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

AGENDA ITEMS

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

<u>The following Board members were present</u>: Harold B. Sparr, R.Ph., MS, President, Donna M. Horn, R.Ph., Secretary, Dan Sullivan, R.Ph. and Dr. Robert P. Paone., R.Ph., Pharm.D.

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

1. 9:30 a.m. Call to order

2. 9:30 a.m. to 10:10 a.m.

Investigative Conference: DS-01-096 & PH-02-002 In the matter of Walgreens Pharmacy #2309, 175 Main Street, Woburn, MA 01801 (Permit #1876) and Bernard Wolfson, R.Ph. (License # 12176)

The complainant alleged that on April 04, 2001 the Registrant dispensed another patient's prescription for Medroxyprogesterone 10mg to the complainant while employed at Walgreens Pharmacy #2309, 175 Main Street, Woburn, MA.

Present for discussion:

Complainant: Not present

Registrant: Bernard Wolfson

Walgreens Manager of Record: Robert O'DonoghueJr.

Walgreens Representative: Bob Gladstone

Investigator: Daniel E. Warren

CEs: Wolfson – non- compliant O' Donoghue - compliant

The Registrant, who worked as a floating pharmacist for Walgreens at the time of the incident, did not recall the medication error incident. O'Donoghue had later advised him that a customer received the wrong bag of medication.

O'Donoghue stated he filed a company incident report for the medication error after the patient notified the pharmacy about the error the day after the patient ingested the wrong medication. According to both pharmacy records and staff reports, Wolfson was responsible for final verification and dispensing. O'Donoghue described new policy that not more than one prescription bag be allowed on the counter at one time prior to final the check and that pharmacy staff are required to ask patients for name and address prior to dispensing.

With regard to CEs, Wolfson stated he completed 2000 credits but disposed of certificates. In 2001, he did no CE due to illness. Wolfson stated he did not apply for a CE waiver but planned to complete double CE's in 2002 and that he had just retired from pharmacy practice. The Board advised Wolfson that he would be required to remedy the deficiency by completing 90 CE hours, including 30 live CE hours and 12 CE hours of Law.

Walgreens Pharmacy Supervisor Gladstone stated that company policy dictates that the managing pharmacist complete incident reports, which are both reviewed and signed by the dispensing pharmacist(s) prior to submission to the supervisor and company headquarters.

Motion/Paone to take the matter under advisement. Second/Horn. The motion carried. Later in the afternoon, **Motion**/Sparr to discuss. Second/Horn. The motion carried.

Motion/Sparr to offer the Registrant a consent agreement requiring surrender of license until CEs. Second/Paone. The motion carried. With regard to the medication error, **Motion**/Paone to issue Registrant an Advisory Letter for the failure to fill a prescription properly with requirement that Registrant complete 4 CE hours on medication error reduction; and dismiss complaint against Walgreens Pharmacy. Second/Horn. The motion carried.

3. 10:10 a.m. to 10:50 a.m.

Investigative Conference: DS-02-029 & PH-02-034 In the matter of Brooks Pharmacy #401, 882 Main Street, Melrose, MA 02176 (Permit #2405) and Thomas L. Famiglietti, R.Ph. (License # 13683).

The complainant (consumer) alleged that on September 10, 2001, the Registrant dispensed Zestril 2.5 mg tablets rather than Vasotec 2.5 mg tablets as prescribed and labeled while employed at Brooks Pharmacy #401, 882 Main Street, Melrose, MA.

Present for discussion: Complainant: Not present Registrant: Thomas L. Famiglietti Brooks Pharmacy Manager of Record: Robert E. Bryant

Brooks Pharmacy Representative: Steve Horn Investigator: James C. Emery Recused: Donna Horn CEs: Registrant and manager of record- compliant

Investigator Emery reported the consumer allegedly ingested the improper medication for approx. 11 days and was hospitalized related to the ingestion. The prescription to be filled was a refill. Brooks Pharmacy #401 is a 24-hour pharmacy department.

The Registrant acknowledged responsibility for the medication error. He stated that he processed the prescription at issue on September 10, 2001 between 7:30 to 8 a.m. There was no technician on duty at the time. He did not recall how the error occurred and is now more vigilant about prescription checking procedures (both NDC validation and hi-lighting).

Manager of Record Bryant stated that pharmacy policy requires that staff pharmacists reduce to writing on oral prescription authorizations both the patient's date of birth and prescriber designee. Bryant stated the pharmacy has reviewed prescription error reduction methods to include hi-lighting, first refill verification, NDC verification, proper bag stapling and initialing accountability steps throughout the prescription filling process.

Motion/Paone for an Advisory Letter to be issued to Registrant and the Pharmacy with stipulations to the include filing of a USP PRN Medication Error Report (copy to the Board) and completion of a two hour ISMP CE Program for Medication Error Reduction (original CE Certificates to the Board. Second/Sullivan. Vote: In favor; Sparr, Paone and Sullivan, Opposed; none; Recused: Horn. The motion carried.

4. 11:00 a.m. to 11:40 a.m.

Investigative Conference: PH-02-024 In the Matter of David J. Little, R.Ph.,(License # 22830).

Complaint alleged that the Registrant engaged in unprofessional and unethical conduct while employed at Littles Pharmacy, 155 Eagle Street, North Adams, MA.

Present for discussion: Registrant: David J. Little Investigator: Alan Van Tassel Recused: Donna Horn

The Board reviewed the Registrant's CE credits for 2000 and 2001. Investigator Van Tassel outlined the complaint filed by a reverse distributor alleging returned certain pharmaceuticals to the distributor (Prilosec, Zestril and Risperdal) and instructed the distributor to mail the credit due allowance to his personal residence.

The Registrant acknowledged that he instructed the distributor to mail proceeds to his personal residence with the intention of forwarding the proceeds to his father. He stated he returned the drugs to a reverse distributor (rather than regular wholesaler) for credit to avoid a family confrontation. He denied that he regularly brought prescription drugs to his home. He remains a business partner of the pharmacy under a trust agreement.

Motion/Sparr to take the matter under advisement. Second/Sullivan. Motion carried. Sparr requested the investigator contact McKesson for historic record of related purchases of Prilosec, Zestril and Risperdal.

Later in the afternoon, **Motion**/Sparr to discuss the matter. Second/Sulllivan. The motion carried. **Motion**/Sparr to offer a Consent Agreement with the following stipulations: 1) one year suspension; 2) MPJE examination; 3) five years probation; and 4) Registrant to petition Board and appear for request for termination of supervision and demonstrate completion of requisite continuing education credits. Second/Paone. Vote: In favor - Harold Sparr and Bob Paone. Opposed: Dan Sullivan, Recused: Horn. The motion carried.

5. 11:40 a.m. to 12:20 p.m.

Investigative Conference: DS-02-049 & PH-02-064 In the matter of deVillers Pharmacy, 1392 Rodman Street, Fall River, MA 02721 (Permit # 6755) and Andre R. DeVillers, R.Ph. (License # 11753).

The MA Department of Public Health, Medication Administration Program, alleged that on November 21, 2001, the Registrant dispensed Neurontin 300mg rather than Neurontin 400mg as prescribed while employed at deVillers Pharmacy, 1392 Rodman Street, Fall River, MA.

Present for discussion: Complainant: Not present Registrant: Andre R. DeVillers Investigator: Leslie S. Doyle

CE: DeVillers; compliant.

The Registrant acknowledged the error and stated he was not the consultant pharmacist, but packaged the prescription with three different strengths for this patient. Registrant drafted policies and procedures to address similar events to prevent any recurrence. He advised the patient's facility administrator to contact the physician, MAP Program and DPH. The patient who received the wrong prescription is fine.

Motion/Paone to issue Advisory Letters to Registrant and the Pharmacy with

stipulations to include filing of a USP PRN Medication Error Report (copy to the Board); completion of a two hour ISMP CE Program for Medication Error Reduction; and written policies and procedures changes to Board within 30 days. Second/ Sparr. The motion carried.

Bob Paone reported on the NACDS training program and competency assessment examination. he provided a favorable rating for the training program but limited his endorsement to the assessment examination. Motion/Sparr to approve the NACDS Pharmacy Technician Training Program and request additional questions to satisfy the 50 questions required by Board policy to address patient confidentiality and storage components. Second/Horn. The motion carried.

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

7. 1:20 p.m. to 2:00 p.m.

Investigative Conference: PH-01-119 In the matter of Lawrence B. Salvador, R.Ph., (License # 25046)

Present for discussion: Registrant: Lawrence B. Salvador and Attorney Paul M. Garbarini DPL MPRS Representative: Tim McCarthy Investigator: Leslie S. Doyle

Registrant informed the Board that he entered into an MPRS contract in Sept. 01.

DPL MPRS Coordinator Tim McCarthy affirmed Registrant's program compliance and surrender of pharmacy license to MPRS.

Registrant's counsel, Paul Garbarini stated his client disputed the total number of controlled substances reported stolen his clients former employer (CVS Pharmacy). Garbarini admitted that his client had a substance abuse problem in 2001 but noted that such involved small amounts of controlled substances.

Motion/Horn to offer the Registrant a consent agreement with stipulations to include: 1) MPRS contract; 2) voluntary surrender for one year; and 3) five year probation. Second/Paone. The motion carried.

8. 2:00 p.m. to 2:40 p.m.

Investigative Conference: DS-02-023 & PH-02-028 In the matter of Shaws Pharmacy #160, 260 Winthrop Street, Taunton, MA 02780 (Permit #3000) and Cheryl A. Studley Straut, R.Ph., (License # 17704).

The complainant (consumer) alleged that on April 26, 2001 the Registrant dispensed Accupril 20mg and Lipitor 10mg in the wrong prescription vials while employed at Shaws Pharmacy #160, 260 Winthrop Street, Taunton, Massachusetts.

Present for discussion: Complainant: Not present Registrant: Cheryl A. Studley Straut and Tim McCrystal, Esq. Shaws Manager of Record: Rodney Finch Shaws Representative: Jim McGrath Investigator: James C. Emery

CEs: Registrant and Manager of record - compliant

Shaws Pharmacy Supervisor Jim McGrath stated the company was notified the day after the alleged incident by the patient, not two months later as stated in response. At no time had the complainant returned the prescription vial to the pharmacy for review. According to McGrath, the complainant alleged that the improper medication was ingested and that following incident reconciliation, the complainant placed the right medication in the proper prescription vial. McGrath said that complainant's wife is a nurse.

Investigator Emery stated that the directions for both of the complainant's medications were the same.

The Registrant stated that in order to decrease the likelihood that such an incident might occur, pharmacy staff now works on one prescription at a time on the pharmacy work counter.

Motion/Sparr to dismiss the complaint on the basis of insufficient evidence. Second/ Paone. The motion carried.

9. 2:40 p.m. to 3:20 p.m.

Investigative Conference: DS-02-039 & PH-02-044 In the matter of Walgreens Pharmacy #4535, 170 N. Main Street, Randolph, MA 02368 (Permit # 2837) and Martin H. Packer, R.Ph., (License # 13915).

The complainant alleged that on April 12, 2001, the Registrant dispensed Coumadin 1mg rather than Coumadin 5mg as prescribed while employed at Walgreens Pharmacy #4535, 170 N. Main Street, Randolph, Massachusetts.

Present for discussion: Complainant: Not present Registrant: Martin H. Packer Walgreens manager of Record: Michael Cerrasulo Walgreens Pharmacy Representative: Steve Pashko Investigator: James C. Emery for Leslie S. Doyle

With regard to corrective measures implemented by the pharmacy department, Packer commented that the Walgreens computer system was enhanced to offer a color rather than black and white tablet description and reference picture. Packer stated that Coumadin 5mg is now the only strength of Coumadin located in the automated dispensing baker cell system and that both generic and brand name Coumadin strengths are now physically separated from other medications on the pharmacy dispensing shelves and are high-lighted by means of shelf talker labels "warning stickers".

The Manager of Record stated the complainant never returned to the pharmacy to have the medication reviewed and or corrected. He stated that the patient telephoned the pharmacy by phone to report the error and that the prescriber subsequently changed the patient's Coumadin dose to a higher strength (5mg) which appeared the same as the Coumadin strength (1mg) recently filled by Walgreens Pharmacy. In addition, the patient traded with the pharmacy only for a short period of time.

Motion/Horn to Dismiss the complaint without prejudice for insufficient evidence. Second/ Sparr. The motion carried. The Board also requested Walgreens Pharmacy to file a USP PRN Incident Report (copy to the Board) because of the similarity in color between both strengths of the Coumadin medication.

10. 3:20 p.m. to 3:45 p.m. Administrative Business Items:

A) <u>Draft Policy</u> on **Return for Re-dispensing of Medications from Long Term Care Facilities**: for Discussion.

Exec. Dir. Chuck Young distributed the Board a new draft policy to review for discussion and comment at the March 05, 2002 meeting.

B) G. Bruce Rumph, R.Ph., Esq. correspondence regarding request to meet with the Board to discuss conditions of pharmacist reinstatement. Motion/Sparr to grant the request for Board appearance (30 minutes). Second/Horn. The motion carried.

C) NABP MPJE Update regarding <u>MPJE State Specific Review Schedule for 2002</u>: for Discussion. The Board will review scheduling issues specific to the MPJE review process for comment at a future Board meeting.

D) Crescent Pharmacy (added item): Investigator Emery reviewed his follow-up inspection report with the Board. The pharmacy is now compliant. **Motion**/Sparr to issue the Registrant and Crescent Pharmacy an Advisory Letter. Second/Bob Paone. The motion carried.

E) Pharmacy Technician issues: Discussion regarding amendment of regulations requiring pharmacy technicians to notify the Board in writing of employment changes.

F) Mandatory Reporting of Medication Errors: Statutory peer review protection language to be reviewed by Board Counsel Susan Manning for future Board discussion.

G) HIPAA issues: The Board will review the subject matter at a future Board meeting.

11. 3:45 p.m. to 4:15 p.m. **File Review**

12. 4:15 p.m.

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

| Respectfully submitted by: _ | 9 allon 2 | 1. Jonus | |
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| | Executive Director | Nate) | |
| | CHUCK YOUNG | - | |

Printed Name

Reviewed by counsel: September 12, 2002 Draft approved: September 13, 2002 Board adopted: September 24, 2002