BOARD OF REGISTRATION IN PHARMACY
BOARD MEETING MINUTES
TUESDAY, SEPTEMBER 10, 2002
239 CAUSEWAY STREET, ROOM 206
BOSTON, MASSACHUSETTS 02114

The meeting was called to order by Secretary Donna Horn at 9:30 a.m.

The following Board members were present:
Donna M. Horn, R.Ph., Secretary, Karen M. Ryle, MS, R.Ph., James T. DeVita, R.Ph., Marilyn Barron, MSW, Public Member (10:30a.m.) and Dr. Robert P. Paone, R.Ph., Pharm. D. (Absent: Sparr & Sullivan)

The following Board staff were present: Charles R. Young, R.Ph., Executive Director, James D. Coffey, R.Ph., Associate Director, James C. Emery, C.Ph.T., Healthcare Investigator and Leslie S. Doyle, R.Ph., Healthcare Supervisor and Investigator.

AGENDA ITEMS

1. **9:30 a.m.**
   Call to order: Business & Investigative Conference Meeting

   Minutes for February 26, 2002: approve ____ amend ____
   Board staff distributed the draft minutes for Board review.
   Minutes for March 26, 2002: approve ____ amend ____
   Board staff distributed the draft minutes for Board review.

2. **9:35 a.m. to 10:00 a.m.**
   Advanced Care Pharmacy, 5 Clock Tower Place, Suite 450, Maynard, Massachusetts 01754.
   The applicant will be represented by the proposed Manager of Record, Anthony Biscotti, R.Ph. (License Number 20426)

   The purpose of the conference was to discuss the merits of an application for licensure as a new nuclear pharmacy with waiver petition (247CMR 13.03 (4,c) - Nuclear Pharmacy Permit: "An exhaust hood and filter system for handling radioactive gases or volatile radioactive material must be installed."

   Mr. Bisconti reviewed application and waiver request; describing protocols related to handling of "Brachytherapy Sealed Sources" of radioactivity (pre-packaged in small titanium tubes that are welded closed on both ends). Bisconti stated pharmacy will not cut and or open tubes. He noted DPH/RCP does not require the proposed pharmacy to submit plans for a ventilation system with both filters and monitors to track radioactivity release because it lacks the potential for hazard. Bisconti said that in the

event of a leak no contaminated air would leak into unwanted areas. Products would be shipped by FedEx (approved by HAZMAT for transport). Medication ½ life was 15 to 30 days and pharmacy has two weeks to fill related physician orders.

Exec. Dir. Young stated that DPH/RCP had advised that the proposed pharmacy would be inspected by DPH/RCP approximately 6-8 months after the radioactive materials license was issued. DPH/RCP would forward a copy of the inspection report to the Board.

Board Decision: Motion/Paone to approve the application and waiver specific to "Brachytherapy Sealed Sources" on a provisional basis; provided the Manager of Record provided the articles of organization executed by the Secretary of State and related DPH/RCP approval documentation. Second/Ryle.
Vote: In support; Ryle, DeVita, Horn and Paone, Opposed; none. The motion carried.

3. **10:00 a.m. to 11:00 a.m.**
Autonomics®, Central Processing Program, 2760 Airport Drive, Columbus, OH 43219, Terry Malone, R.Ph., Autonomics® Director of Pharmacy Operations

Autonomics® requested that cancellation of appearance since the central processing program was recently discontinued.

4. **11:00 a.m. to 11:15 a.m.**
Mid-Stream Interchange issues related to MLID Synthroid amendment

The Board and DPH/DCP approved the following written guidance for pharmacists regarding MLID amendment of levothyroxine sodium:

"Massachusetts List of Interchangeable Drug Products (105 CMR 720.000) has been amended removing levothyroxine sodium form the Addition List of Interchangeable Drugs Products (MLID). This regulation is authorized by M.G.L. c.17, s.13 and M.G.L.c.112, s.12D. This means that pharmacists may no longer interchange prescriptions written for Synthroid and other brands with a BX rating such as Unithroid and Levoxyl. For example: If a pharmacist substituted Levoxyl for Synthroid, the Board recommends that the pharmacist contact the prescribing practitioner for a new prescription in order to continue therapy. Please keep this in mind when refilling a prescription that has been interchanged in the past and follow accepted standards of practice to ensure proper drug therapy for your patient. The Board suggests you review the Department of Public Health Policy on Midstream Substitution. The most important point is to keep the patient and prescribing practitioner involved in the process."

5. **11:15 a.m. to 12:30 p.m.** - Board reviewed correspondence and took actions described below.

a) In the matter of DS-00-096, Whittier Pharmacist Inc., 25 Railroad Square, 3rd Floor, Haverhill, MA 01832, request for removal of probation:
Motion/DeVita to approve the request for removal of probation. Second/ Paone. The motion carried.

b) Mass NARAL Reproductive Freedom and Choice correspondence regarding access to the "morning after pill" in MA pharmacies. Board staff provided an overview of an August 29, 2002 meeting with NARAL representatives. No consumer complaints have been filed. Board decision to take no action at this time.

c) ACPE "Draft" proposed definition of Continuing Education for the Profession of Pharmacy": Donna Horn suggested that post-test questions be required at live/didactic CE programs.

d) Registrant Kevin R. Coit, R.Ph. (License Number 18166)request for "LIVE" CE waiver:
Motion/Paone to approve the CE waiver request. Second/DeVita . The motion carried.

e) Clyde T. Pontoriero, C.Ph.T. request for Board advisory opinion regarding "registered" pharmacy technician /certified technician terminology. On July 09, 2002, the Board tabled the item for further discussion. Board advised staff to advise Mr. Pontoriero that 247 CMR authorizes the title "pharmacy technician" only.

f) In the matter of DS-02-125 CVS Pharmacy #224, 650 Main Street, Reading, MA 01867 & PH-02-125 Barbara A. Swanson, R.Ph..
Recused: DeVita
Motion/Ryle to Dismiss the complaint. Second/Horn.
Vote: In support; Horn, Ryle, and Barron, Opposed: Paone, Recused; DeVita
The motion carried.

Discussion relating to recusal matters:
Board counsel advised Board members that the recommended pratice is for any recused member to exit the meeting room during any discussion of a matter which they are recused from participation based on appearance of impropriety concerns regarding any matter which a member has a conflict of interest (based on employment, familial realtionship; financial interst or any other matter). Board counsel advised members who recuse themselves from a matter but who desire to provide comment to the Board on behalf of their employer may only do so after the member has followed certain procedures (written statement to appointing authority, etc.)
The Board requested staff to schedule a State Ethics Commission educational in-service program at an upcoming Board meeting.

g) NABP correspondence regarding ACPE Accreditation of Lebanese American University School of Pharmacy Doctor of Pharmacy Program & Recognition of Canadian Accreditation: for Discussion as such relates to applications for pharmacist licensure. Lebanon school: **Motion**/Horn to follow the usual and

customary licensure procedures for graduates of the Lebanese American University School of Pharmacy Doctor of Pharmacy Program (no FPGEE). Second/Paone. The motion carried unanimously. Canada issue: **Motion**/Horn to discuss Canadian licensure issues at the October 1, 2002 Board meeting with the existing Board policy in hand for reference. Second/DeVita. The motion carried

h) Board Task Force Updates Compounding (Ryle) & Collaborative Practice (Paone): Karen Ryle stated that the task force is reviewing draft compounding regulations.
Collaborative Practice: Bob Paone distributed hand out; additional members may be added to task force.

i) NABP District 1 Meeting, Newport, Rhode Island: Young he forwarded the NABP model guidelines for election of District officers to the NABP annual meeting to the Rhode Island Board. The Board would like nominations for the related positions to take place at least one day before the actual District election.

j) In the matter of PH-00-121: Phillip Fontana. The Board reviewed Registrant's proposal to revise proposed Consent Agreement. The Board did not agree to revisions.

k) The Board requested staff to schedule investigative conferences with consideration for possible Board member recusals.

6. 12:30 p.m. to 1:30 p.m.
Lunch.

7. 1:30 p.m. to 2:00 p.m.
New England Compounding Center, 697 Waverly Street, Framingham, Massachusetts, 01702
The compounding center is represented by Barry J. Cadden, R.Ph., Director of Pharmacy and Lisa M. Conigliaro, R.Ph., Compounding Specialist.

The purpose of the meeting was to discuss a request for Board approval by New England Compounding Center regarding sterile product area renovation plans and a new self-contained class 10 microenvironment (Microsphere™).

Present for discussion: Barry Cadden, R.Ph.

Mr. Cadden provided an overview of New England Compounding Centers request for approval of renovation plans related to the Microsphere®. Cadden said that the center is seeking to expand the existing laboratory area to incorporate the Microsphere® unit for sterile product preparation.

Cadden stated that the Microsphere® will provide for a class 100 clean room environment for medication compounding. Cadden stated that if the mobile Microsphere unit is moved then the unit will be re-certified. Cadden stated

that the center intends to maintain its Central Intravenous Admixture Service Board certification.

Board Decision: **Motion**/DeVita to approve the request by New England Compounding Center to utilize Microsphere®. Second/Ryle. The motion carried.

8. **2:00 p.m. to 2:40 p.m.**
Investigative Conference: DS-02-115 & PH-03-006
In the matter of Shoppers Drug, 24 Fort Pleasant Avenue, Springfield, MA, 01108 (Permit # 23698) and Monty Schwartz, R.Ph. (License # 14670)

The purpose of the conference was to discuss a complaint submitted with the Board alleging failure to fill a prescription properly. The complainant alleged that on or about March 28, 2002, Registrant dispensed Kaletra capsules instead of the prescribed and labeled Keppra 500mg tablets while employed at of Shoppers Drug, 24 Fort Pleasant Avenue, Springfield, MA 01108.

Present for discussion:
Complainant: Not present.
Registrant: Monty Schwartz
Shoppers Drug Representative: Monty Schwartz
Investigator: Alan Van Tassel

CE: Registrant compliant

The Registrant advised the Board that he had previously appeared before the Board with regard to disciplinary complaints.

Investigator Van Tassel reviewed his report of investigation with the Board.

The Registrant said that the investigator's report sounded accurate. The Registrant acknowledged responsibility for the medication error.

The Registrant stated that he did not recall details specific to the medication error incident. He stated the pharmacy is very busy; that there is inadequate space, and that there are many interruptions and distractions in the current workflow model. He is attempting to reduce the noise level in the pharmacy by creating a separate call center. There were 5 pharmacists on duty on the incident date. Volume continues to increase. The Registrant stated that he is attempting to minimize pharmacy errors and is looking at a new visual checking system to integrate to his QS1 program. The medication at issue involved the second refilling of the patient's medication. The technician likely retrieved the wrong medication for filling purposes. The Registrant stated he did not know the identity of the checking and or verification pharmacist. As Manager of Record the Registrant said that he assumed responsibility for the error. The Registrant

stated that the pharmacy has implemented color-coded markers for pharmacist verification identity purposes. All prescriptions are checked by a pharmacist.

Board member Jim DeVita noted that the prescription at issue was filled within the last year but no colored marker was utilized.

The Registrant stated that three pharmacy technicians are the quality assurance checking personnel. Following their check, the medication is forwarded to the packaging station where a pharmacist does the final verification prior to delivery. The stock bottle does not follow along with the filled prescription to the pharmacist at the final checking station. Checking pharmacists rely on identification medications sheets for reference. The Registrant stated he had not seen the 31 CQI recommendations made by the Board's prior CQI Surveyor. He said he would confer with Quality Assurance pharmacist Marion Hoar regarding the number of CQI recommendations that had been implemented.

The Registrant said that the pharmacy is internally tracking medication error rates and such errors are decreasing. The Registrant said that an innovative voice response (IVR) system has not been implemented in the pharmacy.

CQI Surveyor Arthur Chaput provided a summary of his report related to CQI recommendations made following the August 22, 2002 survey.

Board Decision: **Motion**/Paone to take the matter under advisement. Second/ Ryle. The motion carried.

Continued Discussion: Letter to Registrant requesting a written response (30 days) on following issues: 1) implementation schedule and action plan for the CQI recommendations; and 2) evaluation of long-term care pharmacy models recommended by the CQI Surveyor.

9. **2:40 p.m. to 4:00 p.m.**
Board of Registration in Pharmacy Complaint Resolution Processes

Continued discussion tabled due to a lack of appropriate discussion time.

10. 4:00 p.m.
A Motion to adjourn was made by Jim DeVita. The motion was seconded by Karen Ryle. The motion carried. Meeting adjourned.

Respectfully submitted by: _____ 12/6/02
Executive Director Date

_____
Printed Name

Reviewed by counsel: November 25, 2002
Draft approved: November 26, 2002
Board adopted: December 04, 2002