

# Maryland Board of Pharmacy

## Public Board Meeting – January 16, 2002

President Ades called the Public Session of the January 16, 2002, Board meeting to order at 9:10 a.m.

### **Attendance:**

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

**Absent:** Rev. William Johnson; and Barbara Faltz-Jackson (attended a meeting in Annapolis)

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

**Board Staff:** LaVerne Naesea, Executive Director; Michelle Andoll, Pharmacist Compliance Officer; James Slade, Legislative/Regulations Officer; Joan Lawrence, Public Education Officer; Tamarra Banks, Information Services Manager; Doris James, Licensing Supervisor; Deitra Gale, Compliance Specialist; Angela Long, Executive Secretary; and Jaimi Christensen, Pharmacy Student Intern

**Guests:** Tony Tommasello (PEAC); Howard Schiff (MPhA); Kathryn Lavriha, (Barr Labs); Lisa Moorhead (Univ. of Md.); and Cathy Putz (Division of Drug Control)

### **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 (12/19/01)**

Page 3, under PEAC, the person name is “*Gil Cohen*” **not** “Phil Cogan”

Page 6, under Board/Staff Workload Issues, second paragraph, fourth sentence, “...and use NABP guidelines to develop the guideline” **be deleted**; “eighth sentence” **be deleted**

Board members agreed to submit marked-up typographic and grammatical errors.

### **Board Action**

Dr. Love moved for acceptance of the December 19, 2001, public meeting minutes, with amendments and pending correction of typing and grammatical errors. The motion was seconded by Ms. Schneider and passed by the Board.

### **President/Executive Committee Report**

#### **Drug Therapy Management (DTM) Workgroup**

Pres. Ades reported that Raymond Love, George Voxakis, James Slade, Gary Smith and he met with a small group from Med Chi’s Legislative Committee and counsel, Jay Schwartz on January 7, 2002. They reviewed the language of the draft proposed DTM legislation and edited a number of items in the language. A number of questions centered on BPQA and Med Chi’s continued discomfort by their perception that Drug Therapy Management would be performed in numerous pharmacies around the state. Mr. Ades stated that anecdotal situations were shared regarding Med Chi’s physicians’ interactions with pharmacists.

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Pres. Ades also reported that at Med Chi's House of Delegate meeting on January 12, 2002, members indicated that they would support the DTM legislation contingent upon 18 issues being addressed. The Board and workgroup have addressed and incorporated resolutions to the issues into the most recent language of the bill. A revised copy of the draft bill will be sent to MedChi. Pres. Ades anticipates meeting with Jay Schwartz and Jim Slade to review the most recent language.

Pres. Ades mentioned that the most debated issue was whether Sunset language should be included and if included, for how long a period after the regulations have been passed. The Board wants no Sunset, but MedChi asked for 5 years. Pres. Ades speculated that Med Chi would probably settle with 10 years. He stated that a revised bill is planned for forwarding to the legislative drafters, no later than January 21, 2002.

### *Bio-Terrorism Task Force*

Pres. Ades reported that members of the Bio-terrorism Task Force were asked to attend a meeting requested by the Department. BPQA and their counsel, the Board's counsel, and the Nursing Board were also in attendance to discuss waivers that need to be put in place in case of an emergency. The Task Force submitted a request for the Governor or Secretary to provide waivers for pharmacy sites, pharmacy standards of practice, record keeping requirements, packaging, and labeling; as well as medical administrative. He mentioned that the Department acted favorably towards all of the suggestions.

Dr. Love mentioned that Mel Rubin, Joan Lawrence, and LaVerne Naesea attended a meeting with the Deputy Secretary where the Board's plans were outlined.

Pres. Ades stated that the next meeting is scheduled for Friday, January 18, 2002.

### *Protocols for Acting on Behalf on the Board*

Ms. Naesea reported that Ms. Lawrence had compiled protocols for Board members acting on behalf of the Board. She recommended that the Board adopt the distributed protocols. There were numerous questions regarding the protocol and Pres. Ades suggested that Mr. Ballard review the document before adoption.

## **Executive Director's Report**

### *Compressed Work Week Plan*

Ms. Naesea reported that a compressed workweek plan has been developed for staff and that she is awaiting a response from Richard Proctor for approval. She anticipates the plan going into effect by February 6, 2002. A copy of staff schedules will be forwarded to the Board members once developed.

### *Legislative Audit*

Ms. Naesea reported that she has not heard from the legislative auditors. She received a call from a Budget Analyst who questioned a few items in the Board's budget. Ms. Naesea mentioned that the Analyst wanted additional information about the four positions proposed to be permanent: licensing secretary, Board secretary, renewal secretary and the data entry person. She also mentioned that he questioned the total annual per diem paid annually, but not the daily rate. Ms. Naesea response to him was that the Board is extremely active, the members meet on an average of three to four times a month, and that the Board of Pharmacy is larger than most other Boards.

Ms. Naesea stated that the Budget hearings are scheduled for January 24, 2002, at the House of Appropriation and January 28, 2002, at the Senate Budget Committee. She mentioned that the Board submitted an exception request for the hiring freeze to hire the licensing secretary (contractually), but has not yet received a response.

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### Increase in Controlled Dangerous Substance Fees

Ms. Naesea reported that Division of Drug Control submitted a memo to the Board regarding its controlled dangerous substance fee increases. The fees were amended effective December 24, 2001; changing the fee paid into the general fund from \$40 to \$60 every 2 years for registration of persons who conduct research manufacture, distribute, and administer or dispense controlled dangerous substances in Schedule I-V as listed in Article 27, Section 279, Annotated Code of Maryland.

### PEAC Community Methadone Maintenance Proposal

Ms. Naesea mentioned that Ms. Andoll and she attended a meeting with PEAC and representatives from other groups regarding developing a pilot project to dispense methadone in pharmacies. Mr. Tony Tommasello clarified that this was not a PEAC initiative, but under the auspices of the University of Maryland. Mr. Tommasello described the project and ensured that legal requirements will be satisfied in order to implement the pilot project.

He mentioned that a treatment program out of a New York hospital is currently funded to administer the pilot study. The pilot is proposed for expansion to Baltimore and will be conducted through the University of Maryland methadone maintenance treatment program. It will involve 50 patients of which 25 will receive methadone doses and monitored at the program site and 25 will receive doses at one or more participating pharmacies. Mr. Tommasello stated that pharmacies would be registered as medication treatment units that allow dispensing of methadone as a satellite of the University of Maryland program. Under this designation, participating pharmacies would not require a treatment center license. Participating pharmacies would be under the “medication units” of the MD Drug Abuse Treatment program. DEA and DDC will review the project application, which may be accelerated to initiate the proposed project. In order to comply with DEA regulations, the methadone supply would be kept distinct from other methadone and Schedule II drugs in the pharmacy inventory. He also mentioned that the methadone drugs would be supplied by the University of Maryland program for budgetary efficiency. Assurances were given that pharmacist, and not pharmacist technicians, would administer the methadone. Under the medication unit arrangement, pharmacists will administer methadone in the treatment program as agents of the University of Maryland drug program.

Ms. Naesea stated that Mr. Tommasello has requested the Board to support the concept of the project application. Ms. Andoll clarified that this activity would not be conducted under the auspices of the pharmacy permit issued by the Board. She stated that the pharmacy would be registered as a “medication units” of a registered Narcotic Treatment Program (NTP). Pharmacies are allowed to do these activities as a medication unit. She emphasized that this project would not be included under the scope of pharmacy practice laws but it is under the guidance of the NTP unit.

Dr. Love commented that this would be a positive step forward. He mentioned that the Board was concerned about dispensing when working with health department nurses and had to make special provisions for dispensing methadone. He felt the pilot would put pharmacies back on the path of involvement. Dr. Love also states that this project may set a precedence for the future in that it has the potential to increase accessibility for patients beyond each specialized clinics (which each have associated overhead). He pointed out that pharmacies dispensing methadone would probably be much less expensive because existing community resources are used.

### **Board Action**

Dr. Love moved to endorse the concept and support the pilot project. The motion was seconded by Mr. Yee and passed by the Board.

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### Status of License I.D. cards

Mr. Balch asked about the status of developing the smaller pocket size license identification cards. Ms. James stated that the Board has the new cards, but plans to deplete the supply of the cards currently used. She estimated that approximately 750 remain to be used.

### **Legislative/Regulations Report**

#### Legislation Report

Mr. Slade directed Board members to the calendar of events for the 2002 legislative session, which had been inserted in the Board packets.

Mr. Slade reviewed bills that may have an impact on pharmacy practice. *SB 22* creates an osteoporosis prevention and education program, which will raise awareness of the disease. An important issue to the Board regards the use of long-term medications in the development of osteoporosis. He stated that the Bill lists health care professionals, but it does not list pharmacist. Board members indicated that they want pharmacists specifically listed in the bill.

Mr. Slade mentioned that *SB 44* regards controlled dangerous substances prescription monitoring program. It would require authorized prescribe pharmacy permit holders in Maryland pharmacies to report to a central data bank. He stated that Jack Freedman of the Division of Drug Control stated that his Unit is proposing that a study be conducted for a year. Mr. Slade indicated that comments from some Board members were that the Board should remain neutral on the issue, but continue tracking the status of the bill. Board members suggested that comments be submitted to the Department. Mr. Slade said he would talk to Governmental Affairs about their position.

Mr. Slade informed Board members that copies of *Senate Bills 31, 44, 45, and 117, and HB 41* were also in the packet for review.

#### Regulations Report

Mr. Slade mentioned that the *Compelling Purpose Disclosure* regulations became effective January 7, 2002. He also stated that the public hearing on *User Fee Assessment on Health Care Practitioners* regulations is scheduled on February 21, 2002.

### **PEAC**

Mr. Tony Tommasello reported that PEAC has 29 cases, and received one new case in the past month. Eight of the current cases are board referred. Mr. Tommasello indicated that the number of cases in the database may not be accurate and that he will review the information again. He mentioned that following the CE program in October, cases began to come in rapidly. Over the course of two months, about 10 new cases had come in. He stated that PEAC's current structure could not handle a significant caseload increase. As a result, PEAC is pursuing a full-time paid Director of Development and is seeking support funding from various sources, including chain store operations. PEAC is meeting with chain store owners regarding funding for one year. He stated that PEAC is operating on a budget of approximately \$30,000 a year.

PEAC has a volunteer student from the pharmacy school who has developed PEAC's website. They are in the process of changing from ".com" to ".org." Mr. Tommasello mentioned that three of PEAC's committee members are certified as psychiatric pharmacists and one of them is an addictions counselor.

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Ms. Furman asked about the contract that PEAC have with the Board. Specifically, she asked about the average caseload and for a summary of services provided under PEAC's budget. Mr. Tommasello stated that the average caseload is 25. Ms. Furman suggested that PEAC forward a budget and outline of the services they provided during the most recent contract renewal period. Ms. Banks mentioned that rates for services are included in the RFP bid and that the Board is permitted to review contractors' records.

### **Committee Reports**

#### **Pharmacy Practice Committee**

##### Unlicensed Personnel Task Force

Mr. Rubin mentioned that the task force met last week and he received several comments related to whether there is a necessity for unlicensed personnel regulations. He indicated that the task force would probably end within the next two months. Ms. Furman questioned the structure of the task force, relative to having a clear charge. She mentioned that there should be guidelines for those on the task force who have decision-making authority. Mr. Rubin agreed to meet with Ms. Furman to create general guidelines for all Board task forces.

##### Nurse Dispensing Committee

Mr. Yee reported that the next Nurse Dispensing meeting is scheduled on January 28, 2002. The most recent meeting involved discussion about the development of a training curriculum for nurse dispensing. Ms. Andoll mentioned that she left a message for Mr. Don Fedder, a pharmacist recommended to assist in developing the curriculum.

##### Long Term Care Task Force

Dr. Love mentioned he had not spoken to Pres. Ades regarding the long-term care regulations. However, an issue that has been previously reviewed, regarded changes required in the long-term care regulations. Dr. Love recommended that Pres. Ades appoint a long-term care task force and that it be small with 1 to 2 external participants, if necessary. Pres. Ades indicated that he would review the recommendation.

##### Waiver Permits

Dr. Love reported that the Practice Committee met on January 2, 2002 and discussed possible changes to the Board's procedures for issuing pharmacy permits. Dr. Love stated that the Disciplinary Committee had several concerns regarding pharmacies expanding to other areas. Some expansions would be a violation of the Code of Conduct under the competency section. He also stated that the Practice Committee raised questions about how the changes to procedures could impact the manner in which permits are issued. The Committee reviewed a number of other states and noted that very few states have just one type of permit; some states have a couple of types of permits; and most other states had up to 18 types of permits. Dr. Love reported that the Committee felt that some differing types are necessary to define the functions and areas of practices in which pharmacists participate; as well as to determine their relationship to quality assurance for effective practices.

The Practice Committee will recommend that the Licensing Committee examine the functions of various areas of practice. The Practice Committee will continue to examine the practice end. Dr. Love mentioned that the Committee felt that several types of permits or waivers are not needed unless there is a restricted population. However, the permits should specify the types of pharmacy practices that will occur at locations and provide some sort of evidence that pharmacists are qualified or equipped and/or trained to perform particular activities.

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### Narrow Therapeutic Index (NTI)

Ms. Andoll mentioned that the Board received a request for clarification about the NTI list from a practicing pharmacist. She pointed out that the list only includes specific doses as prohibited from generic substitution and excludes several new strengths of Warfarin. She questioned whether the new doses are also restricted from generic substitution. Ms. Andoll responded that since the Secretary issued the list, interpretation should be left to the Secretary. She explained to Board members that when Medical Assistance (MA) patient receives a prescription for a strength listed on the NTI, then MA pays for the name brand. However, if same patient has a prescription for a new unlisted strength, the pharmacist has to dispense the generic brand, unless the physician goes through the correct DAW process. Ms. Andoll said that it destroys the intent of having a list for patient safety issues when some strengths may be substituted and some strengths might not.

The Board agreed that the entire list should be reconsidered, including generic substitutions related to changes in dosages. Pres. Ades indicated that he would discuss concerns related to the NTI list with Delegate Elliott.

### FDA Opinion

Ms. Andoll reported that DDC received an FDA opinion regarding allowing pharmacists to return stock drugs that have been dispensed, but are still in the control of the pharmacy. FDA found state provisions to be acceptable for allowing the drugs to be returned to stock, if the Board of Pharmacy agrees. Ms. Andoll suggested submitting an article in the newsletter regarding this issue.

### Consumer Brochure

Ms. Schneider mentioned that chain stores have indicated a desire to comment on the consumer brochure before it is distributed. Ms. Naesea mentioned that she had received similar comments from Murhl Flowers and Geraldine Valentino. Dr. Love questioned whether the subject matter or the actual content was a problem. He reminded members that the Board promised the legislature that it would develop this brochure. Pres. Ades stated that the Board would welcome written comments on the brochure.

Ms. Naesea previously forwarded a copy to Ms. Valentino and Mr. Flower. She had asked that that they hold their comments until after the Board meeting. She said she would re-contact them and ask that comments be provided by the end of the January.

## **Licensing Committee**

### Reciprocity – List of Candidates

Mr. Dyke reported that the Reciprocity meeting was held on January 15, 2002. He presented the names of candidates for licensure for reciprocity in Maryland. Sixteen (16) candidates took the examination. All passed the written examination and oral competency test.

### **Candidates - Passed**

Jennifer Brooks	Hilda Fishman	Patricia Klishevich
Jignasa Desai	Angela Han	Theresa Martin
John DiBona	Mindy Helmly	Suzanne Nesbit
William Dillon	Jose Hernandez	David Rohrbaugh
Donna Durfee	Ali Keshavarz-Shokri	
Leanne Faris	Maya Khater	

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### **Board Action**

Mr. Dyke moved to license the sixteen (16) candidates. The motion was seconded by Ms. McCarthy-Hawkins and passed by the Board.

### **Reinstatement**

Mr. Dyke reported that the Committee reviewed the reinstatement process last month. He distributed a draft copy of the reinstatement regulations. Mr. Dyke stated that all licensees who do not renew their license would fall into the reinstatement category. The draft regulations describe the processes involved when licensees reinstate their licenses. He noted that the draft regulations allows for the Disciplinary Committee to evaluate each of the non-renewal applicants and that the Disciplinary Committee will develop internal guidelines for disciplinary cases.

Board members reviewed the draft regulations and requested that Section 03(3)(7)(b) read “1,000 hours of service in licensed pharmacy under the supervision of a licensed pharmacist. “

Mr. Dyke addressed a Medical Assistance (MA) issue that occurred in January regarding MA not approving payments for renewed establishments. Ms. Banks explained that on the first day in January, Medical Assistance receives a list from First Choice Insurance Company of all of the providers in the Medicaid program. The list is usually compared with the Board’s database but in January, that list was not updated. The company’s list stated that establishments were not approved to participate in Medical Assistance but the Board’s list indicated that the establishments were active. Ms. Banks was told by Medical Assistance to inform the permit holders to hold their bills until Medical Assistance received an updated list from First Choice Insurance Company. Ms. Banks placed this information onto the website. She also suggested that in the future, Licensing Unit make sure that Medical Assistance is contacted and has received an updated list.

### **Increase in Licensure Fees**

Mr. Dyke mentioned that the Committee had received very few comments regarding the proposed increase in fees.

### **Wet Lab Examination**

Mr. Dyke reported that the wet lab examination is scheduled for January 29, 2002 and that Board volunteers are needed to proctor the exam.

### **Non-Renewal Establishments**

Ms. Andoll informed the Board that the Board staff met and developed a plan to address establishments that had not renewed by the December 31<sup>st</sup> expiration deadline. She said she received a list of establishments that had not renewed their permits and followed-up with notifying those establishments that their permits had expired and that they are not licensed to operate. Ms. Andoll also sent letters to out-of-state establishments and the Boards of Pharmacy for their home state, which indicated that, according to the Board’s records, the permit holders were no longer licensed to do business in Maryland.

### **Public Relations Committee**

#### **Flower Mart**

Ms. Lawrence reported that the Flower Mart is scheduled on Wednesday, May 15, 2002 and that the rain day will be May 16<sup>th</sup>. The event will commence at 11:00am and concluded at 6:00pm. The PR Committee plans to have two booths. It will cost \$450.00 for both booths including tables and chairs. The Committee

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will be recruiting volunteers from the Board and Oversight Committee members. The Committee will also conduct another consumer survey at the Flower Mart.

### Consumer Web Page

Ms. Lawrence reported that the PR Committee is working with the Network Specialist to re-design the Board's website and create information for consumers. She mentioned that Ms. Banks would elaborate on this during her report.

### Board 100<sup>th</sup> Year

Ms. Lawrence reported that the Committee recommends that the Board sponsor a large celebration or event honoring the Board's 100<sup>th</sup> year in October. The Committee discussed many ideas on how this event would be funded. One idea was that 10 honorees be honored and that tickets be sold to sponsor the event. Mr. Balch suggested the Board have more than 10 honorees. Board members agreed that the Committee develops the concept. Ms. Naesea, Ms. Banks, Ms. Furman, and Ms. Lawrence agreed to compile a draft proposal to be presented to the Board to help determine the feasibility of sponsoring the event.

The Committee also agreed that proclamations should be obtained from the Federal, State, and City Government that celebrate the 100<sup>th</sup> year of the Board and that special stationery (letterheads and labels) be printed and used throughout the anniversary year.

### **Disciplinary Committee**

#### Quarterly Employer Report and Guidelines for Consent Order Standardization

Ms. Andoll reported that Mr. Ballard noted that some of the Disciplinary Committee's policy issues and discussions should be addressed in the public sessions. She stated that the Committee has been working on two issues: standardized forms for a Quarterly Employer Report, and Guidelines for some standardization of Consent Orders.

The quarterly employer report was developed for when the Board places someone on probation and their employers are required to submit quarterly reports. The Board did not have a standard format. The form was designed to list the types of information the Board would want to receive from the employer. There are two forms; one is standard general information and the second is the same information but includes information regarding CDS. Ms. Andoll asked that the Board review this form and to submit any additional information they wish to be reported on a quarterly basis. Mr. Balch suggested that the form include signatures for both parties; the employer and employee. Mr. Lottier suggested that the forms show a different heading for each form. Dr. Love suggested that they add a section regarding specific issues relating to the case.

Ms. Andoll mentioned that the Committee also developed standardized terms and conditions for fraud cases when drafting consent orders. She stated that this form would be used as a guideline for some types of resolution. Pres. Ades suggested that the 1<sup>st</sup> sentence on the form be added to the quarterly employer report as a question. Mr. Ballard suggested that the topic "mandatory" be changed. Ms. Bethman suggested that they delete the 11<sup>th</sup> bullet from the guidelines.

The next Disciplinary Committee meeting is scheduled for January 24, 2002.



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## **Council of the Boards**

Ms. Naesea reported that the Council of Boards is having an Education Day and Legislation meeting and reception at 1:00pm today and Mr. Rubin, Mr. Slade, and Ms. Lawrence will represent the Board at the meeting. Ms. Barbara Faltz-Jackson will serve as a community member at the meeting.

## **Technology and Automation Report**

### Technology Committee

Ms. Banks reported that the Technology and Automation Committee met on January 4, 2002. The Committee obtained a checklist for the website audit from DHMH. There were 26 conditions the auditor would review. Of the 26 conditions to be reviewed by the auditor, the Board will need to become compliant with 11. Ms. Banks can meet six of the conditions, internally, however 5 will be addressed by a vendor solicited to re-design the website. She developed a solicitation to redesign the Board's website, which will be issued by the end of January.

Ms. Banks reported that the following Technology Committee members are assigned to review the website for the period of January 2002 through June 2002.

<u>Committee Member</u>	<u>Web Section Assigned</u>
Ramona Hawkins	Pharmacist Licensure Committee Reports General Grammar & Spelling
William Johnson	Establishment Licensure Complaints Newsletter
Mel Rubin	Pharmacist Licensure Legislation & Regulations Frequently Asked Questions
LaVerne G. Naesea	Home Page Board Business Consumer Information
Tamarra Banks	General Review – All pages
Doris James	Pharmacist Licensure Establishment Licensure
Vladimir Konstantinov	Downloads Verifications Related Web Sites
Paul Ballard	Board Council, as requested

**President Ades adjourned the Public Board Meeting at 11:55pm.**