BOARD OF REGISTRATION IN PHARMACY
PHARMACY BOARD MEETING MINUTES
TUESDAY, MARCH 26, 2002
239 CAUSEWAY STREET, ROOM 206
BOSTON, MASSACHUSETTS 02114

The meeting was called to order by President Harold B. Sparr at 9:30 a.m.

The following Board members were present: Harold B. Sparr, R.Ph., MS, President, Donna M. Horn, R.Ph., Secretary, Karen M. Ryle, R.Ph., MS, James T. DeVita, R.Ph., Marilyn Barron, MSW (excused 2:40 p.m.), Public Member and Dr. Robert P. Paone, R.Ph., Pharm. D. (excused at 11:40 a.m.).

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; Investigative Conference Meeting

   Minutes for December 18, 2001: approve ____ amend __X__
   Vote: A Motion was made by Donna Horn to approve the minutes as amended (page 7, Item L spelling change for HIPA. The motion was seconded by Karen Ryle. The motion carried. Minutes approved.
   Minutes for January 08, 2002: approve ____ amend ____
   Vote: Tabled
   Minutes for January 22, 2002: approve ____ amend ____
   Vote: Tabled
   Minutes: February 05, 2002: approve ____ amend ____
   Vote: Tabled

2. **9:40 a.m. to 10:10 a.m.**
   In the Matter of G. Bruce Rumph, Esquire, Registrant (License No. 15914/ Exp. 12/31/1988) – Request for Reinstatement

   Registrant worked 14 years as a pharmacist and taught pharmacology for 2 years at a state school prior to practicing law. He was licensed in NY, VT and MA. Rumph stated that he has completed 2 CE's to date and has not completed a recent pharmacy externship.

   Board Decision: Motion/Karen Ryle to decrease the number of experiential hours

required from 1500 to 500 but other Board conditions (NAPLEX included) unchanged. Second/Paone. The motion carried unanimously.

3. **10:10 a.m. to 10:50 a.m.**
Investigative Conference: DS-02-042 & PH-02-063
In the matter of CVS Pharmacy #26, 590 Fellsway, Medford, MA 02155 (Permit # 2912) and Kim Chi Ngo, R.Ph. (License # 21824).

The complainant alleged that on October 02, 200I, the Registrant dispensed Topamax 25mg rather than Toprol XL 25mg tablets (refill prescription) as prescribed and labeled while employed at CVS Pharmacy #26, 590 Fellsway, Medford, Massachusetts.

Present for discussion:
Consumer
Registrant: Kim Chi Ngo
CVS Manager of Record: Kim Chi Ngo
CVS Representative: Peter Simmons
Investigator: Alan Van Tassel
Recused: Jim DeVita

CE's: compliant.

The consumer allegedly ingested one tablet of improper medication. CVS Pharmacy #26 is a 24-hour pharmacy department.

The Registrant acknowledged responsibility for the medication error. She stated that she checked the prescription by opening the stock bottle and cross-referencing that against the contents in prescription vial. She recalled seeing "25" on top of the medication so she believed the prescription was dispensed properly.

With regard to corrective actions, Ngo stated she placed a red CVS shelf talker tag on the prescription bottle to highlight the discrepancy between the regular strength and extended release Toprol formulations. She noted that Toprol XL 25mg was not available on the CVS EPIC computer system for pill imaging reference at the time of the incident. She stated CVS policy requires that when a medication pill image is not available on the computer screen for pharmacist final verification, then the manufacturer's stock bottle must accompany the filled prescription vial to the pharmacist checking area. She has completed the CVS Pharmacy "Quality First" medication reduction continuing education program.

The complainant expressed concern that the pharmacy appeared very busy. The family had notified the prescribing practitioner about the medication error. CVS apologized to her family.

CVS rep. Peter Simmons informed the Board that red shelf dividers are utilized in that pharmacy. He was uncertain whether CVS offered a "no pill image"shelf tag for pharmacy reference. Simmons said that CD-ROM pill imaging updates are conducted by CVS on at least on a quarterly basis.

Board Decision: Motion/Paone to issue both the Registrant and CVS Pharmacy #26 an Advisory Letter for the failure to fill a prescription properly with the following stipulations: 1) Registrant to file a USP Medication Error Report with USP PRN (copy to Board); and 2) Registrant to complete a two hour "ISMP" home study medication error reduction continuing education program. Second/Horn with additional stipulations: the pharmacy shall implement quality assurance shelf tags in those circumstances where the CVS EPIC software system does not provide a pill imaging for pharmacist verification and the pharmacy staff should review the CVS company policy for medication incident reporting and the incident should be incorporated into the CVS "Quality First" medication error reduction program. The Motion carried unanimously (DeVita recused).

4. **11:00 a.m. to 11:40 a.m.**
Investigative Conference: DS-02-030 & PH-02-043
In the Matter of CVS Pharmacy #1888, 278 Washington Street, Westwood, MA 02090 (Permit # 2293) and Stephen M. Driscoll, R.Ph. (License # 16539).

The complainant (consumer) alleged that on October 08, 2001, Registrant dispensed Avapro 300mg rather than Avapro 150mg tablets as prescribed and labeled while employed at CVS Pharmacy #1888, 278 Washington Street, Westwood, MA.

Present for discussion:
Consumer
Registrant: Stephen M. Driscoll
CVS Manager of Record: Stephen M. Driscoll
CVS Representative: Bruce Kaplan
Investigator: James C. Emery
Recused: Jim DeVita

CE's: Compliant.

The Registrant acknowledged responsibility for the medication error and outlined the corrective measures that have been implemented by the pharmacy. Registrant stated he did not contact the prescribing practitioner's office because he did not realize that the patient had ingested the medication at issue. He stated that a fill-in pharmacist spoke to the patient about the report of a medication error and likely upset the consumer by allegedly advising the complainant that "accidents happen". Kaplan stated he met with the fill in pharmacist regarding the matter and discussed the incident with the CVS company trainer to reiterate the appropriate company response to any report of a

medication error. Kaplan said that pill imaging was available at CVS for Avapro 150mg at the time of the incident. He stated he did speak to the complainant about the matter. Driscoll said that the prescription was reduced to writing by another staff pharmacist about three (3) months prior to the dispensing. Driscoll had not attended the CVS "Quality First" training program.

CVS rep. Bruce Kaplan stated that the "accidents happen" comment was neither appropriate nor consistent with CVS policy. Kaplan noted that an incident report should have been reconciled and the patient should have been referred to the district manager for related follow-up and should have provided better follow up to the patient following medication error incident reporting.

Board Decision: Motion/Paone to issue both the Registrant and CVS Pharmacy #1888 an Advisory Letter for the failure to fill a prescription properly with the following stipulations: 1) Registrant to file a USP Medication Error Report with USP PRN (a copy to the Board); 2) Registrant to complete a two hour "TSMP" home study medication error reduction continuing education program; and 3) Registrant to complete the CVS "Quality First" program as soon as possible. Second/Ryle. The Motion carried unanimously (DeVita recused).

5. **11:40 a.m. to 12:20 p.m.**
Investigative Conference: DS-02-008 & PH-02-032
In the matter of CVS Pharmacy #946, 158 North Main Street, Route 122, Uxbridge, MA 01569 (Permit # 1457) and Christine L. Silvestre, R.Ph. (License # 22506).

The complainant (consumer) alleged that on May 31, 2001, the Registrant dispensed Putrinethol rather than Propylthiouracil 50mg tablets as prescribed and labeled while employed at CVS Pharmacy #946, 158 North Main Street, Route 122, Uxbridge, MA.

Present for discussion:
Consumer: Not present
Registrant: Christine L. Silvestre
CVS Manager of Record: Edwin Szczepanik Jr.
CVS Representative: Bill Leach
Investigator: Alan Van Tassel
Recused: Jim DeVita

CE's: Registrant and Manager of Record complainant.

The Registrant acknowledged responsibility for the medication error. She said she routinely conducts NDC checks for prescription filling accuracy but could have been distracted during the verification process. The prescription volume was normal on the incident date and there was one additional overlap pharmacist on duty. She has attended the CVS "Quality First" training program.

Szczepanik described the corrective measures implemented following the incident to include EPIC system and a dedicated work area for the verifying pharmacist to decrease the likelihood of interruptions. He stated that he reduced the prescription at issue to writing in the pharmacy. The consumer reported the medication incident to him and an apology was offered. The consumer allegedly developed a rash as a result of the medication error.

CVS District Manager Bill Leach stated that Propylthiouracil is on the CVS quality assurance dispensing list for accuracy and that EPIC is now updated monthly. He stated that CVS policy requires that non-pill image stickers be placed on pharmacy dispensing shelves for all medications are not available in the CVS EPIC system.

Board Decision: Motion/Horn to issue the Registrant and CVS Pharmacy #26 an Advisory Letter for the failure to fill a prescription properly with the following stipulations: 1) Registrant to file a USP Medication Error Report with USP PRN (copy to Board); and 2) Registrant to complete a two hour "ISMP" home study medication error reduction continuing education program. Second/Ryle. The Motion carried unanimously (DeVita recused).

6. **12:20 p.m. to 1:20 p.m.**
   Lunch

7. **1:20 p.m. to 2:00 p.m.**
   Applications for Wholesale Distributors
   In the matter of Denmarks Inc., 105 Rumford Avenue, Auburndale, MA and 550 MacArthur Blvd., Pocasset, MA
   Loree Anderson, VP Operations for Denmarks Pocasset / Mary McGrath, VP Operations for Denmarks/Auburndale and Anne Guarini, Corporate Director of Patient Services.

   Board Member Donna Horn was not present for the discussion.

   The applicants plan to distribute catheters, feeding tubes, ventilator circuits, sterile water and normal saline.

   McGrath stated that approx. one year ago, Allegiance (vendor for Denmarks Inc. supplying stock product) advised Denmarks Inc. that Denmarks needed to provide Allegiance with evidence of registration as a MA wholesale distributor. Denmarks Inc. maintains a controlled substance registration as a distributor of Schedule VI products from the DPH. Denmarks Inc. distributes the following legend products: oxygen, normal saline, bacteriostatic water for injection, catheters , feeding tubes, ventilator circuits, enteral nutrition (no compounded medications but products like Ensure etc.),

respiratory equipment, nebulizers. Denmarks inc. stocks syringes adaptable to hypodermic administration (no needles).

Loree Anderson stated Denmarks Inc. is a medical device retailer that receives physician order sheets/prescriptions for products distributed. Anderson said that Denmarks Inc. has a respiratory therapist on staff but not a pharmacist. Anderson said that patients seeking related prescription medications (i.e. nebulizer solutions) are referred to a sister company in CT, which is licensed as a pharmacy. McGrath stated that Denmarks Inc. maintains a controlled substance registration number as a distributor with DPH for Schedule VI products.

Motion/Ryle to take the matter under advisement. Second/Barron. The motion carried.

8. **2:00 p.m. to 2:40 p.m.**
Investigative Conference: DS-02-028 and PH-02-031
In the matter of Walgreens Pharmacy #3548, 225 Main Street, Stoneham, MA 02180 (Permit #2713) and Karen Williams, R.Ph. (License # 20865)

The complainant (consumer) alleged that on September 12, 2001, Registrant dispensed Coumadin 5mg tablets rather than Coumadin 1mg tablets as prescribed while employed at Walgreens Pharmacy #3548, 225 Main Street, Stoneham, MA.

Present for discussion:
Consumer: Present
Registrant: Karen Williams
Walgeens Manager of Record: Karen Williams
Walgreens Representative: Bob Gladstone
Investigator: Alan Van Tassel

CE's: Complaint

The Registrant advised the Board that she previously appeared before the Board with regard to a disciplinary matter.

The complainant was hospitalized as a result of the medication error, which was discovered by a Harvard Vanguard nurse who reported the matter to the prescribing practitioner. The Walgreens Manager of Record at the time is currently unavailable due to a medical disability.

The Registrant acknowledged responsibility for the medication error. She stated she may have been confused about the prescription dosing since the Coumadin 5mg was written out in large print by the physician on the prescription but the prescription label read 1mg tablets. Williams verified the dosing instructions but suggested that perhaps she checked it too fast.

Walgreens Pharmacy Supervisor Bob Gladstone stated that company policy requires pharmacists and or staff to write the address of the patient on prescriptions. The complainant stated that a second prescription was picked up at the pharmacy on the incident date. The complainant is not currently experiencing any known untoward effects as a result of the medication error and is no longer on this medication.

Ms. Williams reported that an incident report was completed following notification to the pharmacy of the error. Williams stated that the prescribing practitioner reported the medication error to her by telephone. Williams said that another staff pharmacist spoke to the patient about the incident and dispensed the proper strength of medication. Williams outlined the corrective measures implemented after the incident, including separation of different strengths of Coumadin on the dispensing shelves; verifying the appropriateness of data entry; and pill imaging software final verification by the pharmacist.

Mr. Gladstone stated that medication incident reports issues are discussed at the pharmacy staff level and district pharmacy managers meetings. Karen Ryle recommended that the pharmacy consider implementing a policy wherein all Coumadin prescriptions are verified by a second party prior to dispensing.

Board Decision: Motion/DeVita to issue the Registrant and Walgreens Pharmacy #3548 an Advisory Letter for the failure to fill a prescription properly with the following stipulations: 1) Registrant to file a USP Medication Error Report with USP PRN (a copy to the Board); 2) Registrant to complete a two (2) hour "ISMP" home study medication error reduction continuing education program; and 3) pharmacy department to submit documentation of the establishment of a policy that narrow therapeutic medications shall be dispensed only after final product verification by two pharmacists where feasible or one pharmacist and one pharmacy technician / certified technician and or an intern; all within 60 days. Second/Barron. The Motion carried unanimously.

9. **2:40 p.m. to 3:20 p.m.**
Investigative Conference: DS-02-004 & PH-02-004 & PH-02-023
In the matter of CVS Pharmacy #2592, 468 Blue Hill Avenue, Boston, MA 02121 (Permit # 3011) and Jamal D. Liles, R.Ph., (License # 24486).

The purpose of the conference was to discuss a complaint submitted by consumer and the Board alleging the failure to fill a prescription properly and failure to complete requisite continuing education credits. The complainant alleged that on July 01, 2001 the Registrant dispensed Bactrim DS rather than Clonazepam 0.5mg as prescribed while employed at CVS Pharmacy #2592, 468 Blue Hill Avenue, Boston, MA.

Present for discussion:
Consumer: Present and accompanied by an interpreter
Registrant: Jamal D. Liles

CVS Manager of Record:
CVS Representative: Peter Simmons
Investigator: Alan Van Tassel for Leslie S. Doyle
Recused: Jim DeVita

The Board reviewed the Registrant's continuing education certificates and determined Registrant was not in compliance. Registrant was deficient two Live CEs in 2000. Registrant was advised was required to complete six live CEs in 60 days. Registrant was also deficient five live CE's in 2001. Registrant was advised to provide evidence of either five hours of 2001 CE within 30 days or submit 15 hours of remedial live CE to the Board within 60 days.

According to the investigator, the consumer allegedly ingested the improper medication for approx. 30 days. The Registrant had advised the investigator the medication error most likely occurred because the pharmacy technicians were not properly trained.

The complainant provided the prescription vial at issue to the Board to review.

The Registrant stated that the prescription at issue was filled correctly but was bagged improperly with the wrong medication ending up in the patient's bag. Registrant floated for CVS for about 1.5 years before becoming Manager of Record at the Blue Hill Ave. location. He stated that the pharmacy's prescription volume was moderate but that there were two cashiers undergoing training at the time of the incident. The clinic physician notified him about the medication error. He then called the patient to discuss the matter and spoke to the patient's daughter because of a language barrier. He apologized to the patient's representative regarding the medication incident. The customer did not return the medication alleged to be dispensed in error to the pharmacy. An incident report was filed with both the CVS District and Regional Healthcare Managers. He has attended the CVS "Quality First" training program.

Liles and CVS Regional Healthcare Manager Peter Simmons stated that pharmacy policy now requires a pharmacist to bag checked prescriptions. Liles said that the technicians on staff are now adequately trained. He discovered the correct patient's medications in the pharmacy about two weeks after the original filling when returning unclaimed prescription to stock.

Through an interpreter, the complainant represented took the wrong medication for approx. 23 days (36 of 60 tablets were left in the prescription bottle). She went to a clinic due to pain and generally not feeling well. The clinic physician discovered that the wrong medication was in the prescription vial.

Board Decision: Motion/Horn to issue Registrant and CVS Pharmacy #2592, an Advisory Letter for the failure to fill a prescription properly with the following

stipulations: 1) Registrant to to file a USP Medication Error Report with USP PRN (a copy to the Board);and 2) Registrant to complete a two hour "ISMP" home study medication error reduction continuing education program; verification to Board within 60 days. Second/Ryle. Motion carried unanimously (DeVita recused).

10. 3:20 p.m. to 4:10 p.m.
Petition for Waiver: Massachusetts General Hospital Nuclear Pharmacy, Edwards Research Building, Room #20, 55 Fruit Street, Boston, MA 02114; MGH Director of Nuclear Pharmacy, Ronald J. Callahan, Ph.D., B.C.N.P.

MGH Nuclear Pharmacy waiver petition requests waiver of 247 CMR13.05 (11)(a), providing: "Radiopharmaceuticals shall be dispensed in single unit doses".

Dr. Callahan stated the waiver was requested to permit MGH Nuclear Pharmacy to dispense certain radiopharmaceuticals used in Positron Emission Tomography (PET) in multiple dose containers for distribution to authorized practitioners. He stated that the half-life of FDG is approx. 109 and that, due to the complex nature of the FDG production process, the best method of assuring an uninterrupted supply of the PET radiopharmaceuticals is for a production facility to have an alternative supply of the PET radiopharmaceutical from a secondary source such as MGH's Nuclear Pharmacy proposal.

Exec. Dir. Chuck Young commented that under strict criteria the proposed activity is permitted by our regulations.

Motion/Sparr to approve the waiver. Second/Ryle. The motion carried.

11. 4:10 p.m. to 4:45 p.m.
Administrative Business Items

A) Candidate for pharmacist licensure (S.A): reviewed and discussed.
B) NABP memorandum regarding "Proposed Constitutional Amendments to NABP's Constitution and Bylaws" reviewed: all proposed amendments must be submitted to NABP in writing by April 04, 2002.

C) NABP memorandum regarding "Department of Veterans Affairs Reimbursement for NAPLEX / MPJE" reviewed.

D) The Board requested that OxyContin® related issues be scheduled for April 23, 2002 meeting for discussion and vote. Board requested an addictionologist be invited to discuss the impact on patients should the Board decide not to require pharmacy departments to stock OxyContin®.

E) In the matter of PH-98-057 Andrea M. Hilse (License No. 22078)
Motion/Sparr to discuss the matter in executive session (4:10 p.m.). Second/Barron.

12. 4:45 p.m.
Motion/Sparr to end executive session. Second/Horn. The motion carried unanimously.

13. 4:45 p.m.

Motion/Horn to adjourn the meeting. Second/Ryle. The motion carried. Meeting adjourned.

Respectfully submitted by: _____ 10/9/02
Executive Director Date

_____
Printed Name

Reviewed by counsel: September 5, 2002
Draft approved: September 11, 2002
Board adopted: September 24, 2002

Executive Session Minutes
Board of Registration in Pharmacy
March 26, 2002

11. 4:10 p.m. Administrative Business Items

(E) In the matter of [redacted]
Motion/Sparr to discuss the matter in executive session. Second/Barron. The motion carried unanimously.

Board Counsel Susan Manning provided the Board with an overview of new information related to the proposed consent agreement for reinstatement .

The Board advised Susan Manning to amend the consent agreement to request documentation from two physicians attesting to the fact that the Registrant may safely return to practice pharmacy while on her prescribed medication regimen.

Motion/Sparr to end executive session. Second/Horn. The motion carried unanimously.