

**KENTUCKY BOARD OF PHARMACY  
MARRIOTT LOUISVILLE DOWNTOWN**

**LOUISVILLE KY  
November 14, 2008  
9:00a.m.**

**Agenda**

**I. CALL TO ORDER**

**II. MINUTES**

- \*A. September 10, 2008

**III. APPEARANCES**

- \*A. Alesia Bernardo-9:15 a.m.
- \*B. Gary Darst-9:45 a.m.
- \*C. Robert Jared Thornton-10:15 a.m.

**IV. INTERAGENCY**

**V. BOARD REPORTS**

- A. Board President
- B. Board Members
- C. Board Executive Director
  - \*1. eMARS (August-09, September 09, and October 09)
  - 2. Pharmacy Technician Registration
  - \*3. Board Meeting Dates 2009
  - \*4. Trip Approval 2009
- D. Board Staff
- E. PRN Chair

**VI. CURRENT/PENDING CASES**

- A. OAG-Cheryl Lalonde
- \*B. Case Update
- \*C. Case Review

**VII. RECIPROCITY/RELICENSURE/INTERNSHIP**

**VIII. CORRESPONDENCE/COMMUNICATIONS**

**IX. NABP**

**X. LEGISLATION/REGULATIONS**

- \*A. Compounding: New Regulation
- \*B. Fees: Amendment
- \*C. Manufacturer: New Regulation

**XI. CONTINUING EDUCATION**

**XII. FINES**

**XIII. OLD BUSINESS**

**XIV. NEW BUSINESS**

**XV. FYI**

- \*Information enclosed with this agenda**
- \*\*Information previously provided**
- \*\*\*Old material with response**

**KENTUCKY BOARD OF PHARMACY  
MARRIOTT LOUISVILLE DOWNTOWN**

**LOUISVILLE KY  
November 14, 2008 9:00a.m.**

**Agenda  
Addendum**

- V. BOARD REPORTS**
- VI. CURRENT/PENDING CASES**
- VIII. CORRESPONDENCE/COMMUNICATIONS**
- X. NABP**
- XI. LEGISLATION/REGULATION**
- XII. CONTINUING EDUCATION**
- XV. FYI**
  - A. PRN Overtime report

**MINUTES**  
**KENTUCKY BOARD OF PHARMACY**

Marriott Louisville Downtown  
280 W. Jefferson Street.  
Louisville, Kentucky 40202

November 14, 2008

**CALL TO ORDER:** A regular meeting of the Kentucky Board of Pharmacy was held at the Downtown Marriott, Louisville, Kentucky. President Leake called the meeting to order at 9:09 a.m.

Members present: Mike Leake, Peter Orzali, Anne Policastri, Patricia Thornbury, Sandy Simpson and Catherine Shely. Staff: Michael Burleson, Executive Director; Jeffrey L. Osman, Pharmacy Inspections and Investigations Coordinator; Katie Busroe, Steve Hart and Phil Losch, Pharmacy and Drug Inspectors; Lisa Atha, Executive Secretary; and Cheryl Lalonde, Assistant Attorney General and Board Counsel. Guests: Ralph Bouvette, and Sam Lyons, APSC; Jan Gould, Kentucky Retail Federation; Brad Hall, Kentucky Pharmacists Association; Kim Morgan, Target; Scott Greenwell, Humana; Larry Hadley, Board member-elect; Chris Killmeier, Walgreens; Brandi Johnson, CVS; Tom Prose and Duane Parsons, Kroger; Robert Jared, Lisa Thornton, Emily Pidgeon, Kirk Smith, and Aleisa Bernardo. Juanita Toole, Court Reporter, recorded the meeting.

**MINUTES:** On motion by Dr. Policastri, seconded by Mr. Orzali and passed unanimously, the Minutes of September 10, 2008 Board Meeting were approved.

**APPEARANCES:** **Alesia Bernardo.** Ms. Bernardo was sworn in by Juanita Toole, Court Reporter. Ms. Bernardo appeared before the Board asking for reinstatement of her Kentucky pharmacist's license. Ms. Bernardo gave a brief overview of the events that lead to the loss of her pharmacist's license. After discussion, Dr. Shely moved to deny Alesia Bernardo reinstatement of her Kentucky pharmacist's license, and she may not appear before the Board to request reinstatement for one year. During that year Ms. Bernardo must continue to work her recovery. Ms. Simpson seconded, and the motion passed unanimously.

**Gary Darst.** Mr. Darst was sworn in by Juanita Toole, Court Reporter. Mr. Darst appeared before the Board asking for reinstatement of his Kentucky pharmacist's license. Mr. Darst gave a brief overview of the events that lead to the loss of his license. After discussion, Mr. Orzali moved to reinstate Mr. Darst's Kentucky pharmacist's license with the stipulations as follows: 5 years probation; shall maintain a perpetual inventory at all places of employment for Schedule II drugs, with electronic tracking of Schedule III-V drugs, and perpetual inventory shall be made available to the Board upon request and audits may be conducted; shall attend AA/NA meetings no less than 6 times per 2 week period or 12 meetings per calendar month, which shall include a minimum of 2 meetings per week, shall provide the Board and PRN Committee with written monthly reports of all AA/NA meetings; Board shall conduct quarterly inspections for two years after which

time semi-annual inspections shall be conducted for 3 years, at all locations of employment or practice as a pharmacist, the cost of which not to exceed \$500 per inspection, shall be paid to the Board within 30 days of invoicing; continuing education requirements must be satisfied, renewal fees and any penalties must be paid, and a complete renewal application must be submitted; maximum hours of work: 45 hours/week or 90 hours/2 weeks, with a maximum of 50 hours in any 7 consecutive days and no overtime; shall provide a copy of this Agreed Order to all employers and pharmacists-in-charge; shall sign an aftercare contract, to include drug counselor if indicated, with the Pharmacist Recovery Network Committee (PRNC) for the length of the Agreed Order; any violation of this Agreed Order or PRN contract shall be reported to the Board and PRNC Chair within 24 hours of violation; shall notify Board of change of home address, telephone number, and/or email within 7 days of change; shall provide to the Board and PRNC a signed release granting the Board and PRNC access to all written medical records and conversations regarding medical care; shall agree to provide observed urine, other body fluid, or hair samples for drug/alcohol screens at the direction of PRNC, the Board or any other monitoring body; provide copies of any results of any screens ordered to the Board and PRNC; provide notification to PRNC Chair, Board and testing company of anything that may affect pharmacist's availability for screens prior to event, a missed screen shall be cause for reporting such to the Board, any positive screen that is a violation of the Agreed Order or PRN contract shall be communicated to the Board by the PRNC Chair within 24 hours, a report indicating a presumptive presence shall constitute a conclusive basis, without the necessity of a hearing, for a determination that pharmacist is not in compliance with the terms of this Agreed Order of Reinstatement; shall agree to abstain from any and all mood-altering chemicals, except as prescribed by pharmacist's physician and only after consultation with PRNC Chair; shall notify PRNC Chair in advance if any mood-altering and/or potentially addictive medications are required or recommended by pharmacist's physician; shall provide documentation to PRNC Chair of the need for the medication within 3 days; shall renew verification with PRNC Chair every 90 days if need for medication is ongoing; shall give up the right to self medicate with the exception of single entity OTC NSAIDS and acetaminophen; shall be excluded from accepting a position of pharmacist-in-charge, power of attorney, or preceptor; shall advise Board at all times of place of employment and shall only practice at a location with a work schedule that has received prior approval of the Board or its President; shall obtain all prescriptions and those of family at a pharmacy designated in writing to the Board; prescriptions shall not be filled by a family member or at any family owned pharmacy and shall not dispense any drugs for self or family; shall attend within 1 year of entry of this Agreed Order either the University of Utah School on Alcoholism and other Drug Dependencies, CAPTASA, or SE PRN meeting and shall provide a certificate of completion; shall provide monthly written self performance evaluation to the Board and PRNC Chair and shall make all appearances before the PRNC as requested, including an annual appearance closest to the anniversary date of reinstatement; committing any act that results in violation of federal or state pharmacy or drug statute or regulation, may result in an emergency suspension of pharmacist's license, require an appearance before the Board, or result in a complaint against pharmacist's license with the Board imposing any applicable penalties; shall not seek to amend or modify this Agreed Order. Above information shall be reported to

NABP and is subject to disclosure under the Kentucky Open Records Act. Ms. Thornbury seconded, and the motion passed unanimously.

**Robert Jared Thornton.** Dr. Thornton was sworn in by Juanita Toole, Court Reporter. Dr. Thornton appeared before the Board asking for reinstatement of his Kentucky pharmacist's license. Dr. Thornton gave a brief overview of the events that lead to the loss of his license. After discussion, Dr. Shely moved to reinstate Dr. Thornton's Kentucky pharmacist's license with the stipulations as follows: 5 years probation; shall maintain a perpetual inventory at all places of employment for Schedule II drugs, with electronic tracking of Schedule III-V drugs, and perpetual inventory shall be made available to the Board upon request and audits may be conducted; shall attend AA/NA meetings no less than 6 times per 2 week period or 12 meetings per calendar month, which shall include a minimum of 2 meetings per week, shall provide the Board and PRN Committee written monthly reports of all AA/NA meetings; if employed at a dispensing pharmacy, Board shall conduct quarterly inspections for two years after which time semi-annual inspections shall be conducted for 3 years, if employed at a non-dispensing pharmacy Board shall conduct annual inspections at all locations of employment or practice as a pharmacist, the cost of which not to exceed \$500 per inspection, shall be paid to the Board within 30 days of invoicing; agrees that a violation of the Agreed Order of Reinstatement shall cause him to automatically lose his license to practice pharmacy for not less than five years and one day and shall require him to petition the Board for reinstatement only after he has taken and successfully passed the entire Kentucky Board of Pharmacy licensure examination; continuing education requirements must be satisfied, renewal fees and any penalties must be paid, and a complete renewal application must be submitted; maximum hours of work: 45 hours/week or 90 hours/2 weeks, with a maximum of 50 hours in any 7 consecutive days and no overtime; shall provide a copy of this Agreed Order to all employers and pharmacists-in-charge; shall sign an aftercare contract, to include drug counselor if indicated, with the Pharmacist Recovery Network Committee (PRNC) for the length of the Agreed Order; any violation of this Agreed Order or PRN contract shall be reported to the Board and PRNC Chair within 24 hours of violation; shall notify Board of change of home address, telephone number, and/or email within 7 days of change; shall provide to the Board and PRNC a signed release granting the Board and PRNC access to all written medical records and conversations regarding medical care; shall agree to provide observed urine, other body fluid, or hair samples for drug/alcohol screens at the direction of PRNC, the Board or any other monitoring body; provide copies of any results of any screens ordered to the Board and PRNC; provide notification to PRNC Chair, Board and testing company of anything that may affect pharmacist's availability for screens prior to event, a missed screen shall be cause for reporting such to the Board, any positive screen that is a violation of the Agreed Order or PRN contract shall be communicated to the Board by the PRNC Chair within 24 hours, a report indicating a presumptive presence shall constitute a conclusive basis, without the necessity of a hearing, for a determination that pharmacist is not in compliance with the terms of this Agreed Order of Reinstatement; shall agree to abstain from any and all mood-altering chemicals, except as prescribed by pharmacist's physician and only after consultation with PRNC Chair; shall notify PRNC Chair in advance if any mood-altering and/or potentially addictive medications are required or recommended by pharmacist's

physician; shall provide documentation to PRNC Chair of the need for the medication within 3 days; shall renew verification with PRNC Chair every 90 days if need for medication is ongoing; shall give up the right to self medicate with the exception of single entity OTC NSAIDS and acetaminophen; shall be excluded from accepting a position of pharmacist-in-charge, power of attorney, or preceptor; shall advise Board at all times of place of employment and shall only practice at a location with a work schedule that has received prior approval of the Board or its President; shall obtain all prescriptions and those of family at a pharmacy designated in writing to the Board; prescriptions shall not be filled by a family member or at any family owned pharmacy and shall not dispense any drugs for self or family; shall attend within 1 year of entry of this Agreed Order either the University of Utah School on Alcoholism and other Drug Dependencies, CAPTASA, or SE PRN meeting and shall provide a certificate of completion; shall provide monthly written self performance evaluation to the Board and PRNC Chair and shall make all appearances before the PRNC as requested, including an annual appearance closest to the anniversary date of reinstatement; committing any act that results in violation of federal or state pharmacy or drug statute or regulation, may result in an emergency suspension of pharmacist's license, require an appearance before the Board, or result in a complaint against pharmacist's license with the Board imposing any applicable penalties; shall not seek to amend or modify this Agreed Order. Above information shall be reported to NABP and is subject to disclosure under the Kentucky Open Records Act. Ms. Thornbury seconded, and the motion passed unanimously.

#### **INTERAGENCY:**

**Tramadol Regulation.** The amending of 902 KAR 55:030 to include tramadol as a Schedule IV controlled substance in Kentucky passed out of the Administrative Regulation Subcommittee Review and will now be heard before the joint Health and Welfare Committee. If the amendment passes the Health and Welfare Committee, tramadol will become a Schedule IV controlled substance in Kentucky.

#### **BOARD REPORTS:**

**Board President.** President Leake recognized the appointment of two new Board members, Larry Hadley and Joel Thornbury, who will begin their terms on January 1, 2009.

After discussing the Advisory Council appointments, Dr. Shely moved to invite organizations, including colleges of pharmacy, and individuals to submit candidates for the Advisory Council and to review the curriculum vitae (CV) of all candidates, including current Advisory Council members who wish to continue to serve as well as review current members' attendance, so that the Board may appoint the Advisory Council at the January 2009 Board Meeting. The Executive Director is to notify the organizations and set a deadline for submittals so that the CV's may be reviewed for the January 2009 Board Meeting. Ms. Thornbury seconded, and the motion passed unanimously.

**Board Members. Ms. Thornbury.** Ms. Thornbury is the Board representative on the Advanced Registered Nurse Practitioner (ARNP) Advisory Board. Her appointment is until July 2009. Ms. Thornbury informed the Board that the Board of Pharmacy

representative to the ARNP Advisory Board does not have to be a current Board member. The Board will decide at the January 2009 Board Meeting whether Ms. Thornbury is to continue on the ARNP Advisory Board or to appoint a new representative.

**Dr. Policastri.** Dr. Policastri served on the NABP Task Force to review Test of English as a Foreign Language (TOEFL) iBT score requirements. The Task Force went into a lot of detail and reviewed the TOEFL exam. The Task Force report will be public in February 2009.

**Board Executive Director.** 1) EMars monthly report for August, September and October were presented to the Board. 2) Software for Technician Registration is in process. 3) Dr. Shely moved to approve Board Meeting dates for 2009: January 14, March 11, May 13, July 8, September 9 (UK campus), November 13, and December 16. Mr. Orzali seconded, and the motion passed unanimously. 4) Mr. Orzali moved to approve the following trips: NABP Executive Committee for Executive Director in February 2009 (no cost to the Board); APhA annual meeting for President and Executive Director in April 2009; and NABP annual meeting for all Board members and staff in May 2009. Dr. Policastri seconded, and the motion passed unanimously. 5) Dr. Jeff Osman has submitted notice of retirement effective close of business December 31, 2008. Ms. Thornbury moved for the Board to approve for staff to begin the process for filling the vacancy that will be created by the retirement of Dr. Jeff Osman. Dr. Shely seconded, and the motion passed unanimously. 6) Katie Busroe was presented with her 10 year service certificate.

**Board Staff. Steve Hart.** Mr. Hart thanked the Board for allowing him to go the CLEAR conference.

**Jeff Osman.** Dr. Osman stated that continuing education credit would be granted for the Board Retreat in two separate sections, up to 6 hours for Saturday and up to 3 hours for Sunday for a total of up to 9 hours. No partial credit will be given for any section.

**PRN Committee.** Brian Fingerson is at the South Eastern PRN in Atlanta.

### **CURRENT/PENDING CASES:**

**OAG.** Cheryl Lalonde recommended hiring a Personal Service Contract Hearing Officer because of the shortage of staff in the Office of Attorney General. She recommends Tom Helman. Mr. Orzali moved to proceed with hiring a Personal Service Contract Hearing Office with a budget line of \$25,000. Dr. Policastri seconded, and the motion passed unanimously.

**Case Updates:** Dr. Policastri moved for acceptance and entry of the proposed Agreed Orders as written. Mr. Orzali seconded, and the motion passed unanimously.

Case No. 05-0101; Case No. 07-0006; Case No. 07-0095A; Case No.08-0006; Case No. 08-0052B; Case No.08-0065; Case No. 08-0066A; Case No. 08-0066B; Case No.08-



0067A; Case No.08-0067B; Case No. 08-0068; Case No.08-0069; Case No.08-0070; Case No.08-0080A; Case No.08-0080B; Case No. 08-0082; Case No.08-0085; Case No.08-0089; and Case No.08-0091.

**Case Review:** Dr. Shely moved for acceptance of the Case Review Committee recommendations for the following case reports. Dr. Policastri seconded, and the motion passed unanimously.

**Case No. 05-0015.** Pharmacist was allegedly arrested in Florida for possession of controlled substances without proper authorization. Alleged violation of law: 315.121(1)(c). **CRC Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 08-0047. Revisit.** Pharmacist allegedly completed only 14 of 15 required hours of continuing education (CE) for 2007. Pharmacist found missing one hour of CE. Alleged violations of law: KRS 315.065 and 201 KRS 2:015. **CRC Recommendation:** Case is dismissed.

**Case No. 08-0058B. Revisit.** Consultant pharmacist allegedly allowed a special limited gas permit holder to file a change of address application, have an inspection by the Pharmacy and Drug Inspector, be issued a new permit with a new address, but failed to move and failed to notify the Board office of not moving. As a result, oxygen and oxygen records were stored at an unlicensed facility. Alleged violation of law: 201 KAR 2:225 Section 2(1). **CRC Recommendation:** There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

**Case No. 08-0071.** Pharmacist allegedly engaged in unprofessional or unethical conduct pertaining to filling a prescription without authorization. Alleged violation of law: KRS 315.121(2)(f). **CRC Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 08-0072.** Pharmacist allegedly provided inappropriate prospective drug use review that resulted in an adverse reaction. A prescription for clindamycin was given to a patient that had a documented allergy to erythromycin and all "mycins." Alleged violation of law: 201 KAR 2:210 Section 4. **CRC Recommendation:** Case is dismissed.

**Case No. 08-0073A.** Pharmacy permit holder allegedly sold a misbranded prescription by filling a prescription for Topamax 25mg with Topamax 200mg. Alleged violation of

law: KRS 315.121(2)(d). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

**Case No. 08-0073B.** Pharmacist allegedly committed a medication error by filling a prescription for Topamax 25mg with Topamax 200mg. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 08-0073C.** Pharmacist allegedly committed a medication error by filling a prescription for Topamax 25mg with Topamax 200mg. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

**Case No. 08-0074.** Pharmacist allegedly refused to fill a prescription for Percocet because of a DUR concerning narcotics. Alleged violation of law: KRS 315.121(2)(e). CRC Recommendation: Case is dismissed.

**Case No. 08-0075A.** Pharmacy permit holder allegedly sold a misbranded drug. A prescription was filled for certirizine 10mg, but in the prescription vial received by the patient was two different looking pills. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: Case is dismissed.

**Case No. 08-0075B.** Pharmacist allegedly committed a medication error. A prescription was filled for certirizine 10mg, but in the prescription vial received by the patient was two different looking pills. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: Case is dismissed.

**Case No. 08-0077A.** Pharmacy permit holder allegedly sold a misbranded product. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

**Case No. 08-0077B.** Pharmacist allegedly committed a medication error. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

**Case No. 08-0078.** Pharmacist allegedly engaged in unprofessional and unethical conduct pertaining to a patient's privacy, by discussing the complainant's pharmacy care. Alleged violation of law: KRS 315.121(2)(b). CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

**Case No. 08-0079A.** Pharmacy permit holder allegedly sold a misbranded drug, by filling a prescription for Ambien with different looking pills than the patient received before. It is also alleged that the pharmacy has charged cash for prescriptions that could be charged to Medicaid. Alleged violation of law: KRS 315.121 (2)(d). CRC Recommendation: Case is dismissed.

**Case No. 08-0079B.** Pharmacist allegedly committed a medication error by filling a prescription for Ambien with different looking pills than the patient received before. It is also alleged that the pharmacist has banned the complainant from coming in his pharmacy. Alleged violation of law: KRS 315.121 (2)(d). CRC Recommendation: Case is dismissed.

**Case No. 08-0084.** Pharmacist allegedly engaged in unprofessional and unethical conduct when a refill for Diovan was requested but insurance had changed and the spouse did not know about a new insurance and did not want to pay cash for the prescription. The patient was without medication for approximately three days and allegedly suffered a stroke. Alleged violation of law: KRS 315.121 (2)(e). CRC Recommendation: Case is dismissed.

**Case No. 08-0090 Revisit.** Special limited medical gas pharmacy permit holder allegedly failed to renew in a timely manner and continued to operate as a special medical gas pharmacy. Alleged violations of law: KRS 315.035(1) and (4) and 201 KAR 2:225. CRC Recommendation: Case is dismissed.

**Case No. 08-0092A.** Pharmacy permit holder allegedly provided inappropriate prospective drug use review and dispensed doxepin to a pediatric patient. Alleged violation of law: 201 KAR 2:210 Section 4. CRC Recommendation: Case is dismissed.

**Case No. 08-0092B.** Pharmacist allegedly provided inappropriate prospective drug use review and dispensed doxepin to a pediatric patient. Alleged violation of law: 201 KAR 2:210 Section 4. CRC Recommendation: Case is dismissed.

**Case No. 08-0093.** Pharmacist allegedly relapsed. Pharmacist admitted to taking hydrocodone products from the pharmacy without proper authorization. Pharmacist surrendered license. Alleged violation of law: KRS 315.121(1)(i). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 08-0094.** Pharmacist allegedly engaged in unprofessional and unethical conduct by counseling a caregiver incorrectly on the directions of a prescription resulting in a four month old being given 6 ml of prednisolone solution instead of the prescribed 3 ml dose. The infant became agitated. Alleged violation of law:

KRS 315.121(2)(e). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 08-0095.** Special limited medicinal gas permit holder allegedly moved without proper notification to the Board office. Alleged violation of law: 201 KAR 2:225 Section 2 (3). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 08-0096.** Special limited medical gas pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a special limited medical gas pharmacy. Alleged violations of law: KRS 315.035(1) and (4) and 201 KAR 2:225. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 08-0097A.** Special limited medical gas permit holder allegedly failed to conduct quarterly inspections. Alleged violations of law: 201 KAR 2:225 Section 2(1)(b) and (2)(a). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 08-0097B.** Special limited medical gas permit holder's consultant pharmacist allegedly failed to conduct quarterly inspections. Alleged violations of law: 201 KAR 2:225 Section 2(1)(b) and (2)(a). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 08-0098.** Pharmacist allegedly committed a medication error by filling a prescription for HCTZ 25mg with HCTZ 50mg. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 08-0099.** Pharmacist allegedly committed a medication error by typing the dosage as 1 teaspoon instead of ¼ teaspoon on a prescription for Phenergan DM 120 ml. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 08-0100.** Pharmacist allegedly violated previous Agreed Order. Agreed Order required CE to be completed by July 9, 2008 CE was completed after July 9, 2008 and received October 6, 2008. Alleged violation of law: KRS 315.121(1)(i). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 08-0101.** Pharmacist allegedly completed 14 of the 15 hours of continuing education for 2007. Alleged violations of law: KRS 315.065 and 201 KAR 2:015. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 08-0102.** Pharmacist allegedly completed 12 of the 15 hours of continuing education for 2007. Alleged violations of law: KRS 315.065 and 201 KAR 2:015. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

### **RECIPROCITY/RELICENSURE/INTERNSHIP:**

**Kirk K. Smith.** Mr. Smith was sworn in by Juanita Toole, Court Reporter. Mr. Smith requested reinstatement of his Kentucky pharmacist's license that lapsed in 1979. He does not have a current pharmacist's license in any state and gave an overview of his past circumstances and why he would like to get his pharmacist's license reinstated. After discussion, Mr. Orzali moved to grant Mr. Smith's request to sit for the NAPLEX and MPJE, after paying back fees, completing an application and completing 1500 internship hours which may be transferred from Colorado. Ms. Thornbury seconded, and the motion passed four to one, with Mr. Orzali, Dr. Shely, Ms. Simpson, and Ms. Thornbury voting for the motion, and Dr. Policastri voting against the motion.

## **CORRESPONDENCE/COMMUNICATIONS:**

**Kroger Refill Center.** Duane Parsons and Tom Prose, representing Kroger, were sworn in by Juanita Toole, Court Reporter. Kroger was requesting a change in regulation 201 KAR 2:230 to delete the words “in the Commonwealth” from Section 1 as it relates to pharmacies being serviced by the Central Refill Pharmacy. After discussion, Mr. Orzali moved to begin the process of amending 201 KAR 2:230 to delete “in the Commonwealth” in Section 1 as it relates to pharmacies being serviced by the Central Refill Pharmacy. Mr. Bureson is to file the amended regulation by December 15, 2008 with a public hearing scheduled on January 27, 2009 at the Board office at 9:00 a.m. Dr. Policastri seconded, and the motion passed with Mr. Orzali, Dr. Policastri, Dr. Shely, and Ms. Simpson voting for the motion and Ms. Thornbury abstaining.

**Request for expungement EX 02-08.** Ms. Thornbury moved to expunge EX 02-08. Dr. Shely seconded, and the motion passed unanimously.

**Med Care Pharmacies.** Joe Mashni, representing Med Care pharmacies, requested an alternate daily log signature. Mr. Orzali moved to allow the alternate daily log signature process for Med Care Pharmacies. Ms. Thornbury seconded, and the motion passed unanimously.

## **LEGISLATION/REGULATIONS.**

**201 KAR 2:105, Wholesale Distributor.** Three written comments were received regarding the new wholesale distributor regulation, 201 KAR 2:105. Pharmaceutical Research and Manufacturers of America (PhRMA) requested that language be added that allowed for an exemption for a wholesale distributor to distribute legend drugs directly to the consumer or patient when the manufacturer is providing the legend drug to a patient through an established patient assistance program. Dr. Policastri moved to deny the request and not add the exemption to 201 KAR 2:105 allowing wholesale distributors to ship legend drugs directly to a patient when a manufacturer is providing the legend drugs to a patient through an established patient assistance program because a pharmacy and pharmacist needs to be involved in this process for patients to receive appropriate pharmaceutical care. Ms. Thornbury seconded, and the motion passed unanimously.

Health Industry Distributors Association (HIDA) requested that the Board halt finalization and implementation of 201 KAR 2:105. Mr. Orzali moved to respond to HIDA that the statute mandates that the Board promulgate a regulation. Ms. Thornbury seconded, and the motion passed unanimously.

Genentech requested that the Board amend 201 KAR 2:105 Section 4(3)(e) so that a unique corporate identifier be submitted instead of the individual social security numbers of corporate officers and directors. Ms. Thornbury moved to respond that the use of social security numbers of corporate officers and directors is mandated by federal regulation and must remain part of 201 KAR 2:105 Section 4(3)(e), but to inform

Genentech that this information will be kept confidential. Ms. Simpson seconded, and the motion passed unanimously. Dr. Shely moved that the unique identifier be added to all Sections of 201 KAR 2:105 as required by federal regulation. Ms. Thornbury seconded, and the motion passed unanimously.

**Compounding: New Regulation.** After discussion, Ms. Thornbury moved to approve the regulation regarding pharmacists compounding drugs for administration in a practitioner's office or in an institution as amended and Mr. Burleson is to file the regulation by December 15, 2008 with a public hearing scheduled for January 27, 2009 at the Board office at 10:00 a.m. Ms. Simpson seconded, and the motion passed unanimously.

**CONTINUING EDUCATION:**

Ms. Thornbury moved to accept the continuing education programs 08-47 through 08-61 as recommended. Ms. Simpson seconded, and the motion passed unanimously.

**OLD BUSINESS:** Ms. Thornbury stated that she had been keeping the Board Manual updated for new board members and since her term ends December 31, 2008, she needs to pass that responsibility to another Board member. Dr. Policastri volunteered to keep the Board Manual updated.

Brad Hall reported that the meeting on October 27, 2008 hosted by the Kentucky Association of Health Care Facility resulted in a partnership being formed between KPhA and the Kentucky State Police (KSP) in which KSP will designate officers to travel to long term care facilities to collect and dispose of the unused controlled substances.

**ADJOURNMENT:** On motion by Ms. Thornbury, seconded by Dr. Policastri and passed unanimously, President Leake adjourned the meeting at 3:08 p.m. The next regularly scheduled Board Meeting is scheduled to begin at 9:00 a.m. on December 17, 2008 at Board Office in Lexington, Kentucky.

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Michael Burleson, R.Ph.  
Executive Director