BOARD OF REGISTRATION IN PHARMACY
MINUTES: PHARMACY BOARD MEETING
TUESDAY, MARCH 22, 2005
239 CAUSEWAY STREET, ROOM 206
BOSTON, MASSACHUSETTS 02114

Present: Karen Ryle, R.Ph., M.S. President, James T. DeVita, R.Ph., Past Pres. (excused at 12:20 p.m.), Marilyn M. Barron, MSW, Public Member, Joel Berman, R.Ph., Sophia Pasedis, R.Ph., Pharm.D. (arrived 10am), George Cayer, R.Ph., Pres. Elect, and Harold B. Sparr, R.Ph., M.S.

Absent: William Gouveia, R.Ph., M.S., Donald Accetta, M.D., M.Ph., and Katherine Fabisewski, R.N., Ph.D., and Steven Budish

Staff present: Charles R. Young, R.Ph., Exec. Dir., James Coffey, R.Ph., Assoc. Dir., Susan Manning, Administrative Counsel, Leo McKenna, R.Ph., Pharm.D., CQI Surveyor, Sam Penta, R.Ph. Investigative Supervisor and James Emery, C.Ph.T., Investigator

1. 8:40 a.m. – Call to Order – President Karen Ryle

2. 8:40 a.m. to 9:15 a.m. - File Review
   Office of Investigations: Healthcare Investigators James C. Emery and Samuel J. Penta

In the matter of PH-05-091: Registrant, Paul Lussier:
Investigator Penta reviewed his report of investigation with the Board. Motion/Ryle refer to the matter to prosecutions upon receipt of certified court documents and request a motion for summary decision. Second/Sparr. Motion carried. Mr. Penta noted that a related drug store complaint has been issued.

Criminal Offender Records Information (CORI):
Motion/Ryle to review existing statutes and regulations to discern the feasibility of requiring CORI checks on all new and renewal applications for licensure of pharmacists, pharmacy interns and pharmacy technicians. Second/Sparr. The motion carried.

In the matter of PH-05-087: Catherine McCormack:
Recused - Board Member Joel Berman
Investigator Penta reviewed his report of investigation with the Board (voluntary surrender of license). Motion/Ryle to offer a consent agreement with related referral to MPRS and accept a one year voluntary surrender followed by four years of probation. Second/Sparr. The motion carried.

In the matter of DS-05-075: Registrant, IVP Care Pharmacy, Wilmington:
Investigator Penta reviewed his report of investigation with the Board. Allegedly, the pharmacy engaged in a limited service pharmacy practice without Board waivers. Mr. Penta stated that the pharmacy stocked a limited number of federally controlled

substances (no Schedule II medications). Furthermore Penta represented that the pharmacy stocks on or about 375 total products to include 275 specialty drugs (i.e. fertility and Multiple Sclerosis medications). Mr. Penta stated that the pharmacy primarily engages in mail order business. Motion/Sparr to schedule an investigative conference with IVP Care Pharmacy. Second/Cayer. The motion carried. The Board requested that IVP Care Pharmacy bring daily logs to the conference being that the pharmacy allegedly dispenses approximately 700/800 prescriptions per day with two pharmacists and two technicians on duty. In addition, the pharmacy must demonstrate compliance with USP Standard 797 since it engages in sterile dilution of parental Lupron.

In the matter of PH-05-088: Registrant, Altaf Farooqi (Follow up to DS-05-061: Walgreens Pharmacy, Fall River - case presented 3/15/05). Motion/Sparr to schedule an investigative conference. Second/Cayer. The motion carried.

3. 9:15 a.m. to 9:30 a.m. - Report of Offices
   a) Board counsel: Susan Manning
      i) Pending legal matters

   Motion/Sparr to enter into Executive Session. Second/Ryle. The motion carried.

   Motion/Sparr to return to open session. Second/Cayer. The motion carried.

4. 9:45 a.m. to 10:10 a.m. Investigative Conference: DS-05-045 & PH-05-057. In the matter of North Falmouth II NH Pharmacy, 111 Country Road, North Falmouth, MA, 02556 (Permit No. 3304) and Registrant, Francis P. Bagarella, R.Ph., (License #17872).

   The purpose of the conference was to discuss a complaint filed with the Board alleging the failure to fill a prescription properly for a patient. The complaint alleged that on or about April 09, 2004, the Registrant (Bagarella) dispensed an incorrect dose of lorazepam wherein 1mg was ordered and 0.5mg was dispensed. The complainants (parents of the patient) stated that the dispensed blister pack was labeled as lorazepam 1mg. The complainants noticed that the size of the dispensed tablets were smaller than the usual and contacted the Poison Control Center who confirmed that the dispensed tablets were lorazepam 0.5mg.

Investigator:	Samuel J. Penta
Respondent:	Francis P. Bagarella, R.Ph., Manager of Record
Complainants:	Unable to appear due to scheduling conflict

   Ces: Registrant - compliant

   Investigator Penta reviewed the summary of investigation with the Board.

   According to Registrant, he prepared a replacement blister pack for the patient following incident report notification and notified the facility accordingly.

Mr. Bagarella informed the Board that he has not seen the blister pack at issue despite requesting that the complainants show him the same.

The Registrant stated that the facility allegedly does not have a record of the medication at issue being signed into or out of the control substance book. In addition, Bagarella said that the prescribing practitioner had not recorded any reports from the facility related to alleged side effects suffered by the patient (increased agitation).

Bagarella stated that following the alleged incident report in April of 2004, the complainants continued to obtain medications from his pharmacy through September of 2004.

Bagarella noted that facility policy dictates that only RN's can sign medications into and out of the controlled substances book.

Registrant advised the Board that he is very sorry if an error occurred, but he has not been able to substantiate the allegation.

Investigator Penta stated that according to the complainant, her son ingested 85 out of the 90 doses allegedly dispensed in error.

Decision
Motion/Ryle for Dismissal due to insufficient evidence. Second/Berman. The motion carried.

5. 10:10 a.m. to 10:50 p.m. Investigative Conference: DS-05-052.
In the matter of Walgreens Pharmacy #6295, 229 Andover Street, Peabody, MA, 01960 (Permit No. 3045) and Manager of Record, Shannon L. Bancroft, R.Ph., (License #25021).

The purpose of the conference was to discuss a complaint filed with the Board alleging the failure to adhere to professional standards of pharmacy practice. The complaint alleged that on or about November 24, 2004, Board Agent, Samuel Penta, conducted a compliance inspection and discovered that the Registrant (Walgreens Pharmacy #6295) had 12 outdated Schedule II controlled substances secured in the safe but not reconciled in the perpetual inventory.

Investigator:	Samuel J. Penta
Respondent:	Shannon L. Bancroft, R.Ph. (relocated to S. Carolina on or about December 15, 2004)
Walgreens Representatives:	Patrese Palmese, Pharmacy Supervisor - Boston Central (standing in for Susan Deleo – currently on family leave) & Kristine Sateriale, R.Ph., the current Manager of Record, (License #19989) (standing in for Ms. Bancroft)

Investigator Penta reviewed the summary of investigation with the Board.

Ms. Bancroft stated that she assumed Manager of Record status for Ms. Bancroft at this pharmacy on or about April 2004.

Supervisor Palmese explained that Walgreen's Pharmacy Supervisors oversee approximately 20 pharmacies and generally visit each store at least twice monthly. In addition, Ms. Palmese added that supervisors conduct a yearly audit of each of their assigned pharmacies.

Ms. Palmese stated that Ms. Bancroft now works for Walgreens in S. Carolina. According to Ms. Palmese, all the Walgreen Pharmacies in her district are compliant with regard to Board regulations concerning perpetual inventory requirements.

Decision
Drug Store: Motion/Ryle for Advisory Letter. Second/Cayer. The motion carried.

Pharmacist: Motion/Ryle to file a complaint against Shannon Bancroft and issue an Advisory Letter. Second/DeVita. The motion carried.

Motion/Pasedis to file a complaint against Walgreens Pharmacy Supervisor Susan Deleo and issue an Advisory Letter. Second/Berman. The motion carried.

6. 11:00 a.m. to 11:40 Investigative Conference: DS-05-034 and PH-05-054
In the matter of Walgreens Pharmacy #5445, 1440 Boston Road, Springfield, MA 01129 (Permit #2964), and Ralph A. Guiggio R.Ph., License #24126 (Registrant).

The purpose of the conference was to discuss a complaint filed with the Board alleging failure to fill a prescription properly. The complaint alleged that on or about September 27, 2004, the Registrant dispensed Adderall XR 30mg instead of the prescribed Ritalin LA 30mg.

Investigator:	Samuel Penta, R.Ph.
Respondent:	Ralph A. Guiggio, R.Ph.
Walgreens Representatives:	Theresa O'Brien, R.Ph., (Manager of Record) & Steve Pashko, R.Ph., Pharmacy Supervisor
Complainants:	Present

Ces: Registrant - **not** compliant in 2004 (deficient by 8 CE's).
Motion/Ryle to issue an Advisory Letter (based upon CEs only) to complete 24 credits in 60 days (originals to the Board). Second/DeVita. The motion carried.

Investigator Penta reviewed the summary of investigation with the Board.

Mr. Penta indicated that the that the pharmacy does not document an offer to counsel.

According to the complainant, Mr. Guiggio did not fill the prescription at issue being that she witnessed only two females present behind the pharmacy counter when she dropped off the prescription in the morning. The complainant stated that she waited at the pharmacy counter for the prescription to be filled. The complainant conceded that it was possible that Mr. Guggio was working in the back of the pharmacy out of her line of sight.

The complainant distributed the prescription vial at issue to the Board for review (9/27/04 dispensing date).

Mr. Guiggio explained that on the incident date, there was pharmacist overlap between 2 p.m. and 4 p.m. However, he personally cancelled the prescription at issue and data entered the prescription into computer. Mr. Guggio affirmed that his initials were evident on the prescription vial, computer data entry and final product verification. The Registrant offered an apology to the complainant.

According to Manager of Record O'Brien, a company incident report was immediately completed and an was provided to the patients mother. Ms. O'Brien stated that she notified the Registrant about the incident.

Mr. Pashko represented that currently the Walgreens computer verification information is available in color format for pharmacist review. However, Mr. Pashko noted that specific to the incident date, only a black and white format was available to pharmacists for reference.

The Board requested that Mr. Pashko consult with the Walgreens corporate office to consider providing consumers with a colored picture of medication(s) dispensed.

With regard to corrective actions, Walgreens now uses an electronic scale which is interfaced with NDC number of drug, to diminish the possibility of an error.

The Registrant said that he asks all patients whether they have any questions about their medications if he is working at the register. However, the Registrant stated that in this case, he likely did not wait on the complainant.

According to Mr. Pashko, Walgreens pharmacy technicians are trained that they must consult with the pharmacist for all new prescriptions in order for counseling to be provided. The designation of "New Prescription" is evident to pharmacy technicians upon the prescription receipt.

Mr. Pashko stated that since the prescription was not logged in, a pharmacist must check off all entries on the usage reports. (no perpetual inventory in the computer).

The complainant advised the Board that she filed this complaint because she wanted to be sure this type of incident does not happen again.

Ms. O'Brien stated that when she noticed she was short 30 Adderral XR 30mg on the perpetual inventory, she reviewed the prescriptions at issue for follow up with all patients and called each to determine whether they received an extra 30 tablets. However, the problem was that the drug was not logged into the perpetual inventory.

The Registrant said the pharmacy does not document whether the offer to counsel was made and or provided.

Mr. Pashko indicated that the company standard is for all pharmacists to provide counseling for all new medications. However, Mr. Pashko stated that this company policy is not reduced to writing.

Motion/Sparr to take the matter under advisement. Second/Cayer. The motion carried.

Decision:
Drug Store: Motion/ Cayer for Advisory Letter to include a USP Medication Error Report. Second/Ryle. The motion carried.

Pharmacist: Motion/Cayer for Advisory Letter and shall complete 2 Ces in Medication Error Prevention (in addition to the 24 hour CE penalty referenced above). Second/Ryle. The motion carried.

7. 11:40 a.m. to 12:20 p.m. Investigative Conference: DS-05-009 & PH-05-069. In the matter of Children's Hospital Pharmacy, 300 Longwood Avenue, Boston, MA, 02115 (Controlled Substance Reg. No. 143), Richard J. Simon, R.Ph. License # 21206 (Registrant)

The purpose of the conference was to re-discuss (original conference held on 11/23/04) a complaint filed with the Board alleging the failure to fill an order properly for a pediatric patient on July 2, 2004. The complaint alleged that the pharmacy department (M-7 satellite) dispensed an incorrect dose (prepared in response to a nursing staff "missing medication request") of intravenous Pentamidine wherein 2mg/ml was ordered and 37.7mg/ml was dispensed. According to the Director of Pharmacy, Albert J. Patterson, Pharm.D., R.Ph., the Pentamidine dose was incorrectly prepared on July 02, 2004 by a certified pharmacy technician (Janice M. Jourdan, Reg. No. 4027) and dispensed for administration without being checked by a pharmacist (pharmacists on duty included: Amy Delorme, R.Ph., Lic. No. 25692, Richard J. Simon, R.Ph., Lic. No. 21206 and Lynne Traskus, R.Ph., Lic. No. 24150).

Investigator:	Samuel J. Penta
Respondent:	Richard J. Simon, R.Ph. and Amy Delorme, R.Ph.
Attorney:	Paul Garbarini, Esq. Representing Registrant
Attorney:	James S. Hamrock, Jr. representing Children's Hospital and Dr. Albert J. Patterson, Pharm.D., R.Ph.
Attorney:	John P. Puleo representing Amy Delorme, Pharm.D., R.Ph.

Witnesses: Dr. Albert J. Patterson, Pharm.D., R.Ph., Director of Pharmacy

Investigator Penta reviewed the summary of investigation with the Board.

Dr. Patterson was requested by the Board to produce evidence of the prefilled syringe and vial to review signatures and/or initials of responsible pharmacists. Registrant had seen the syringe prior to this conference.

The evidence was first shown to Registrant's attorney, Mr. Garbarini prior to being submitted to the Board members for their review.

Upon review of the prefilled syringe and related vial, Mr. Simon stated that the initial and or signature on such was not his. Simon said that he recalled seeing the product in the bin but does not remember handling the product.

Mr. Simon stated that specific to the incident date, he set the prefilled syringe aside for administrator review after it was returned to the pharmacy by a nurse during the evening shift who asked that the product be validated for appropriate concentration.

Dr. Patterson said that the specific gravity of the product at issue was tested by the hospital the following morning.

Amy Delorme reviewed both the prefilled syringe and related vial, and stated that the initial and or signature on such was not hers. Ms. Delorme said that she used blue ink to check prescriptions and that her signature is bubbly.

Dr. Patterson said the nurse who administered the medication to the patient did not put her initials and or signature on the involved vial and pharmacy technicians would not affix their initials and or signature to the same either.

Decision
Motion/Cayer to take the matter under advisement. Second/DeVita. The motion carried.

Pharmacist: Motion/Cayer for dismissal (Simon) due to insufficient evidence. Second/Sparr. The motion carried. The motion carried unanimously.

Hospital Pharmacy: Motion/Sparr for Advisory Letter with stipulation that the pharmacy department develop a system to identify and authenticate the licensee(s) responsible for both data entry and final prescription check prior to any medication being dispensed for administration to a patient. In addition, pharmacy technicians should not be permitted to produce missing dose labels without pharmacist validation. Second/Ryle. The motion carried

Pharmacy Technician: Motion/Ryle for Advisory Letter to include reference in the decision letter that the Board is aware that the involved technician received remedial training. Second/DeVita. The motion carried.

8. 12:20 p.m. to 1:20 p.m. – Lunch

9. 1:20 p.m. to 2:00 p.m. Investigative Conference: DS-05-044 & PH-05-055. In the matter of CVS Pharmacy #594, 105 Davis Straights, Falmouth, MA, 02540 (Permit #2839), and Luigi Zezze, RPh., License #19124 (Registrant).

The purpose of the conference was to discuss a complaint filed with the Board alleging the failure to fill a prescription properly for a patient. The complaint alleged that on or about November 24, 2004, the Registrant dispensed Zetia labeled for Zyrtec 10mg while employed at CVS #594, 105 Davis Straights, Falmouth, MA 02540.

Investigator:	Samuel J. Penta
Respondent:	Luigi Zezze, R.Ph.
CVS Representatives:	John Correira, R.Ph., Pharmacy Supervisor & Todd Macauley (Manager of Record)
Complainant:	Present

Ces: Registrant and Manager of Record - compliant

Investigator Penta reviewed the summary of investigation with the Board.

The complainant stated that the report was accurate. The complainant presented the Board with the prescription vial for reference (original stock bottle). The complainant indicated that she picked up the medication on a weekday (the day before Thanksgiving), and that the pharmacy appeared to be very busy.

Registrant confirmed that he was the dispensing pharmacist specific to the medication error. Registrant apologized to the complainant for the incident. The medication was the 1st refill. The pharmacy does not have bar code scanning for quality assurance purposes for purposes of drug identification.

Pharmacy Manager of Record Macauley stated that on or about 75-80% of medications are available for reference in the computer with pill imaging.

The pharmacy technician initials of "CB" appeared on the prescription vial

Macauley said that the medication was moved post incident. Macauley contacted both the patient and the physician about the incident. In addition, Mr. Macauley filed a company incident report.

CVS Supervisor Correira stated that CVS requires a required list of on or about 30 medications to be separated on the shelves with red shelf dividers and yellow stickers related to the Quality First Program. The incident report data is correlated at the CVS corporate office.

Decision:
Drug Store: Motion/Sparr to Dismiss the complaint. Second/Barron. The motion carried.

Pharmacist: Motion/Sparr for an Advisory Letter and shall complete 2 Ces in Medication Error Prevention and file a USP Medication Error Report. Second/Ryle. The motion carried.

10. 2:00 p.m. to 2:40 p.m. Investigative Conference: DS-05-022
In the matter of CVS Pharmacy #1875, 414 Union Street, Ashland, MA, 01721 (Permit No. 3348) and Manager of Record, Val I. Uzoma, R.Ph., (License #18834).

The purpose of the conference was to discuss a complaint filed with the Board alleging the failure to fill a prescription properly to a pediatric patient. The complaint alleged that on or about September 17, 2003, CVS Pharmacy #1875, located on 414 Union Street, in Ashland, filled a prescription for Hydrocortisone / Acid Mantle cream wherein the hydrocortisone powder was contaminated with testosterone powder. The patient experienced precocious sexual development as a result. The September 17, 2003, prescription for Hydrocortisone / Acid Mantle cream was data processed and the related label and compounding ingredients were verified by Registrant, Val I. Uzoma, R.Ph. (License #18834). The prescription was purportedly compounded that same evening by Registrant, W. Rick Allard, R.Ph. (License #14566). On April 06, 2004, the prescription was refilled by data entry pharmacist, Registrant, John W. Hebb, R.Ph. (License #15131) and was verified and compounded in two batches (4/6/04 & 4/7/04) by Registrant, Rima N. Gerges-Maalouf, R.Ph. (License #22715) and or W. Rick Allard, R.Ph. It should be noted that the pharmacy did not maintain a compounding log specific to either of the above-referenced dispensing.

Investigator:	James C. Emery
Respondent:	Val Uzoma, R.Ph.
Complainant:	Not present
CVS Representatives:	W. Rick Allard, R.Ph., Rima N. Gerges-Maalouf, R.Ph., Todd Pikor, Pharmacy District Manager

Investigator Penta reviewed the summary of investigation with the Board.

Pikor apologized to the Board on behalf of the involved pharmacists for the incident(s).

Val Uzoma apologized for the incident(s) as well. Mr. Uzoma does not allow certified pharmacy technicians to engage in compounding. Uzoma noted that only pharmacy interns are allowed to assist the pharmacy with compounding. Uzoma noted that the pharmacy compounds about 3 to 5 prescriptions per week.

Mr. Allard noted that he is a floater with CVS and does not recall certified technicians being involved with the compounding procedures.

The hydrocortisone was not tested by CVS with regard to concerns for contamination. Uzoma was not sure that the stock compound on hand at CVS when the incident was reported was one in the same as the stock bottle used for the dispensing.

With regard the 9/17/03, compounding, Mr. Allard does not recall compounding the medication but could have compounded such time permitting.

Uzoma stated that a manufacturing / compounding log was not maintained by CVS specific to the compounding at issue. However, a new log was instituted following the incident and pharmacists are required to initial this log. Uzoma stated that he is familiar with USP non-sterile compounding procedures.

Mr. Pikor believes that the 9/17/03, compound was picked up the following day.

According to the Board, the April 6th and 7th, 2004, compounding refill was not an issue.

Decision:
Drug Store: Motion/Sparr for Advisory Letter and shall submit copy of written policies and procedures to the Board which describe compounding procedures and must reference compliance with current USP Standard 795. In addition, the pharmacy shall file a USP Medication Error Report describing the "look alike packaging". Second/Cayer. The motion carried.

Pharmacists:
Motion/Cayer for Advisory Letter to Uzoma for the 9/17/03 filling (The Board shall file a related complaint). Second/Pasedis. The motion carried
Motion/Cayer for Advisory Letter for Allard for the 9/17/03 filling (The Board shall file a related complaint). Second/Pasedis. The motion carried.

11. 2:45 p.m. Request for Waiver to 247 CMR 6.02(4) and 9.01(15)
In the Matter of Priority Healthcare.
Priority Healthcare Pharmacy previously met with the Board on March 15, 2005 to discuss an application for a retail pharmacy. Following description of the specialty services they intended to provide to the public, the Board advised the applicant to submit a waiver petition to the Board. The waiver sought authorization to operate as a limited service pharmacy with limited inventories.

Motion/Pasedis to approve the waiver submission. Second/Berman. The motion carried.

Additional Discussion: The Board discussed the March 15, 2005 Palladone risk management presentation by Purdue Pharmacy and continues to be concerned about the safety and diversion issues with its availability.
Motion/Ryle to add Palladone to the existing OxyContin policy regarding requirement choice to stock, or not stock a representative inventory. Second/Berman. The motion carried.

Motion/Sparr to request that DPH be notified that Board would like DPH-DCP to consider the benefits of rescheduling of Palladone (hydromorphone) to Class I. Second/Cayer. The motion carried unanimously.

12. Motion/Ryle to adjourn. Second/Sparr. The motion carried. The Board meeting adjourned at 2:55 p.m.

Respectfully submitted by:

8/09/05

Charles R. Young, R.Ph.
Executive Director
Date:

Submitted to Board Counsel: March 30, 2005
Approved: March 30, 2005
Approved by Board: April 26, 2005

BOARD OF REGISTRATION IN PHARMACY
EXECUTIVE SESSION MINUTES
TUESDAY, MARCH 22, 2005
239 CAUSEWAY STREET, ROOM 206
BOSTON, MASSACHUSETTS 02114

Board Counsel Susan Manning reviewed the following matters with the Board.

In the matter of PH-05-091: Registrant, Paul Lussier:
Investigator Penta noted that there are current criminal charges pending against Mr. Lussier. In addition, there are prior convictions of record for Board consideration. Board Counsel advised Mr. Penta to obtain certified records of related court dispositions.

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure
239 Causeway Street, Boston, MA 02114

MITT ROMNEY
GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

RONALD PRESTON
SECRETARY

PAUL J. COTE, JR.
COMMISSIONER

JEAN K. PONTIKAS
DIRECTOR

TO : William Galvin, Secretary of the Commonwealth

FROM : Charles R. Young, Executive Director, Board of Registration in Pharmacy

DATE : March 16, 2005

RE : Additional Public Meeting

Please be advised that the Board of Registration in Pharmacy has voted to schedule an additional Public Meeting on Tuesday, March 22, 2005, from 8 :30 a.m. to 5 :00 p.m., at 239 Causeway Street, Room 206, Boston, MA 02114.

Thank you.

Cc : Ronald Preston, Secretary, Executive Office of Health and Human Services
Paul J. Cote, Jr. Commissioner
Jean Pontikas, Director of Division of Health Professions Licensure