BOARD OF REGISTRATION IN PHARMACY BOARD MEETING MINUTES TUESDAY, JUNE 25, 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. (1:20 p.m.), Secretary, Karen M. Ryle, R.Ph., MS, Robert P. Paone, R.Ph., Pharm. D., and Marilyn M. Barron, MSW, Public Member.

The following Board staff were present: Charles R. Young, R.Ph., Executive Director, Susan Manning, J.D., Administrative Board Counsel, James D. Coffey, R.Ph., Associate Director, James C. Emery, C.Ph.T., Healthcare Investigator, Alan Van Tassel, Healthcare Investigator, and Leslie S. Doyle, R.Ph., Healthcare Supervisor and Investigator.

AGENDA ITEMS

1. 9:30 a.m. to 10:10 a.m.

Call to Order: Investigative Conferences and Business Meeting

Investigative Conference: PH-02-101 In the matter of Kevin Tam, R.Ph., License # 24615

Complaint alleged failure to adhere to professional standards of pharmacy practice and unlawful possession of a controlled substance.

Present for discussion:

Investigator: Leslie S. Doyle Registrant: Kevin Tam

D 1 D1 D (4' (C 1 O

Brooks Pharmacy Representative (formerly Osco Drug): Michael Viggiano

DPL MPRS Coordinator: Tim McCarthy

Investigator Doyle reviewed her report of investigation with the Board.

Tam stated that he did not alter the prescription at issue; that he did not speak to the dentist's office the day after his appointment, and that he did not request five additional Percocet tablets from the dentist. Tam stated that he consulted with another dentist office in the North Andover area following the appointment at issue. Tam brought the subject prescription vial to the investigative conference.

Tam said that he took about three (3) Percocet tablets a day for a while for

excruciating dental pain. Tam stated that said he has not received Percocet from any other medical practitioners.

Brooks Representative Viggiano stated that he visited the dentist's office to discuss the matter after he learned of the incident. According to Viggiano, the dentist advised him that he wrote a Percocet prescription for 8 - not 80 - tablets. The dentist told Viggiano that in his professional practice he always makes a point to write out in word format the number of tablets authorized i.e. (eight v. 8). The dentist stated to Viggiano that someone had added a "y" to the word "eight".

Viggiano consulted with Brooks Pharmacy staff and was advised that there were no apparent drug shortages at the pharmacy.

Tam informed the Board that his attorney could not attend the investigative conference because of a conflict with a pre-trial conference.

Tim McCarthy, MPRS, stated MPRS would perform an assessment of Tam if acceptable to Registrant's counsel.

Tam advised the Board that that his VISA expired on July 14, 2002.

Tam was deficient 1.5 CE's for calendar year 2001 and stated that he had not done any 2002 CE's yet because of pending VISA issues.

Board Decision: Motion/Bob Paone - Registrant to complete 4.5 additional hours of continuing education in 15 business days for 2001 CE deficiency (to forward original CE certificates of completion to the Board) and Board to take matter under advisement until MPRS assessment and an electronic data transmission (EDT) report for past year reviewed. Second/Karen Ryle. **Vote:** In Support: Ryle, Sparr, Paone and Barron; Opposed: none. The motion carried.

Re-discussion: Motion/Bob Paone - offer voluntary surrender agreement until such time that the Board reviewed both the MPRS assessment and the EDT report. Second/ Harold Sparr. Vote: In Support: Ryle, Sparr, Paone and Barron; Opposed: none. The motion carried.

2. 10:10 a.m. to 10:50 a.m.

Investigative Conference: PH-02-055 In the matter of Brian J. Joao, R.Ph., License # 23652

Complaint alleged unlawful possession of controlled substances and failure to complete required continuing education credits.

Present for discussion:

Investigator: Leslie S. Doyle Registrant: Brian J. Joao

DPL MPRS Coordinator: Tim McCarthy

Investigator Doyle reviewed her report of investigation with the Board.

Joao acknowledged the unlawful possession of controlled substances for personal use and remorse about the incident. Joao stated he is enrolled in the MPRS program and an employee assistance program (EAP). He is employed by the pharmacy oncology department of Baystate Medical Center with no access too federally controlled substances.

Investigator Doyle advised the Board that DPH/DCP closed their investigation of the matter based in part upon the complaint at hand and the MPRS arrangement.

Board Decision: Motion/Karen Ryle - offer Registrant a consent agreement requiring MPRS enrollment, 5 years probation, and 22.5 CE's (7.5 CE year 2000 deficiency). Second/Bob Paone.

Vote: In favor: Ryle, Sparr, Paone and Barron; Opposed: none. The motion carried.

3. 11:00 a.m. to 11:40 a.m.

Investigative Conference: DS-02-037 & PH-02-052 In the matter of CVS Pharmacy #1875, 350 Union Street, Ashland, MA 01721 (Permit # 2065) and Robert P. Duca, R.Ph., (License # 17200)

Complaint (consumer) alleged failure to fill a prescription properly: on September 19, 2001, Registrant alleged to have dispensed Zantac15mg/ml Syrup with incorrect directions for administration while employed at CVS Pharmacy #1875, 350 Union Street, Ashland, MA.

Present for discussion: Complainant: Present

Investigator: Leslie S. Doyle Registrant: Robert P. Duca

CVS Manager of Record: Helen Munroe

CVS Representatives: Barry Jasilli and Jim Scanlon

The Registrant acknowledged responsibility for the medication error. He stated an apology was made to the family and the prescriber was notified about the incident. Duca stated that he data entered the prescription at issue and was responsible for final checking and or verification as the sole pharmacist on duty on the incident date. Duca stated that approx. 208 prescriptions were processed (106 new) on the incident date and that CVS Pharmacy utilized the basket method of prescription filling.

Duca recalled that he provided the patient's family with an oral syringe for prescription dosing administration. Duca stated that this was the first Zantac prescription for this patient at the pharmacy. Duca reported that he pays closer attention to both the patient's date of birth and the computer software program entries relating to pediatric dosing.

The patient's representative stated that the family still has prescriptions filled at the pharmacy and was glad to hear about the corrective measures implemented by the pharmacy department. The representative said that the pharmacy appears generally busy and believed that no offer to counsel was made by the pharmacy. The representative said that the patient was doing fine.

The Manager of Record (Munroe) informed the Board that the pharmacy department now has a second overlap pharmacist on Mondays (8 hour shift) to lessen former workload concerns and that current staffing is deemed sufficient. He stated that an incident report was completed and forwarded to both the Regional Healthcare Manager and CVS corporate office for review

Karen Ryle suggested that the pharmacy department consider reviewing the pediatric APhA dosing guidelines and utilizing pediatric stickers for hardcopy prescription identification purposes.

Barry Jasilli advised the Board that CVS maintains a company intranet site regarding "Quality First" medication error reduction recommendations. In addition, Jasilli informed the Board that he would write a Quality First article on the incident to share with other company pharmacists for quality assurance purposes. Jasilli stated that company incident reports are not filed with ISMP but he does consult with ISMP on a periodic basis.

Registrant (Duca) and the Manager of Record (Munroe) were compliant regarding continuing education.

Board Decision: Motion/Paone to issue an Advisory Letter to both the Registrant (Duca) and CVS Pharmacy for the failure to fill a prescription properly with conditions to include:

1) CVS Pharmacy shall file a USP Medication Error Report with USP PRN (copy to the Board); 2) the Registrant (Duca) shall complete a two hour home study medication error reduction continuing education program; and 3) the CVS Manager of Record (Munroe) shall confer with the CVS corporate office to obtain a hardcopy pediatric reference source for the pharmacy department (30 days following receipt of Advisory Letter). Second/Marilyn Barron.

Barry Jasilli noted that a reference to pediatric dosing was available on the company intranet.

Vote: In support: Barron, Paone, Sparr and Ryle; Opposed: none. The motion carried.

4. 11:40 a.m. to 12:20 p.m.

Investigative Conference: DS-02-062 & PH-02-072 In the matter of CVS Pharmacy #707, 500 Grafton Street, Worcester, MA 01604 (Permit # 24373) and Tam C. Huynh, R.Ph. (License # 24927)

Complaint (consumer) alleged failure to fill a prescription properly; on November 19, 2001, Registrant allegedly dispensed a prescription vial for Hydrocodone/ Acetaminophen 7.5/750 mg containing both 7.5/750 mg tablets and 5/500mg tablets, while employed at CVS Pharmacy #707, 500 Grafton Street, Worcester, MA.

Present for discussion: Complainant: Not present Investigator: Alan Van Tassel Registrant: Tam C. Huynh

CVS Manager of Record: David O'Reilly

CVS Representatives: Angela Reardon and Barry Jasilli

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

Registrant acknowledged responsibility for the medication error.

The Manager of Record (O'Reilly) stated that medication error possibly occurred due to a return to stock issue. O'Reilly said that the medication supply was likely a return to stock prescription vial which was either discarded and or returned to the stock shelf by a technician after counting rather than forwarded to the checking/verification pharmacist for review. O'Reilly stated that the medication at issue was primarily dispensed by means of a baker cell.

With regard to corrective actions implemented, O'Reilly reported that the CVS EPIC software computer provides images of medications for pharmacist verification purposes. In addition, O'Reilly stated that any return to stock medications utilized for dispensing purposes will be forwarded to the checking/verification pharmacist for physical reference. O'Reilly stated that medication dispensed in error was returned to the pharmacy department by the patient.

Huyhn informed the Board that she always matches the hardcopy prescription image on the computer screen against both the image of the medication dispensed and the pills evident in the prescription vial.

Jasilli advised the Board that CVS company policy requires the medication stock bottle to accompany the prescription vial dispensed to the pharmacist checking station in those cases (about 10%) where EPIC pill imaging is not available. Both the Huyhn and O'Reilly were CE compliant.

Board Decision: Motion/Paone to issue an Advisory Letter with copy of Board's "Best Practice recommendations", to both Huyhn and CVS Pharmacy for the failure to fill a prescription properly, with conditions to include: 1) the Manager of Record to review return to stock policy and procedures for appropriateness in response to the medication error described above; 2) the Manager of Record shall ensure that all return to stock bottles utilized for dispensing purposes are forwarded to the dispensing and or verification pharmacist for final product validation; 3) the Manager of Record shall conduct an in-service for all pharmacy staff regarding proper return to stock policies and procedures; and 4) the Manager of Record shall confer with the CVS Director of Professional Practices to ensure that both a blinded description of the incident and a statement/article of related corrective actions is distributed to other CVS Pharmacies; compliance within 30 days. Second/ Karen Ryle.

Vote: In support: Barron, Paone, Sparr and Ryle; Opposed: none. The motion carried.

5. 12:20 p.m. to 1:20 p.m. Lunch

6. 1:20 p.m. to 2:00 p.m.

Investigative Conference: DS-02-024 and PH-00-125 In the matter of Bruce Kline, R.Ph. (License # 17604).

Complaints (consumer and Board) alleged unethical and or unprofessional conduct. Registrant's counsel notified Board counsel by telephone this morning that Registrant had notified him by telephone that morning that he would not be appearing for the conference.

Board Decision: Motion/Bob Paone to refer complaints to DPL

Office of Prosecutions. Second/Harold Sparr.

Vote: In favor: Barron, Paone, Sparr, Horn and Ryle. The motion carried

7. 2:00 p.m. to 2:40 p.m.

Investigative Conference: DS-02-078 and PH-02-096 In the matter of Brooks Pharmacy #401, 884 Main Street, Melrose, MA 02176 (Permit # 2405) and Christina M. Mogni, R.Ph. (License # 19870).

Complaint (consumer) alleged the failure to fill a prescription properly; on January 28, 2002, Registrant allegedly dispensed Effexor XR 75 mg rather than Effexor IR 75mg as prescribed and labeled while employed at Brooks Pharmacy #401, 884 Main Street, Melrose, MA.

Present for discussion:

Complainant: Present

Registrant: Christina M. Mogni Brooks MOR: Robert Bryant

Brooks Representative: Stephen Horn, Pharmacy Specialist

Investigator: James C. Emery.

Recused: Donna Horn

Investigator James C. Emery reviewed his report of investigation with the Board; reported that the DPL complaint database referenced a prior complaint against Mogni.

Mogni acknowledged responsibility for the medication error with her initials appearing as the checking/verification pharmacist. Mogni stated she did not know who pulled the medication at issue from the shelf; counted the medication; or performed the DUR on the prescription because the medication was a first refill. Mogni assumed the DUR was performed automatically by the computer. Mogni stated that the medication error occurred on the first refill. Mogni said that the hardcopy prescription is pulled for verification after dispensing by the night pharmacist (24 hour store).

With regard to corrective measures implemented at the pharmacy, Mogni stated that pharmacists physically cross reference and circle NDC numbers on all prescription dispensed.

The Manager of Record (Bryant) informed the Board that the "basket method" of prescription processing was to be implemented by the Brooks Corporation in August of 2002. Bryant said that an apology was made to the family and that the prescriber was notified about the incident. Bryant advised the Board that a medication incident report was filed by the pharmacy with the corporate office.

Brooks Pharmacy Specialist Steve Horn advised the Board that the company planned to implement a new computer system in December of 2002 and is developing revised quality assurance prescription filling processes to be rolled out to its stores in the near future.

Karen Ryle suggested that the pharmacy consider physically circling the dosage (i.e. SR, IR) form on the label to assure proper dispensing.

The complainant advised the Board that the improper medication was taken for about one week. The complainant stated that she became sick while taking the medication and called her physician who advised her to stop the medication. The complainant stated that an apology was offered to her by the pharmacy and that took the medication

because she assumed that it was another generic version of same medication or that the insurance company mandated a switch to a comparable product. Mogni and Bryant were CE compliant.

Board Decision:

Motion/Bob Paone to take the matter under advisement as to Mogni until complaint history was reviewed. Second/ Harold Sparr. Vote: In Support: Barron, Paone, Ryle and Sparr; Opposed:none; Recused: Horn. The motion carried.

Motion/Bob Paone to issue Brooks Pharmacy #401 an Advisory Letter for the failure to fill a prescription properly with condition that the pharmacy department provide a written statement to the Board regarding policy and procedures changes implemented to minimize the likelihood of a similar medication error. Second/ Karen Ryle.

Vote: In Support: Vote: In Support: Barron, Paone, Ryle and Sparr; Opposed:none; Recused: Horn. The motion carried.

8. 2:40 p.m. to 3:20 p.m.

Investigative Conference: DS-02-068 and PH-02-086 In the matter of Walgreens Pharmacy #2311, 1919 Wilbraham Road, Springfield, MA 01129 (Permit #1943) and Registrant, Mary F. Ryan, R.Ph. (License # 21679).

Complaint (consumer) alleging the failure to fill a prescription properly; on November 20, 2001 the Registrant dispensed Fluoxetine 20mg tablets rather than Famotidine 20mg tablets as prescribed and labeled while employed at Walgreens Pharmacy #2311, 1919 Wilbraham Road, Springfield, MA.

Present for discussion: Complainant: Present

Investigator: Alan Van Tassel

Registrant: Mary Ryan

Walgreens MOR: Christine Colucci

Walgreens Representatives: Steve Pashko and Gary A. Peters, Esq.

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

Registrant acknowledged responsibility for the medication error. Ryan informed the Board that she removed the cap from the prescription vial to verify the medication contents but assumes that she did not completely follow through with the verification in view of the medication error, in violation of Walgreens company policy.

The Manager of Record (Colucci) advised the Board that staffing was appropriate on the incident date albeit a little busier than normal (day before Thanksgiving). Colucci stated that she discussed all of the patient's medication history with his mother when she returned to the pharmacy to report the medication error and that she contacted the patient's physician about the incident.

The complainant advised the Board that her son's medication is still not stabilized as a result of the alleged medication error. The complainant stated that her son is compliant with his medication regimen.

Colucci advised the Board that customarily either the patient and or his grandmother picks up the patient's prescription rather than the patient's mother. According to

Colucci, the improperly dispensed medication was returned to the pharmacy by the complainant's mother three weeks after dispensing not five as reported. Colucci advised the Board that an medication incident report was completed and forwarded to both the Walgreens District Manager and corporate office for review.

Walgreens Pharmacy Supervisor Steve Pashko stated that he reviews the incident reports on an individual basis with the involved pharmacist. Thereafter, he discusses the filed incident reports with all pharmacy district MORs on a quarterly basis. Ryan and Colucci were each deficient one "live" CE credit. Both parties will be required to complete three 3 additional CEs.

Board Decision: Motion/Bob Paone to issue an Advisory Letter to both Ryan and Walgreens Pharmacy with conditions to include:

1) Walgreens Pharmacy shall file a USP Medication Error Report with USP PRN (copy to Board); 2) Ryan to complete a two hour home study medication error reduction CE program; and 3) Colucci and/or the Walgreens Pharmacy Supervisor Pashko to submit copy of pharmacy policies and procedures related to an additional checking and final verification procedure to Board with confirmation that a related in-service was conducted for pharmacy staff regarding proper drug product selection and reinforcement of Indian Health Service module for pharmacy patient counseling ("medication show and tell") within 30 days. Second/Karen Ryle.

Vote: in favor: Barron, Ryle, Horn and Paone; Opposed: Sparr. The motion carried.

9. 3:20 p.m. to 4:00 p.m.

Investigative Conference: PH-02-056 In the matter of Steven Gilboard, R.Ph. (License # 14780)

Complaint alleged unlawful possession of controlled substances.

The Registrant failed to appear for the investigative conference.

Board Decision: Motion/Donna Horn to offer the Gilboard a voluntary surrender agreement. Second/Karen Ryle.

Vote: In support: Sparr, Barron, Ryle, Horn and Paone. The motion carried.

10. 4:00 p.m. to 4:30 p.m.

Administrative Business Items

A) Board of Registration in Pharmacy <u>Draft</u> Complaint Review Policy: Discussion re-scheduled for July 9, 2002 meeting.

B) Review of Board Minutes	_		
Minutes for December 04, 2001:	approve	amend	
Vote: Tabled			

Minutes for February 05, 2002: a	pprove	amend <i>X</i>		
Motion/Bob Paone to approve the mir	nutes subject	to the follow	ving	
amendment; Agenda Item #4, page 2 c	hange Paul t	to Paula G. S	econd/Donna Horn.	
The motion carried.				
Minutes for April 23, 2002:	approve	amend _	_X	
Motion/Bob Paone to approve the minutes subject to the following				
amendments; Agenda Item # 8 advised to replace the name of Donna Horn with				
Dan Sullivan regarding question posed and Agenda Item #9 add the word "error"				
to the last paragraph. Second/Harold S	parr. The mo	otion carried	•	

C) In the matter of DS-02-070 Lincoln Discount Drugs, 161 East Main Street, Milford, MA 01757 (Permit #21238) and Michael G. LaCava, R.Ph. (License # 24404):

Discussion and or Vote of Decision: related to May 28, 2002 Investigative Conference (Board requested Registrant to forward CE documentation). Assoc. Dir. James D. Coffey advised the Board that LaCava failed to submit the Board requested CE documentation.

Motion/Karen Ryle to take required action to suspend LaCava's pharmacy license for 2 weeks. Second/ Harold Sparr.

Vote: In Support: Ryle, Paone, Sparr, and Horn; Opposed: none; Abstain: Barron. The motion carried.

D) DPL Deputy Director Bob Stone provided the Board with an overview of recent Department of Revenue (DOR) Child Support Enforcement Unit efforts involving DPL licensees and coordination of enforcement efforts pursuant to statutory mandate.

Board Counsel Susan Manning and DPL Chief Counsel Gail Gabriel also provided information to the Board

Motion/Harold Sparr, as revised by Bob Paone for Board to adopt "Standing Vote" in DPR Child Support referrals that Board take action as directed by relevant statutes and DOR directives and that Board staff (ED/AD/Board Counsel) act in accordance with standing vote. for specific cases involving DOR child support enforcement violations. Second/Karen Ryle. Vote: In support: Sparr, Barron, Ryle, Horn and Paone. The motion carried.

- E) Exec. Dir. Chuck Young provided the Board with an overview of a DPH/DCP correspondence regarding the proposed removal of Levothyroxine Sodium from the MLID. Mr. Young stated that the related public comment period was July 19-26, 2002. Donna Horn requested that Board staff track the MLID substitution issue.
- F) Exec. Dir. Chuck Young provided the Board with an overview of a DPH/RCP correspondence regarding the Potassium Iodide (KI) program.

 Motion/Bob Paone for the Board to encourage and or support pharmacists voluntary involvement in the KI program. Second/Harold Sparr. Vote: In support: Sparr, Barron, Ryle, Horn and Paone. The motion carried.
- H) In the matter of PH-02-024, Registrant David J. Little, R.Ph. (License Number 22830).

Recused: Donna Horn

Board Counsel Susan Manning provided the Board an overview of Attorney Pavlan's response regarding alternative disposition terms.

Motion/Harold Sparr to agree to alternate disciplinary terms. Second/Bob Paone. Vote: In Support: Barron, Ryle, Paone and Sparr; Opposed: none; Recused: Horn. The motion carried.

I) The Board requested Board staff to commission a special assignment for an investigator to inspect the "Pet Drug Store" in Walpole, MA.

11. 4:30 p.m.

Motion/Donna Horn to adjourn the meeting. Second/Karen Ryle. Vote: In support: Sparr, Barron, Ryle, Horn and Paone. The motion carried. Meeting adjourned.

Respectfully submitted by: _

Executive Director Da

Printed Name

Reviewed by counsel: August 07, 2002

Draft approved: August 08, 2002 Board adopted: August 13, 2002