

Maryland Board of Pharmacy

Public Board Meeting

January 15, 2003

President Ades called the Public Session of the January 15, 2003 Board meeting to order at 9:15 a.m.

Attendance:

Commissioners Present: Stanton Ades, President; John Balch; Melvin Rubin; Ramona McCarthy-Hawkins; Raymond Love; W. Irving Lottier, Jr.; Jeanne Furman; Wayne Dyke, Donald Yee and Rev. William Johnson

Absent: None

Board Counsel: Paul Ballard, Assistant Attorney General; and Linda Bethman, Staff Attorney

Board Staff: LaVerne G. Naesea, Executive Director; James Slade, Legislative/Regulations Officer; Shirley Costley, Fiscal/Personnel Officer; Joan Lawrence, Public Education Officer; Deitra Gale, Compliance Specialist; Tamarra Banks, Information and Licensing Services Manager and Sandra Hines, Administrative Assistant

Guests: Matthew Gainey, Pharm.D, Purdue Pharma L.P.; Jack Freedman, Division of Drug Control; Howard Schiff, MPha; Catherine Putz, Board Appointed Compliance Officer; Jason Long, Biovail Pharmaceuticals, Inc.; Corey Johnson, HCCL; Kathryn Lavriha, Barr Labs; Tony Tommasello, UM-OSAS and PEAC and Rebecca Ward, UM-SOP/OSAS

Introduction

President Ades asked each guest to introduce him or herself.

Recusals

There were no recusals of members due to conflicts of interest.

Corrections and Approval of Minutes (12/18/02)

Board Action

Dr. Love moved for acceptance of the December 18, 2002 public meeting minutes. The motion was seconded by Ms. McCarthy-Hawkins and passed by the Board.

PRESIDENT/EXECUTIVE COMMITTEE REPORT

(?) May 3rd. Drug Therapy Management. Error Data Collection.

EXECUTIVE DIRECTOR'S REPORT

Staffing Updates

Ms. Naesea announced that all of the Board vacancies have been filled. She stated that Ms. Catherine Putz, formerly of the Division of Drug Control (DDC), will be assuming the position of Compliance Officer on January 22, 2003, and Ms. Latonya Dickerson will assume the post of Board Secretary on February 5, 2003. Ms. Naesea acknowledged and thanked Ms. Sandra Hines for substituting for the duties of the Office Secretary III position during vacancies and Ms. Deitra Gail for performing wonderfully in holding together the Compliance Unit during the six months while the Board had the Compliance Officer vacancy. Ms. Naesea also thanked Ms. Tamarra Banks for directing the Licensing Unit during its transitional period. Ms. Naesea announced that she was very pleased to work with such a strong, cooperative and competent team; particularly during times of crisis and/or transition.

Maryland Board of Pharmacy

Public Board Meeting

January 15, 2003

Office Renovations

Ms. Naesea noted that now that all the Board vacancies have been filled, she would like to review and continue with the plans to alter the board's physical space to accommodate a better workflow. She said it would entail two phases: first to move location of some staff from one area to another and then, once the new fiscal year begin, the physical renovations would take place.

NABP Poster Session

Ms. Naesea called members attention to the notice in the Board packet regarding the possibility of a Poster session at NABP's next Annual Meeting in May 2003. Dr. Love and Ms. Furman described what a poster session entailed and following some discussion it was agreed that the Board would support the NABP session if it were held. The Board discussed the possibility of displaying DTM, Automation regulations, on-line licensing, the disciplinary process and/or other Board activities. Ms. Furman agreed to discuss the concept further with Ms. Lawrence if NABP moves forward with its plans.

BOP 2003 Schedule

Ms. Naesea distributed the Board of Pharmacy's January thru December 2003 schedule of meetings and a revised Board Members' phone number directory.

SECOND QUARTER BUDGET COMMITTEE REPORT

Mr. Lottier reported that the Board's budget appropriation for fiscal year 2003 is \$1,113,534. Expenditures, as of December 31 have been \$647,254. Board revenues, as of December 31, 2002 were at \$1,263,076.

The Board currently employs one temporary staff person in the Office Secretary III vacancy. This position supports the Executive Director, Compliance Officer and the Legislative Officer. In FY 2004, there will be a decrease in the projected Board revenues related to the decrease in reciprocity fees because the Board no longer administers the reciprocity examination. In addition, Mr. Lottier mentioned that the Board has no control over some Departmental charges, indirect costs, which usually increase each year. These include increases in building rent, utilities, health insurance, Attorney General support, employees' cost of living increases, etc.

The Board incurred a deficit of \$6,100 in the budget line item, which covered the cost for printing the new law books. Mr. Lottier noted that the cost to purchase a new law book has increased to \$23.00 a copy, which is related to inclusion of the companion CD.

Workshop – Opioid Addiction Treatment

Ms. Naesea announced that she and Mr. Lottier attended an Opioid Addiction Treatment Workshop in Arlington, VA sponsored by NABP and the National Federation of Medical Boards to learn about the new drug "Buphenorphine."

Mr. Lottier reported that the one-day workshop, held at the Marriott Hotel in Arlington, VA, addressed the new drug "Buphenorphine," an Opioid substance used to treat Opioid Addiction. The drug Trexall was formally used in the treatment of Opioid Addiction. Practitioner guidelines are still being developed. Mr. Lottier stated that the Sun newspaper had an article on "Buphenorphine" on the date of the Board meeting (1/15/03). The Center for Substance Abuse Treatment has placed a list of physicians who are eligible to prescribe Buprenorphine. The web-site address is www.buprenorphinesamhsa.gov. Physicians are not required to have their name placed on the list.

Maryland Board of Pharmacy

Public Board Meeting

January 15, 2003

Buprenorphine is a sublingual tablet under the tongue and the first two dosages are taken in the physician's office. Adjusted doses are used so that the patient can be weaned off the drug. The pharmacist who dispenses the drug must counsel the patients.

Mr. Tommasello, of PEAC was present at the meeting and reported that not all physicians are eligible to prescribe Buprenorphine. The Drug Enforcement Administration originally administered a test to certify physician in order to qualify to dispense Buprenorphine. The Center for Substance Abuse Treatment (CSAT) has taken over the process of certifying the physicians and all qualified physicians are urged to place their new DEA number on the prescription.

Ms. Naesea reported that the Center for Substance Abuse Treatment is still developing policies and procedures and has asked States to work with them in specific regions. Ms. Naesea informed the trainers that the MD Board would definitely be interested in having a representative from the Board to work with CSAT. The Board will have to develop regulations related to how pharmacies should respond to the dispensing of this type of narcotic.

Mr. Lottier and Mr. Tommasello agreed to work with Ms. Lawrence in developing a general description of Buprenorphine and the related pharmacy issues for the Board's Newsletter. More specifics will be provided in the Newsletter's first article.

Drug Study Research

Mr. Tommasello reported that Baltimore is a potential site for a research project involving methadone maintenance patients. He reported that Maryland has applied for a release waiver that will allow a sample of female methadone patients to have their methadone administered at a pharmacy rather than at customary narcotic addictions and methadone maintenance clinics. The Harrison Narcotic Act (1914) prevents physicians from prescribing and pharmacies from dispensing methadone drug treatment; thus, forcing patients into clinics where treatment is obviously very straining, commented Mr. Tommasello. The research initiative involves trying to move methadone maintenance into a more customary medical care model with primary care physicians treating the addiction and the patient having methadone filled and administered at pharmacies.

New Mexico has satisfied the basic concerns from the Drug Addictions Administration and is currently a research site for the project.

PEAC (PHARMACISTS EDUCATION AND ASSISTANCE COMMITTEE) – UPDATE

Mr. Tommasello reported that the Pharmacists Education and Assistance Committee met on January 9. However, Mr. Tommasello stated that since he was not expecting to attend the Board meeting, he did not have the current patient count. He reported that PEAC purchased a new computer in order to move up to a faster access. He also announced that PEAC representatives met with the Disciplinary Committee since the last Board meeting to identify some communication issues that needed to be addressed. Mr. Tommasello requested to reconvene during the next Disciplinary Committee Meeting on the following Thursday, January 23. Ms. Furman recommended that PEAC review their contract before the meeting. Mr. Tommasello indicated that one particular area of interest would be the procedure for Voluntary Surrender.

Mr. Tommasello reported that PEAC's current RFP will expire soon and has requested an extension. Ms. Naesea reported that the Board is waiting for an approval from DHMH to try to extend PEAC's contract for another six months so the Disciplinary Committee can thoroughly review the scope of work that was in the RFP during the last issuance. The Board will notify PEAC as-soon-as the Board receives formal approval from DHMH.

Maryland Board of Pharmacy Public Board Meeting January 15, 2003

LEGISLATIVE/REGULATIONS REPORT

Mr. Slade reported that bills are moderately arriving at the Board. No Bills from the Board have been filed.

COMAR 10.34.09 Notice of Emergency Action – Fees

Mr. Slade reported that the reduced reciprocity fees were proposed not yet approved.

General Assembly of Maryland – Official Dates of Interest

Mr. Slade indicated that a the list of important dates for the General Assembly between January 8th and April 7th had been included in the Board packets.

Regulations Status Report

Mr. Slade reported an update on the Examination for Licensure and Professional Experience Programs and Reinstatement. The Board has filed the notice for final action, which should be effective March 2003.

Mr. Slade reported that he and Mr. Ades met with the BPQA Practice of Medicine Committee and Med Chi representatives to discuss the Drug Therapy Management regulations. The Committee will meet with Mr. Schwartz on Tuesday morning to resolve Med Chi concerns. The Drug Therapy Management regulations will be presented for voting by both Boards in February.

COMMITTEE REPORTS

PHARMACY PRACTICE COMMITTEE

Dr. Love reported that the Pharmacy Practice Committee met on January 8 to discuss comments received on the Patient Safety regulations. The Committee reviewed the suggested responses to the comments and made changes to the regulations.

Board Action

Dr. Love moved to withdraw the original version as revised and approved and for the Board to accept the newly revised submission as the proposed set of Patient Safety regulations. The motion was seconded by Ms. McCarthy-Hawkins and passed by the Board.

Review of Med Chi's Comments

Dr. Love reported that the Committee reviewed Med Chi's comments regarding Collaborative Drug Therapy Management and offered some guidance to Mr. Slade for the meeting with Med Chi. Dr. Love reported that the Committee had preliminary discussion on the concept of 'pharmacist-in-charge' and how it should be addressed at the next Practice of Pharmacy meeting. Dr. Love noted that the committee spent a large amount of time of their meeting on the issue of pharmacies wanting to have multiple permits. The Committee suggested conditions under which the Board would be willing to issue multiple permits and how they would work. Dr. Love and Mr. Slade will compile the notes taken at the meeting and will have those notes ready for the next Committee meeting for discussion.

LICENSING COMMITTEE

Mr. Dyke reported that the Licensing Committee met January 14 and part of their discussion pertained to the number of pharmacist licenses and establishment permits that were processed in the past month.

Maryland Board of Pharmacy Public Board Meeting January 15, 2003

Ms. Banks had compiled a summary of non-renewed licensees and permit holders, all establishment applications mailed, and new and renewed licensure and new permits for the previous month. The list of non-renewed licenses will be compiled each month and submitted to the Division of Drug Control to use during their inspection visits.

Reciprocity – List of Candidates

Mr. Dyke reported the following pharmacists who have met the Board requirements for reciprocity this month:

Sejal Shan	Licensed 12/02/02
John Rafi	Licensed 12/13/02
Anne Kumar	Licensed 12/11/02
Peter Trovich	Licensed 12/12/02
Prince Boakye	Licensed 12/18/02
William Proctor	Licensed 12/16/02
Eucharía Nnadi	Licensed 12/23/02
Tamarra Foreman	Licensed 12/24/02
Ivan Cephas	Licensed 12/30/02

Ms. Banks reported that testing of the online system is completed. The system was tested for 16 days. Over 500 pharmacies and distributors participated. The system will now be available all year long. The first set of pharmacists will be able to renew on-line in June 2003. The on-line payment system is still not available. Ms. Costley stated that the State Treasury's Office is working on a method for accepting checks.

Wet Lab Exam

Mr. Dyke announced that the next Wet Lab Exam would be held on Tuesday, January 21 at 8:45 a.m. As of the day before the Board meeting, 51 candidates registered to take the exam.

Oral English Competency Requirement

Mr. Dyke reported on the research conducted on Oral English Competency Exam. Research results demonstrated the lack of necessity for the Board to administer its own exam since candidates are tested on the national level. Mr. Slade was directed to create a proposal to make the change to the Practice Act which will allow the Board the option of not requiring all candidates to take an Oral Competency exam, but would allow the Board to retain the authority to require the exam if deemed necessary in the future.

Board Action

Dr. Love moved that the Board approved and endorse the wording in the document presented. The motion was seconded by Ms. McCarthy-Hawkins and passed by the Board.

FPGEC

Mr. Dyke provided an update on the FPGEC security breach. FPGEC essentially stopped processing the certificates that the Board required as part of processing to receive a Maryland license. NABP is developing a new more secure test and is not processing certificates or issuing certificates to foreign candidates who have already passed all the examination requirements. A number of persons desiring to practice in Maryland have satisfied every requirement, but cannot receive their FPGEC certificate. .

Maryland Board of Pharmacy

Public Board Meeting

January 15, 2003

Mr. Dyke announced that the Committee decided to present before the Board, the names of the candidates who fall into this category of a temporary status until the FPGEC starts up again. On behalf of the Committee, Mr. Dyke proposed that the Board request the FPGEC certificates for MD candidates and have NABP provide all the information to the Board that it needs to decide whether a candidate is eligible for licensure in Maryland.

After considerable discussion, Mr. Dyke agreed to wait to see what NABP will temporarily provide to the Board for the foreign candidates. The Board will set up a priority approval system during the interim.

Distributor Application

Mr. Dyke reported that the Committee discussed the Board's Distributor Application at its meeting. One of the sections on the application asked which products were distributed. To satisfy that requirement on the application the Board has been receiving reams of lists and catalogs of distributors' products and it has been difficult for the Board to review and store all the paperwork.

Board Action

Ms. Furman moved that the section be removed from the application. The motion was seconded by Ms McCarthy-Hawkins and passed by the Board.

Renewals -Name Change

Ms. Banks reported that the Board presented a question to Mr. Ballard, Board Counsel, about the current renewal policy. Specifically, if a pharmacy changes its name then should the Board require the pharmacy to re-apply for licensure and be inspected? A request for a proposal to come up with a shorter policy to eliminate the inspection was addressed. The Board currently has approximately over 60 pharmacies pending disciplinary actions for changing their name and not notifying the Board nor being re-inspected after the name change.

Board Action

Dr. Love moved that Licensing Committee create draft regulations to resolve the situation. The motion was seconded by Mr. Yee and passed by the Board.

Discount Drug Program

Mr. Rubin reported that a small clinic for the homeless and low-income persons, in Frederick, MD would be working in a Federal discount drug program to receive drugs at a reduced price. The drugs will be sent to the local pharmacies at the discount price. Mr. Rubin will contact the Center for Medicaid/Medicare Services to comply with their regulations.

DISCIPLINARY COMMITTEE

Mr. Furman reported that the Committee would meet next week to discuss the PEAC contract and the Board's objectives for next year based on last year's standard disciplinary action vs. the cases that need to be brought to the Disciplinary Committee. The Committee will also be providing orientation to Ms. Catherine Putz, the newly hired Compliance Officer.

Ms. Gale reported that within a few weeks legislative auditors are expected to review the number of cases that were rendered standardized decisions as reported by the Board Compliance Unit in its Managing for Results report.

Maryland Board of Pharmacy

Public Board Meeting

January 15, 2003

Inspection Form

Mr. Rubin reported that the Committee re-wrote the Inspection Form to cut-down on the amount of work that needs to be done. The draft form will be distributed at the MPHA meeting next week for comments and approval.

Technology and Automation Report

Ms. Bank reported that after January 21, that Ms. Naesea, Mr. Konstantinov and Division of Drug Control staff will test the inspection forms that have been loaded on to the DDC laptops at a pharmacy.

Status of On-Line System

Ms. Banks reported that the Board had 60,920 visitors up to the second quarter of 2003. There were 8,213 web-site visitors by the second quarter in 2002. This quarter, the Board had 396 pieces of e-mail vs. the same time last year when the Board had 264.

A Customer Service section has been added to the web site to learn how the Board can better serve the public.

Public Relations Report – Joan Lawrence

Ms. Lawrence reminded the Board members that pictures would be taken immediately following the Board meeting.

Announcements

Ms. Naesea announced a Legislative Reception sponsored by the Council of Board would be held on January 29th 11 a.m. to 1 p.m. Board members were asked to contact Ms. Jeffers to confirm their attendance.

MPhA is having its mid-year meeting, February 2 at the School of Nursing. The meeting is offering .6 CEUs for the attendees. After the meeting, there will be a reception at the remodeled Kelly Building.

Pres. Ades adjourned the Public Session at 11:53 a.m.