (Order of Correction), 4315 (Letter of Admonishment) and 4314 (Order of Abatement)**

Chairperson Goldenberg stated that at the September Enforcement Committee meeting, the citation processes used by the Ohio and Pennsylvania Boards of Pharmacy were put

forward as models for California to consider. As described to the committee, it appears that in both states, it is the inspector (or similar type of personnel) who determines that a violation of law did occur. A notice of that violation is then issued and the licensee must respond within a specified time as to what actions he or she has taken to correct the violation or to prevent future incidents from occurring. If the licensee does not correct the violation or there are repeat violations, then he or she may be subject to a fine or other board action.

Based on this suggestion, the Enforcement Committee requested that language be drafted to model the Ohio and Pennsylvania programs. These models would provide the board with additional tools to address non-compliance issues at the administrative level. The language was provided at the October board meeting and discussed during the December Enforcement Committee meeting. The proposed language was modified to be consistent with the recommendation that the executive officer issue citations and fines, and consider an informal appeal be delegated to the executive officer or designee.

- **Add Section 4083 – Order of Correction**
  This provision would allow an inspector to issue an order of correction to a licensee, directing the licensee to comply with Pharmacy Law within 30 days, would allow the licensee to contest the order of correction to the executive officer for an office conference, would provide for judicial review and would not be considered a public record for purposes of disclosure
- **Add Section 4315 – Letter of Admonishment**
  This provision would authorize the executive officer to issue a letter of admonishment to a licensee for failure to comply with Pharmacy law, would allow a licensee to contest the letter of admonishment to the executive officer or designee, would provide for judicial review and would be considered a public record for purposes of disclosure.
- **Add Section 4314 – Issuance of Citations**
  This provision would allow the board to issue an order of abatement that would require a person or entity to whom a citation has been issued to demonstrate how future compliance with the Pharmacy Law will be accomplished and provides that such demonstration may include, but not be limited to, submission of a corrective action plan, as well as requiring the completion of up to six hours of continuing education courses in subject matter specified in the order of abatement.

Chairperson Goldenberg stated that overall there was general support for these legislative proposals. In the original proposals, the primary concern from the Center for Public Interest Law (CPIL) was that board members would be involved in the process. This concern was considered and the language was modified accordingly. Also, the CPIL's position that the proposals may not be necessary. They contend that the current order of abatement can be drafted to require that the licensee abate the unlawful condition and demonstrate to the board how it plans to prevent such violation from recurring in the future. While this is correct, proposed section 4314 would give the board the authority to

direct the licensee on how to abate the unlawful condition and be in compliance, such as taking a continuing education course.

Mr. Fong stated that this is an efficient process that is working well in Ohio.

Herbert Weinberg, pharmacist and attorney, stated that occasionally a letter of reprimand or public reproval is accepted as a disciplinary matter and it becomes a form of discipline. He asked the board if a letter of admonishment would be considered a form of discipline when a licensee submits an application for a pharmacy permit and must answer the question asking if the person was disciplined.

Mr. Diedrich responded that it was not intended for a letter of admonishment to replace or be equal to a letter of reprimand and it is not considered a disciplinary action. Mr. Diedrich added that a letter of admonishment is intended as a lesser directive to the licensee to fix a problem without the negative impact of a disciplinary action or citation. He explained that this would not be a formal disciplinary action but it would still protect the public in minor matters and fulfill the board's obligation to enforce board regulations.

Mr. Cronin stated that the California Pharmacist Association would support this approach. He added that licensees should have a clear understanding of the process however.

Steve Gray representing Kaiser Permanente, suggested that the board issue a statement explaining that a letter of admonishment, an order of correction or a citation is not considered a formal discipline. He added that in addition to affecting responses on the board's applications, the matter of discipline also effects Medi-Cal provider applications and DEA registration. Mr. Gray added that for those who handle 100 pharmacies to know if any single pharmacy was disciplined in the past creates a huge administrative burden to report. He added that this would be relevant on an individual's application but not an organization that manages many pharmacies.

Collette Galvez representing the Center for Public Interest Law asked for clarification on the hierarchy of options available to inspectors and asked if inspectors have to issue an order of correction before they can order a letter of admonishment.

Mr. Diedrich stated that all cases should be evaluated on a case-by-case basis and the hierarchy would be determined by the priorities of the board and the Enforcement Committee.

Mr. Powers stated that it appears that the board is sending mixed messages to inspectors by trying to protect consumers on one hand and trying not to overburden pharmacists or their companies on the other hand.

Ms. Harris clarified that there is really no change from the procedure that occurs now. She added that during an inspection, inspectors are likely to find violations in a pharmacy if they look hard enough. She added that this procedure is in place now but it is not referred to as an order of correction.

MOTION: Enforcement Committee: The Board of Pharmacy sponsor legislation to add Business and Profession Code sections 4083 (Order of Correction), 4315 (Letter of Admonishment) and 4314 (Order of Abatement).

SUPPORT: 9 OPPOSE: 0

- **Proposed Revisions to the Citation and Fine Process – Delegation to the Executive Offer to Issue Citations**

This change will require regulatory notice to amend the board regulations. The board next resumed action on other Enforcement Committee recommendations.

MOTION: Enforcement Committee: The Board of Pharmacy revise its citation and fine process to delegate to the executive officer or designee the authority to issue a citation and fine.

SUPPORT: 9 OPPOSE: 0

- **Recommendation to Support the Requirement that Inspectors be Pharmacists**

Chairperson Goldenberg stated that the Joint Legislative Sunset Review Committee also requested that the Board of Pharmacy consider the current requirement that inspectors of the Board of Pharmacy be pharmacists.

During the board's last Sunset Review in 1996, the Legislative Analyst's Office recommended the elimination of the statutory requirement that board inspectors be licensed pharmacists, and instead use industry experts (pharmacist consultants) if the need arises for technical expertise. The recommendation was due in part to the board's difficulty in recruiting quality pharmacists for the board's inspector positions because of the low salary established for this classification at the state level.

The Legislative Analyst's Office stated that the board should have the option to hire pharmacist inspectors or other state investigators. Mandating that all inspectors be licensed pharmacists is unique to the board. Other boards do not require that only licensed professionals perform investigation or inspection of suspected violations of their respective licensing acts. Most will use expert professional witnesses as needed.

Subsequently, legislation (SB 827, Chapter 759, Statutes of 1997) was enacted which allowed non-pharmacist inspectors to inspect or investigate non-pharmacy licensees. The earlier version of the bill was somewhat broader and closer to what the Legislative Analyst's Office recommended, but opposition from the board and various other sources opposed those provisions and they were amended into the existing language.

The Center for Public Interest Law (CPIL) believes that the Board of Pharmacy should be open to hiring a mix of pharmacists and non-pharmacist inspectors to investigate complaints against all of its licensees. They argue that it is not necessary for an inspector to be a pharmacist to understand the elements of many violations committed by pharmacists and pharmacies. Opening all of the board's inspector positions to non-pharmacists would widen the pool of individuals eligible to apply, reduce the board's difficulties in hiring quality inspector staff, and better protect the public. Further, it is CPIL's view, that the board should increase all its license renewal fees to their statutory maximum, triple the number of investigators, hire qualified inspectors who are both pharmacists and non-pharmacists, authorize all of them to investigate complaints against any licensee, and authorize them to cite and fine on the spot for any violation that they observe.

There was general support that the board retain its staff of pharmacist-inspectors. Many law enforcement and regulatory agencies look to the board's inspectors for assistance in cases that involve prescription drugs. Moreover, one of the roles of inspectors is to educate licensees on quality of care issues that they observe during an inspection, and this important "peer review" and education cannot be done if the inspector is not a pharmacist. However, there are areas of pharmacy practice that do not require the expertise of a pharmacist, such as checking for out-dated drug stock on the prescription shelf, observing if patient consultation is being performed, and review of quality assurance documents.

Currently the board uses complaint analysts to investigate consumer complaints and other cases that do not require an inspection. All investigations that are performed by the analysts are reviewed and approved by a supervising inspector. It appears that the law does not preclude the board from using other civil service classifications to assist inspectors; however, the law may need to be clarified. Moreover, the law allows the board to use non-pharmacist inspectors to investigate and inspect other board licensees that are not pharmacists or pharmacies.

MOTION: Enforcement Committee: The Board of Pharmacy retain its pharmacist inspectors because they are vital to executing the board's public protection mandate but the board should also have the authority and flexibility to use other civil service classifications to investigate and inspect pharmacies in those situations that do not warrant the expertise of a pharmacist, such as assisting inspectors in complex investigations or performing drug audits.

SUPPORT: 9 OPPOSE: 0

- **Proposal to Grant 6 hours of Continuing Education to Pharmacists that Attend Board Meetings**

  At the October meeting, the Board of Pharmacy approved the Enforcement Committee's recommendation that continuing education be awarded to pharmacists who attend board meetings. However, the parameters of this action were not decided. The board agreed that the goal is to involve more pharmacists in the board processes and to improve a pharmacist's understanding of the board's responsibilities and mandates.

  The goal is to encourage more pharmacist participation at board meetings. The committee concluded that pharmacists who attend the primary business day of a board meeting should be granted 6 hours of CE credit.

  Mr. Fong clarified that the maximum amount of CE credit granted for attending board meetings is recommended at 6 hours per year.

  The board considered fiscal impact, the impact on record-keeping and limiting CE credit to 6 hours per year. The goal is to streamline the process so it does not become labor-intensive to administer.

  Steve Feldman supported this recommendation and stated because there are a lot of CE hours offered for many non-pharmacy courses; it is valuable for a pharmacist to periodically attend board meetings.

  Ms. Harris stated that pharmacists can be informed of this change through the board's website and information about it can be published in the board's newsletter.

  MOTION: The Board of Pharmacy grant 6 hours per year of continuing education to pharmacists attending the business day portion of a board meeting, the board will approve this as CE (not using ACPE) and board members will not be eligible for credit.

  M/S/C: GOLDENBERG/TILLEY

  SUPPORT: 8 OPPOSE: 0 ABSTAIN: 1

- **Proposed Adoption of 16 CCR 1784 and 1785 – Wholesale Drug Transactions and Statement of Prior Sales – Presentation of 60 Minutes Video on Counterfeit Drugs**

Chairperson Goldenberg stated that the Enforcement Committee requested comments on proposed new regulations California Code of Regulations, title 6, sections 1784 and 1785. Concerns were expressed at prior meetings regarding the proposed language. Based on some of the concerns, the language was modified by the Enforcement Committee.

Chairperson Goldenberg stated that the proposed amendments will help the Enforcement Team and inspectors track the movement of drugs, especially those drugs that move from a pharmacy back to another avenue (wholesaler, pharmacies etc.).

The board watched a video taped segment produced by CBS for its 60 Minutes program on counterfeit drugs. The investigation found that prescription drugs make many stops from the manufacturer to nationwide distributors to pharmaceutical wholesalers, making as many as 10 stops along the way. The price charged for these drugs depends on the buyer, where the buyer is located and how much the buyer is buying. Further, this process is unregulated and almost impossible to trace the path that a particular drug takes. The report found that this could and has lead to counterfeit and tampered drugs being sold by pharmacies to patients, with serious patient harm resulting. The board expressed extreme concern over this patient harm.

In reviewing the committee's proposed language, Mr. Weinberger stated that the regulations are covered by the 1987 PDMA and reporting paper trails are mandated by that act.

Mr. Fong referred to subsection (b) where the wholesaler cannot pay more to the pharmacy, either in cash or credit, than the pharmacy originally paid to the wholesaler for the dangerous drugs. He expressed concern that when credit for returned drugs is given, the wholesaler will pay the most current amount. This proposed regulation would significantly change the way business is conducted with wholesalers and will have a financial implication.

The board determined that more time is needed to review the regulation before moving forward.

MOTION: Table the proposed adoption of 16 CCR 1784 and 1785 – Wholesale Drug Transactions and Statement of Prior Sales until the Enforcement Committee has had time to address this further at the March 5, 2003, Enforcement Committee Meeting

M/S/C: POWERS/GOLDENBERG

SUPPORT: 9 OPPOSE: 0

- **Implementation of the Federal HIPAA Requirements**

Chairperson Goldenberg stated that the Enforcement Committee discussed the new HIPAA requirements that take effect on April 14, 2003. Implementation issues were discussed. One issue is that pharmacies must account for disclosures of protected health information made to pharmacy board inspectors; however, licensees stated that they are unclear as to the threshold of when such a release must be documented. Inspectors may skim through hundreds of hard copy records and/or computerized files in one inspection. The time it would take to document each viewing will add a significant amount of time to the inspection process, increasing the burden and impeding the ability of boards to perform a thorough inspection and on the pharmacy that must track the disclosure.

The National Association of Boards of Pharmacy has written 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.

Also, the NABP requested clarification on prescription monitoring programs, which requires pharmacies to report to a designated state agency the filling of certain controlled substances. The documentation of such reporting does not enhance patient confidentiality provisions, but could hamper investigatory operations to curb or stop drug diversion. Again, the required accounting documentation would adversely affect patient care as pharmacies would have to divert time aware from patient care activities to comply with record keeping requirements.

Clarification on these issues will be sought from the Health and Human Services Agency, California Office of HIPAA Implementation.

Another area of concern is that protected health information is restricted to research and education purposes. It was noted that schools of pharmacy have students review records without signed authorization from each patient and the information is not being used in the manner as allowed by the federal law.

Comments were made that pharmacies are changing many of their operating procedures because of the new HIPAA requirements. Because of this, the board may be inundated with complaints from consumers. It was suggested that the board might want to gear up for this onslaught of complaints and inquiries.

President Jones stated that he participated on the interview committee on HIPAA and the board needs to be ready to talk to consumers.

MOTION: Enforcement Committee: The Board of Pharmacy continues the discussion on the implementation of the Federal Health Insurance Portability and Accountability Act.

SUPPORT: 9 OPPOSE: 0

**LEGISLATION AND REGULATION COMMITTEE**

- **Adoption of Amendment 10 16 CCR 1732.2(b) – Coursework from Non-Accredited Providers**

Chairperson Litsey reported that this regulation would allow the board to accept continuing education coursework approved by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California, upon completion of the coursework by the pharmacist. This amendment would eliminate the required written petition to the Board of Pharmacy for such coursework, and the resultant fee.

Chairperson Litsey stated that the notice of proposed action was published on November 1, 2002. The 45-day comment period closed December 16, 2002.

Chairperson Litsey stated that the board received two comments during the 45-day written comment period:

- In an email dated November 27, 2002, John Sie, Pharm.D., offered support for the board's proposal. Dr. Sie stated that working in a group of Ambulatory Care pharmacists, he assists cardiologists in managing patients' drug therapy. In order to provide such assistance, he must attend CME programs that are not given ACPE credit. In addition, he has to attend ACPE accredited programs to satisfy his continuing education requirements for the Board. Dr. Sie stated that attending disease specific symposiums or CME programs allow for better thinking processes and clinical decisions for him as a pharmacist.

- In an email dated December 5, 2002, Sharon D. Ow-Wing, Pharm.D., offered support for the board's proposal. Dr. Ow-Wing stated it would be helpful to claim hours spent at education courses provided by UCSF School of Medicine without the $40 per unit expense. Dr. Ow-Wing fully supports pharmacists obtaining continuing education in specialty areas of interest.

Mr. Fong stated that pharmacists should be limited to the number of continuing education coursework received outside of the area of pharmacy.

President Jones stated that the board does not currently direct that a specific amount of hours of CE be obtained in a certain area and he questioned whether the board should place limits on CE when a pharmacist may benefit from specialized CE.

Steve Gray representing Kaiser Permanente requested that the board not place limits on CE at this time but consider it at a future date if needed.

President Jones stated that reviewing continuing education coursework would be a discretionary measure for staff to determine if the CE was suitable in a particular case.

Ms. Herold suggested that the board might want to consider waiting for a year or two after the regulation becomes effective to see the effect it has made on the submission of non-board –approved CE

MOTION: Legislation and Regulation Committee: The Board of Pharmacy adopt the proposed regulation to add section 1732.2 Coursework from non-recognized providers.

SUPPORT: 9 OPPOSE: 0

- **Proposal to Sponsor Amendments to Section 4312 and 4403 in the Annual Omnibus Bill**

Chairperson Litsey stated that two technical changes to existing pharmacy law have been identified for possible inclusion in the annual omnibus bill. The first, in amendments proposed for section 4312 would replace "void" with "cancel" to make the usage consistent with other aspects of pharmacy law and delete a reference to "medical device retailers" which are no longer regulated by the board. The second, in section 4403 would add "reissue" with "renew" to make the usage consistent with other aspects of pharmacy law.

MOTION: Legislation and Regulation Committee: Sponsor amendments to section 4312 and 4403 in the annual omnibus bill.

SUPPORT: 9 OPPOSE: 0

- **Proposal to Sponsor Legislation to Update the Qualifications for Licensure as a Pharmacy Technician**

Chairperson Litsey stated that this proposal came from the Licensing Committee to update the qualifications for issuing a pharmacy technician license. The proposal would eliminate the qualifying experience option for obtaining a pharmacy technician license and would restrict the associate of arts (AA) degree qualification option to those who obtain an AA degree in pharmacy technology. Pharmacy technicians who are currently licensed by the board based on existing qualifications would not be affected by this proposal; the revisions

would only affect those seeking licensure after January 1, 2004. The proposal would also add certification by the Pharmacy Technician Certification Board (PTCB) as a qualification option.

Chairperson Litsey stated that existing law for qualifying as a pharmacy technician has not been updated since the advent of pharmacy technicians in the early 1990s. Since that time, community colleges and other institutions have developed courses of study specifically for pharmacy technicians and the PTCB has been created and adopted in a number of states as a pharmacy technician qualifier (most notably Texas requires all pharmacy technicians to be PTCB certified). The proposed changes reflect developments in this area in recent years and would also have the effect of streamlining pharmacy technician application processing by the board. The qualification of an AA in a related field or the prior experience as a clerk/typist qualification both require additional evaluation of the application to ensure the adequacy of the degree program or prior experience.

Steve Gray, representing Kaiser Permanente, asked what effect this would have on private programs other than community college programs.

Mr. Riches responded that private programs will not be affected – their application will qualify under subsection (2) – Has completed a course of training specified by the board.

Gail Askew, representing Santa Ana College, expressed concern about having PTCB as the sole qualifier. She referred to a situation in Texas where training sessions were set up specifically to learn how to pass the PTCB without having a pharmacy background or education. She stated that review books can be purchased that offer candidates a good chance of passing the PTCB. She questioned whether someone could safely practice as a pharmacy technician in California under these circumstances.

Teri Miller representing CSHP stated that the PTCB as a sole qualifier may not be the best approach, but the CSHP would work with the board to help refine this issue.

Mr. Goldenberg stated that if the bar were raised on licensing technicians, it would help to eliminate some of the enforcement problems that occur.

President Jones clarified that this committee recommendation does not specify the ways the board would update the qualifications for licensure as a pharmacy technician, only that it will sponsor legislation to update the qualifications.

MOTION: Legislation and Regulation Committee: Sponsor legislation to update the qualifications for licensure as a pharmacy technician.

SUPPORT: 7 OPPOSE: 1 ABSTAIN: 1

- **Encourage Stakeholders to Introduce Legislation in Cooperation with the Board to Permit Flexibility in the Supervision of Ancillary Personnel in a Pharmacy**

  Chairperson Litsey stated that at the October 2002 meeting, the board indicated its support for legislation to create flexibility in pharmacy staff ratios. The board supported a draft proposal permitting a pharmacist to supervise no more than four ancillary personnel (defined as pharmacy technicians, pharmacy technician trainees, or pharmacy interns) at any one time. The proposal permits only one pharmacy technician trainee to be on duty at any one time. The proposal also permits a pharmacist to decline to supervise additional staff if in the pharmacist's professional judgment, staff would interfere with their professional responsibilities.

  MOTION: Legislation and Regulation Committee: Encourage stakeholders to introduce legislation in cooperation with the board to permit flexibility in the supervision of ancillary personnel in a pharmacy.

  SUPPORT: 9 OPPOSE: 0

- **Consideration to Sponsor Legislation Permitting the Board to Waive Statutes and Regulations to Protect the Public Health in Response to a Declared Emergency**

  Chairperson Litsey stated that this proposal was developed in response to recent concerns regarding emergency preparedness and terrorism responses. In such circumstances, existing legal requirements could interfere with efficient and effective responses to natural disasters or the release of biological and or chemical weapons. Specific questions have been raised regarding the use of pharmacy students and pharmacy technicians to repackage drugs released from the National Pharmaceutical Stockpile and the mechanism for dispensing those drugs to thousands of affected people.

  Specifically, the proposal permits individual pharmacists to deviate from the Pharmacy Law if, in their professional judgment, it is needed to protect the public health or assure good patient care. Such deviations must be documented at the earliest possible time and retained in the pharmacy for three years. This authority could only be used during a declared emergency. In addition, the proposal would grant the Board of Pharmacy authority to waive specific statutory and/or regulatory requirements during a declared emergency to protect the public health or assure good patient care.

  Steve Gray, representing Kaiser Permanente, stated the board's intent is unclear regarding deviations that must be documented at the earliest possible time and retained in the pharmacy for three years. He added that during a declared emergency, pharmacists often are involved with dispensing drugs, especially from the National Stockpile, and may be working from a school gymnasium, removed from a licensed pharmacy and he questioned whether this would allow a broad enough authority to work outside of a pharmacy during an emergency. He suggested that staff contact David Breslow, Senior Vice President of the

California Pharmacists Association, who has become an expert in this area who works with various state and local agencies on disaster and public planning involving pharmacists.

MOTION: Legislation and Regulation Committee: The board sponsor legislation permitting the board to waive statutes and regulations to protect the public health in response to a declared emergency.

SUPPORT: 9 OPPOSE: 0

- **Future Legislation and Regulation Committee Meeting**

Chairperson Litsey announced that the next Legislation and Regulation Committee meeting will be a public meeting on March 27, 2003, at 10 a.m. in the board's office in Sacramento. At that time, the board should have knowledge of all introduced 2003 legislation and will seek public input for presentation at the April Board Meeting. He encouraged the public to attend.

**COMMUNICATION AND PUBLIC EDUCATION COMMITTEE**

Chairperson Powers updated the board on the committee's meeting on January 9, 2003.

- ***The Script***

Chairperson Powers stated that the board contracted with Hope Tamraz to produce two issues of *The Script* annually. The next issue has been written and is undergoing review by the Legal Office. This issue should be mailed in February 2003 to all pharmacies. To reduce printing and postage costs, other licensees will be encouraged to download the newsletter from the board's Web site.

Additionally, the Educational Foundation of the CPhA may be able to mail the newsletter to California pharmacists.

- ***Health Notes***

Chairperson Powers stated that also nearing completion is the "Geriatrics" issue of *Health Notes*. This issue was developed with UCSF. Since the last board meeting, all articles have been edited and approved for publication. Currently the graphic designer is working on the layout. UCSF received outside funding to develop this issue, and CSHP has obtained a grant to assist with printing. The board will pay for postage.

- **"Notice to Consumers" Poster Update**

Chairperson Powers stated that the board has obtained translations of the new "Notice to Consumers" poster into five languages -- Spanish, Vietnamese, Chinese, Korean and Russian. Each translation has been converted into an 8.5 x 11 inch sized poster that looks like a small version of the English poster. The translated posters are available for downloading from the board's Web site and from the board.

Chairperson Powers expressed concern about the location of the "Notice to Consumers" poster in pharmacies and he suggested that the board recommend where these posters should be placed in the pharmacy so consumers have the full benefit of this information prior to filling their prescriptions.

- **"Hot Topics in Pharmacy"**

  Chairperson Powers stated that the board-sponsored series "Hot Topics in Pharmacy" began with its first seminar on "Antibiotic Use and the Risk of Bacterial Infection" on October 18 in the State Capitol. The board is cosponsoring this series with the UCSF's Center for Consumer Self Care and the Department of Consumer Affairs.

  The second seminar was held January 17 on "Consumers and the Dietary Supplement Marketplace." And the third seminar is set for February 21 on "What Everyone Needs to Know about Managing Pain Effectively."

- **Outreach Efforts to Increase Board Attendance at Consumer Information Forums and Fairs**

  Chairperson Powers stated that the committee wants to encourage and increase board attendance at consumer information forums and fairs to provide publications and information about the board. Recent activities on outreach are listed in the committee's status report, and include:

  - President Jones presented a seminar on quality assurance at the NABP Executive Officers Biennial Meeting.
  - Board Member Goldenberg met with long-term care pharmacy providers.

  Chairperson Powers stated that future plans include:

  - A continuing education program at CPhA's annual meeting and education forum.
  - Information to pharmacists-in-charge of the California State University System.
  - Consumer information to those attending a consumer education forum sponsored by the Department of Consumer Affairs at California State University Sacramento in February.

Mr. Zia announced that he was invited to participate in a discussion at Hope Hospital at 2107 N. Broadway, Santa Ana, CA. He added that he and Dr. Perry would be hosting a discussion on January 30, 2003, about purchasing drugs from other countries, buying drugs online and legality issues.

Gail Askew, representing Santa Ana College, expressed concern that pharmacists not working in pharmacies would not get the information published from *The Script* unless they routinely checked the board's website. She requested that the board notify pharmacists that the newsletter is available online. Ms. Harris stated that there is such an article in the newsletter.

Teri Miller representing the California Society of Hospital Pharmacists (CSHP) stated that when the *The Script* is available, CSHP would make an announcement in CSHP's weekly informational e-mail to their members with a link to the board's website.

Mr. Litsey asked staff to continue to keep board members informed of future public events

**INFORMATIONAL HEARING ON HOW TO EDUCATE THE PUBLIC ABOUT BUYING DRUGS FROM OTHER COUNTRIES AND BUYING DRUGS ONLINE**

President Jones stated that the board is interested in developing much-needed consumer information about purchasing drugs from foreign counties as a means to reduce drug costs. This is an emerging area of major consumer and media interest.

President Jones stated that there was a discussion during the second day of the October Board Meeting when public attendance was low. To provide a greater opportunity for public comment, the committee is holding an informational hearing at this meeting.

President Jones stated that a major concern for those who purchase prescription medications is the high cost. He added that often it is a difficult decision between food and housing expenses and the purchase of medication.

Patients hoping to reduce their drug costs are purchasing medications from outside the U.S., typically from Canada where the costs are less. Whereas such drug purchases are illegal, the FDA is not enforcing restrictions against patients who obtain a 90-day supply for personal use.

There is some indication that some drugs purchased from such sources are occasionally not what they are labeled to be. But these reports are rare and some states are encouraging their citizens to purchase drugs from Canada. In October a large prescription benefit company agreed to reimburse patients for drugs obtained from

Canada or other foreign countries. Recently other companies have agreed to reimburse patients for drugs purchased in Mexico.

Chairperson Powers stated that the committee envisions a fact sheet that provides the pros and cons of such purchasing.

Another comment was made that Congress should pass a meaningful drug benefit for Medicare because over 50 percent of those 65 and older do not have a benefit for prescription drugs and if they do have a benefit, it is insufficient. Also, seniors should be encouraged to use generic brand medications.

President Jones stated that the board plans to have discussions with wholesalers to determine how they are responding to concerns about counterfeit drugs and what they are doing to ensure product safety.

Mr. Fong suggested that the board make public service announcements to educate consumers.

Mr. Hiura stated that patients want drugs at the lowest price. Many solutions to getting patients lower priced drugs are beyond the control of the board.

Former Board Member Bob Elsner recommended that the board focus on education. He added that the board has to consider the efficacy of the drugs and warn consumers that if they purchase drugs on-line or out of the country, they may be purchasing outdated, ineffective medicine.

President Jones also stated that consumers should be warned that if they take drugs purchased on line or out of the country they risk complications from other drugs they may be taking or from existing physical conditions they may have. Consumers would not be under the care of a health care professional under these circumstances.

Mr. Gray stated that seniors and the public should approach the FDA to adopt regulations and issue special licenses to allow the public to take advantage of the global market and avoid driving health care out of the country.

## COMMITTEE REPORTS AND ACTION

### Organizational Development Committee

### President's Report - Sunset Review Process

President Jones reported that the Department of Consumer Affairs held two public hearings on the regulatory programs scheduled for Sunset Review before the Joint Legislative Review Committee (JLSRC) this year. The purpose of the hearings was to provide comments to the department to assist it in preparation of recommendations to the JLSRC. Members of the public

were encouraged to attend. The first hearing was October 29, 2002, in Sacramento and the second one was November 6th, in Los Angeles.

President Jones reported that on November 4, 2002, he and Vice-President Don Gubbins, and Executive Officer Patricia Harris met with the Department of Consumer Affairs. Representatives from the department were: Kathleen Hamilton – Director, Lynn Morris – Deputy Director, Board Relations, Kristy Wiese – Deputy Director, Legislative & Regulatory Review Division, and Terri Ciau – Manager, E-Government and Special Programs Division. This meeting provided the board with the opportunity to advise the department of the board's significant accomplishments, to address issues that were presented during the public hearings and to respond to any departmental concerns.

On November 5, the JLSRC released 31 questions and issues for the Board of Pharmacy. The committee identified these issues for the board's response during its hearing on November 19, 2002. At the hearing, President Jones presented an overview of the board and its significant accomplishments. Committee Chair Senator Figueroa asked President Jones to respond to about 15 of the 31 issues. During the hearing, Senator Figueroa requested that the board discuss the following issues: changes to the citation and fine process, the requirement that board inspectors be pharmacists, the addition of two public board members, the definition of "actively engaged in the practice of pharmacy" as a requisite for pharmacists appointed to the board, and making all committee meetings public. Upon conclusion of the board's testimony, other interested parties were invited to testify and submit written comments.

President Jones stated that during the next two months the JLSRC and the Department of Consumer Affairs would be preparing their recommendations. The department's recommendations will be presented at a public hearing sometime at the end of March. Then in early April, the JLSRC will issue recommendations at a subsequent hearing.

- **Report on the Meeting of January 9, 2003**

  Chairperson Gubbins stated that the Organizational Development Committee met on January 9, 2003, in a teleconferenced meeting.

  During the board's legislative hearing before the Joint Legislative Sunset Review Committee (JLSRC) on November 11, there were five items the committee requested the board to consider. Three of these items were referred to the Organizational Development Committee for initial discussion.

- **Consideration to Make all Committee Meetings Public**

  Chairperson Gubbins stated that under California law, the board must make its decisions in public meetings. The involvement of the public is important in this process and the board accepts comments on matters before it or in bringing matters to it during public meetings as well as in correspondence.

Chairperson Gubbins stated that over the last five years, the committee believes that the board has widely expanded the opportunities for the public to provide comment to the board on matters before it. For example, as the board has fully transitioned to the committee structure of its strategic plan, the board has gone from five public board meetings each year to a minimum of 16 meetings planned for 2003 (four board meetings, four Licensing Committee meetings, four Enforcement Committee meetings, two Legislative Committee meetings and one public meeting for the Organizational Development and Public Education Committees).

Chairperson Gubbins reported that the high interest in enforcement and licensing issues would continue to assure that these committees hold each of their meetings as public meetings each quarter. Also in response to public comment, the Legislative Committee will increase to two public meetings this year to permit greater input from the public as the committee considers positions to recommend to the board on introduced legislation (as well as the public meeting where the committee seeks recommendations for future legislative proposals from the public).

Chairperson Gubbins stated that meetings of the Competency Committee (which develops and grades the California pharmacist licensure examination) and the Citation and Fine Committee could not be public meetings. However, matters involving the exam or the Cite and Fine Committees are ongoing agenda items for the Licensing or Enforcement Committees, and activity reports of these committees are provided at board meetings.

The Administrative Procedures Act now also requires informational hearings before the board can initiate the rulemaking process required for adopting regulations.

This leaves up to three meetings of the Organizational Development Committee, Communication and Public Education Committee and two meetings of the Legislative and Regulation Committee each year as non-public meetings. Typically these meetings are short (one hour or less) and are done via telephone with board members. Meeting summaries, recommended actions to the board and minutes of each of these meetings are provided to the public at the same time the board members receive this information.

Moreover, establishing these additional eight meetings each year as public meetings will increase board expenses when its budget can least absorb additional expenses.

Nevertheless, the committee recommends that the committees that hold only one or two public meetings annually carefully evaluate the need for informational hearings during board meetings or on days where other public meetings will be held to facilitate public comment on controversial or highly visible topics. As an example, the Communication and Public Education Committee convened a specifically scheduled informational hearing during this board Meeting on purchasing drugs from foreign countries.

John Cronin representing the California Pharmacists Association stated that the CPhA is a strong proponent of public meetings and that they hope to participate in these meetings to the greatest extent possible.

MOTION: Organizational Development Committee: The board will determine if a committee meeting should be public based upon the interest of the public in matters before the committee.

SUPPORT: 8 OPPOSE: 0 ABSTAIN: 1

- **Consideration to Increase the Number of Public Board Members**

Chairperson Gubbins stated that the committee believes that the board's current structure and size encourages and requires the active participation of every board member in board activities. The expansive description in the board's Sunset Review Report of its activities over the last five years, including its three national awards for innovations in developing significant public policy initiatives, attests to the board's successes from the integrated efforts of both its public and professional members. The committee knows of no other board with such an extensive list of achievements, activities or awards. Professional and public members have active roles in all board matters and in developing board policies, and are essential to this success.

However, if the Legislature and/or administration determine that additional public members would strengthen the board's public protection efforts and productivity, then this decision needs to be made by these entities.

The addition of board members would increase board costs and as such would require the allocation of additional resources as a fiscal impact of any change.

Mr. Powers stated that it is the nature of boards and commissions for the industry to dominate and this does not always prove to be the most productive for consumers. The addition of public members will provide more tools for the board to address consumer concerns.

Collette Galvest representing the Center for Public Interest Law agreed with Mr. Powers and stated that the position of the Center for Public Interest Law is that all boards and commissions have public member majorities.

John Cronin questioned how an increase of the board's public members would better serve the board. He added that there are many issues that public members do not understand because they do not have experience in the profession.

Mr. Powers stated as a public member, he listens to the issues as they are presented and seeks further understanding if needed to represent public interest to the best of his ability.

Mr. Zia stated that having been a public board member for 10 years, he has found that the interest level differs from public members versus pharmacist members and it helps to have a more balanced representation on the board. He recommended the addition of two public members.

Shane Gusman representing United Food and Commercial Workers stated that the proposals made during the Sunset Review process was to increase the board by two (13-member board with 6 public members), one member appointed by the pro tem and one member appointed by the speaker. He added that the UFCW is supportive of this effort and that the increase in consumer perspective helps the board. He acknowledged the perspective of professional members on the board and their importance, and stated this is why public membership should not be a majority of the board.

Mr. Fong stated that pharmacy is a profession rather than an industry and input from public members assists the board in making the best recommendations and decisions but professional membership of the board should not be reduced to accomplish this.

Mr. Tilley expressed concern that too many board members serving on the board may hinder the board's ability meet its goals.

MOTION: Organizational Development Committee: No position on the recommendation of the Sunset Review Committee to expand the number of public members on the board by two, increasing the board's composition to 13 members.

SUPPORT: 2 OPPOSE: 7

MOTION: Support the recommendation of the Sunset Review Committee to expand the public membership of the board by two.

M/S/C: POWERS/ZINDER

SUPPORT: 6 OPPOSE: 2 ABSTAIN: 1

- **Appointment of Pharmacist Board Members "Actively Engaged" in the Practice of Pharmacy to the Board**

Chairperson Gubbins stated that the committee recognizes that the knowledge of a pharmacist is required in a number of diverse environments. Moreover, the scope of practice of a pharmacist has been broadened in recent years by the Legislature to now be wherever the pharmacist is, recognizing the important cognitive skills required of pharmacists in areas that are not limited to dispensing prescriptions in a pharmacy.

Ms. Harris stated that the Governor's Office appoints all professional board members. She added that several years ago a Legislative Counsel's opinion addressed this issue. Staff of the Joint Legislative Sunset Review Committee is seeking a copy of this opinion. A copy will be shared with the board once it is received. She added that generally the opinion was very broad and that an individual is "actively engaged" if he or she is working in any capacity that requires a pharmacist license.

- **Proposed DCA Regulations Regarding Conflict of Interest – Addition of Board Inspectors**
  Chairperson Gubbins stated that two years ago, as a board strategic objective, the board requested that inspectors be added to those board staff who must file annual conflict of interest statements with the Fair Political Practices Commission. The department has now acted upon this request by preparing a revised list of those departmental staff and individuals who need to submit annual conflict of interest statements.

  Currently board members, the executive and assistant executive officers and the supervising inspectors must file these statements. However, the board believes that board inspectors, whose autonomous activities in the field will directly influence any subsequent board action, also need to file such statements. The department agreed and is proceeding with this pending rulemaking. There is no timeline for implementation.

  MOTION: The Board of Pharmacy not take a position on the proposed DCA regulations regarding Conflict of Interest – Addition of Board Inspectors

  SUPPORT: 7 OPPOSE: 0 ABSTAIN: 2

**BUDGET REPORT**

- **Request for AG Deficiency Augmentation for 2002/03**

  Chairperson Gubbins stated that the board's AG funding level would be inadequate to meet board needs this year. Over the last few years, the board has submitted budget change proposals, deficiency augmentations and finance letters to secure adequate funding on an ongoing basis to this important area of board operations. The board has had only limited success in augmenting this item. To assure that the board would have adequate AG resources this year, the board submitted three separate requests to augment its AG funding. All have been denied.

  As of November 1, 2002, the board has spent $318.306 of its $777,000 annual AG budget. If AG spending continues at this rate, the board will spend a total of $954,918 this fiscal year for AG services – and will deplete its AG budget in March or April, leaving it without access to legal services.

  The board is unlikely to be able to redirect sufficient money to its AG line item to allow it to continue spending as it has for the last three years.

Any money approved for the augmentation that is not needed for AG services will revert to the board's fund at the end of the fiscal year.

MOTION: Organizational Development Committee: That Board of Pharmacy staff submit a deficiency augmentation to maintain ongoing access to AG services.

SUPPORT: 9 OPPOSE: 0

This report provides data from the Governor's newly adjusted 2002/03 and 2003/04 state budgets.

## 1. 2002/03 Budget Year

***Projected Revenue: $5,170,890***

Actual revenue for the year is likely to be higher than this because:

- Fees for the sterile compounding licensure program, which must be in place by July 1, 2003, are not included (likely start up is planned for April 2003). As the legislation was being considered, the board projected 300 pharmacies would become licensed; if accurate, this will add $150,000 more in revenue.
- No estimated cost recovery or fines paid are included in this figure. Instead cost recovery payments and fines paid via issuance of citations and fines are added to revenue over the year only after these amounts are collected.

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

The board's authorized expenditures for this year have recently been reduced by $185,000 due to the elimination of four vacant positions, as part of the Governor's cost cutting measures.

***Fund Condition Estimate: $2,595,256 (or 4.2 months)***

The board is expected to end the fiscal year on June 30, 2003, with only 4 months of reserve.

## 2. 2003/04 Budget Year

***Projected Revenue: $4,855,000***

Actual revenue for next year is projected to be lower than projected revenue for

this year due to the much lower amount of interest the board will be paid on its fund ($541,000 in 2002/03 versus $125,000 in 2003/04).

***Projected Expenditures: $7,374,000***

***Fund Condition Estimate: $76,281 (or 0.1 months)***

The board expects to end the fiscal year on June 30, 2004, with only 2.7 DAYS of reserve. This is obviously insufficient.

The board will need to seek the Administration's assistance in establishing repayment of its $6 million loan to the state's General Fund sometime about mid-2003/04. The Administration (specifically Director Kathleen Hamilton) and the Governor's Budget have expressed the intent that the loan will be repaid before there is an adverse effect on the board's programs.

However, if this repayment is not feasible, the board will have to increase fees no later than January 1, 2004 via a regulation change. The board would likely need to take action on an increase in fees at the July 2003 meeting (via adoption of noticed regulations to increase fees) in order to have the fees in place by January 1, 2004. Increasing fees to their statutory maximum will generate $1.3 million more annually in revenue.

- **Personnel Update**

The board lost four positions this fiscal year with enactment of the state budget. These positions were vacant on June 30, 2002, and 6,000 such positions were eliminated statewide. The board will pursue reestablishment of these positions once the fiscal climate permits; there is a need for restoration of these positions:

- Associate analyst – public outreach
- Associate analyst – newsletter editor
- Office assistant – receptionist
- Office technician – complaint assistance

Sandi Moeckly, an associate analyst with the board's licensing program, retired December 27, 2002. Among other duties Ms. Moeckly dealt with difficult licensing issues involving pharmacies.

The board received three new positions to start in November 2002 to implement the sterile compounding licensure program. The board has been authorized another supervising inspector, one inspector and one application technician.

The board filled the application technician position by promoting Suelynn Yee. Ms.

Yee is currently a lower level technician in the Licensing Unit. By doing so, the board did not use a hiring freeze exemption granted for the position.

In December, the executive and assistant executive officers served on the interview panel to create a new hiring list for the supervising inspector classification. Six individuals (four of them current board inspectors) participated in these interviews. Actual employment interviews of those who scored in the top 3 ranks are planned for later this month or in early February. The new supervising inspector should start in late February.

Board staff now is working with the department to assure the scheduling of the inspector classification qualification interviews so that the board may fill the new inspector position.

**Current Vacancies:**

Associate Analyst (Licensing)
Office Technician (Licensing)
Two Supervising Inspectors
Inspector (Compounding)

For the first two positions, the board will seek to hire existing state employees on layoff lists. If this is not productive, the board will seek hiring freeze exemptions.

**Other Personnel Issues**

- **Communications Team Report (TCT)**

The board reviewed the report of the TCT. The TCT conducted the December staff meeting in Sacramento, and provided an opportunity to update staff on budget issues that will affect the board in the coming year and brief t staff on the Sunset Review process. Team building exercises also occurred.

## APPROVAL OF MINUTES

**Full Board Minutes**
**October 24 and 25, 2002**

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

MOTION: Approve the October 24 and 25, 2002, Board Meeting Minutes.

M/S/C: POWERS/ZIA

SUPPORT: 9 OPPOSE: 0

**ITEMS FOR FUTURE AGENDA AND PUBLIC COMMENT**

A request was made that the board define which actions are "disciplinary" and which are not (e.g., is a citation and fine "disciplinary". Such questions are asked on applications for board-issued permits.

Caleb Zia suggested the board establish a rating system for pharmacies (e.g., "A", "B", "C").

**ADJOURNMENT**

There being no further business, President Jones adjourned the meeting at 5:05 p.m.

**Thursday, January 23, 2003**

**CLOSED SESSION**

The board also moved into Closed Session to confer with legal counsel pursuant to Government Code Section 11126(e) regarding the following pending litigation: Doumit v Board of Pharmacy, Sacramento Superior Court Case #98A504499.

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

**REINSTATMENTS**

The board moved into Closed Session pursuant to Government Code Section 11126(c)(3) to deliberate upon disciplinary cases and the petitions for reinstatement and early termination of probation.