

**KENTUCKY BOARD OF PHARMACY**  
**23 Millcreek Park, Bldg. 2**  
**Frankfort, KY 40601-9230**  
**October 6, 2004 - 9:00 a.m.**

**AGENDA**

- I. CALL TO ORDER**
  
- II. APPEARANCES**
  - \*A. 9:00 AM Sally Droste
  - B. 9:30 AM Greenbaum Doll & McDonald PLLC/Vicki Yates Brown  
Pharmacist dispensing based on Internet questionnaire evaluations
  - \*C. 10:00 AM Greenbaum Doll & McDonald PLLC/Vicki Yates Brown  
Pharmacist-In-Charge Regulation (201KAR 2:205)
  - \*D. 10:30 AM KY-DOC/Cindy Gray
  - E. 11:00 AM USP-797/Trish Freeman
  - \*F. 1:00 PM Gerald Weigel
  - \*G. 1:30 PM Alesia Bernardo
  
- III. MINUTES**
  - \*A. September 12, 2004
  
- IV. INTERAGENCY**
  - A. Drug Control
  
- V. BOARD REPORTS**
  - A. Board President
    - 1. Board Retreat
    - 2. January, 2005 - Board Exam
    - 3. Board Room Renovation
  - B. Board Members
  - C. Board Executive Director
  - D. Board Staff
  - E. IPC Chairman
  
- VI. CURRENT/PENDING CASES**
  - A. OAG - C. Lalonde-Mooney
    - 1. CRC-AG Opinion
    - 2. Ethics Commission Response
    - 3. Case Updates
  - B. KBP Case Updates
    - Case No. 02-0137A
    - Case No. 03-0044
    - Case No. 03-0131
    - Case No. 03-0135A
    - Case No. 03-0150
    - Case No. 04-0001
    - Case No. 04-0041A
    - Case No. 04-0046A
    - Case No. 04-0046B
    - Case No. 04-0070A
    - Case No. 04-0070B
    - Case No. 04-0070C
    - Case No. 04-0070D
    - Case No. 04-0070E
    - Case No. 04-0070F
    - Case No. 04-0070H
    - Case No. 04-0070I

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Case No. 04-0070K  
Case No. 04-0070L  
Case No. 04-0070N  
Case No. 04-0070P  
Case No. 04-0070Q  
Case No. 04-0070R  
Case No. 04-0070S

C. Case Review Committee

**VII. RECIPROCITY/RELICENSURE/INTERNSHIP**

A. Chad M. Reynolds

**VIII. CORRESPONDENCE/COMMUNICATIONS**

- \*A. Telepharmacy Solutions, Inc. – Richard Slone
- \*B. Mission Frankfort Pharmacy – Larry Hadley
- \*C. PharMerica – Joseph Buganski
- \*D. hospice pharmacia – David Kupperman

**IX. NABP**

**X. LEGISLATION/REGULATIONS**

**XI. CONTINUING EDUCATION**

A. Program Review

**XII. FINES**

A. Fines Report

**XIII. OLD BUSINESS**

- A. Website Update – Katie Busroe
- B. Office Computer Installation Update

**XIV. NEW BUSINESS**

- A. November Hearing Dates
- B. 2005 Board Member Appointments

\*Information enclosed with this agenda

\*\*Information previously provided

\*\*\*Old material with response

**MINUTES**  
**KENTUCKY BOARD OF PHARMACY**  
Frankfort, Kentucky  
October 6, 2004

**CALL TO ORDER:**

A regular meeting of the Kentucky Board of Pharmacy was held at the Board office, 23 Millcreek Park, in Frankfort, Kentucky. President Armstrong called the meeting to order at 9:15 a.m.

Members present: Tim Armstrong, Becky Cooper, Mark Edwards, Georgina Kindall Jones, Greg Naseman, and Patricia Thornbury. Staff present: Michael Burleson, Executive Director; Jeffrey L. Osman, Pharmacy Inspections and Investigations Coordinator; Katie Busroe and Phil Losch, Pharmacy and Drug Inspectors; and Cheryl Lalonde-Mooney, Assistant Attorney General and Board Counsel. Guests: Brian Fingerson, Pharmacist Recovery Network; Paula York, Drug Enforcement and Professional Practices, Cabinet for Health and Family Services; Ralph Bouvette and Tera McIntosh, American Pharmacy Services Corporation; Mike Mayes and Joel Thornbury, Kentucky Pharmacists Association; Todd Downing, CVS Pharmacies; Steve Hart and Kevin Lamping, Rite Aid Pharmacies; Greg Baker, Chris Killmeier, and Chad Downing, Walgreens Pharmacies; Beverly Weigel and Joseph Weigel; Jody Jagers, Kim Bottom, Shanna Jackson, and Ashlie Sykes, University of Kentucky College of Pharmacy intern students; and Christi Ratliff, Shenandoah College of Pharmacy intern student. Juanita M. Toole, Court Reporter, recorded the meeting.

**APPEARANCES:**

**Sally Droste.** Ms. Droste appeared to petition the Board for modification of her existing Agreed Order. Ms. Droste was placed under oath by Ms. Toole, Court Reporter. Ms. Droste was under an Agreed Order on Reinstatement for impairment. The Agreed Order on Reinstatement contains the stipulation that should Ms. Droste violate any part of the Agreed Order on Reinstatement she would automatically lose her Kentucky pharmacist's license for not less than 5 years and 1 day. Ms. Droste gave a brief overview of the cause leading her to violate this Agreed Order on Reinstatement. Ms. Thornbury moved to recognize the fact that the Pharmacist Recovery Network has evolved from the time that Ms. Droste's Agreed Order on Reinstatement was drafted and signed, particularly concerning alcoholism, and therefore moved to amend the Agreed Order on Reinstatement due to the wisdom that has transpired from the Pharmacist Recovery Network and that Ms. Droste be placed on a stricter Agreed Order to include being on probation for 10 years. The motion died due to a lack of a second. Ms. Kindall Jones moved to accept the surrender of Ms. Droste's license, memorialize this in an Agreed Order of Surrender under terms of six months suspension and after that time period, Ms. Droste may petition the Board for reinstatement of her Kentucky pharmacist's license. The Board reserves the right to grant or deny the petition for reinstatement. Mr. Edwards seconded, and the motion passed unanimously.

**Greenbaum, Doll and McDonald PLLC/Vicki Yates-Brown.** Ms. Yates-Brown appeared before the Board to discuss Internet pharmacies in Kentucky and the opinion issued by the Board of Pharmacy at the August 11, 2004, Board meeting. Ms. Yates-Brown was placed under oath by Ms. Toole, Court Reporter. After discussion, Mr. Edwards moved to enforce the August opinion that the Kentucky Board of Pharmacy feels that a valid physician/patient/pharmacist relationship cannot be established based solely upon an on-line questionnaire evaluation; therefore, the Kentucky Board of Pharmacy considers that knowingly dispensing prescriptions obtained from Internet prescribing, through questionnaire based evaluations to be unethical and unprofessional, and to move forward with codification of a statute that would clearly define the invalidity of a prescription that was issued based solely upon an on-line Internet questionnaire based evaluation. Ms. Thornbury seconded, and the motion failed. Mr. Edwards voted for the motion, Ms. Cooper, Ms. Kindall Jones, Mr. Naseman, and Ms. Thornbury opposed the motion. After further discussion, Mr. Edwards moved to seek codification of the opinion in a statute that would clearly define the validity of a prescription that was issued based solely upon an on-line Internet questionnaire based evaluation. Ms. Kindall Jones seconded and the motion passed unanimously. Mr. Naseman moved to direct the Executive Director, Pharmacy Inspections and Investigations Coordinator, and Pharmacy and Drug Inspectors of the Board's opinion issued in August and the intent of the Board to seek codification regarding the validity of a prescription that was issued based solely upon an on-line Internet questionnaire based evaluation and for staff to proceed with caution until the outcome is solidified with statute. Mr. Edwards seconded, and the motion passed unanimously.

**Greenbaum, Doll and McDonald PLLC/Vicki Yates-Brown.** Ms. Yates-Brown presented the Board with an alternative Agreed Order regarding Case No. 03-157A Kroger Corporation, Case No. 03-157B Christie Raleigh, and Case No. 03-157C Phelicisima Roberts. Ms. Yates-Brown proposed that Kroger Corporation pay a \$5000 fine and the violations against both the pharmacists-in-charge, Christi Raleigh and Phelicisima Roberts be dismissed. After discussion, Mr. Naseman moved to reject the proposed Agreed Order from Ms. Yates-Brown and to uphold the original decision that 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 for Case No. 03-0157A, B, and C. Mr. Edwards seconded, and the motion passed unanimously as demonstrated by a hand vote.

**Trish Freeman.** Dr. Freeman appeared before the Board to request clarification on the United States Pharmacopeia's Chapter 797 (USP 797). Dr. Freeman was placed under oath by Ms. Toole, Court Reporter. After a brief discussion, Ms. Thornbury moved to interpret USP 797 so that the compounded sterile products that are prepared, stored, and dispensed are regulated per USP 797. If the compounded sterile products are prepared and dispensed for immediate use, but not stored, USP 797 does not apply. Ms. Kindall Jones seconded, and the motion passed unanimously.

**Kentucky Department of Corrections/Scott Haas, M.D.** Dr. Haas, medical director for the Kentucky Department of Corrections, appeared before the Board to discuss the possibility of the correctional facilities in the Commonwealth of Kentucky utilizing stock medication without a pharmacy permit. Dr. Haas was placed under oath by Ms. Toole, Court Reporter. After discussion, Mr. Naseman moved to direct the Board of Pharmacy staff to work with the Kentucky Department of Corrections should this entity choose to pursue licensing a pharmacy at each facility, by amending

201 KAR 2:074 to include correctional facilities as an “other organized health care facility.” Mr. Edwards seconded, and the motion passed unanimously.

**Gerald Weigel.** Mr. Weigel appeared before the Board to petition for reinstatement of his Kentucky pharmacist’s license. Mr. Weigel was placed under oath by Ms. Toole, Court Reporter. Mr. Weigel gave a brief overview of the cause leading to the loss of his pharmacist’s license. Mr. Fingerson reviewed the recommendation of the Impaired Pharmacist Committee for reinstatement of license. Mr. Edwards moved to reinstate with an Order of Reinstatement with stipulations as follows: Probation for 5 years; employment of no more than 40 hours per week or no more than 80 hours in a two week period; shall not serve as pharmacist-in-charge or have power of attorney; provide a copy of Agreed Order to all employers; enter into an aftercare contract with the Impaired Pharmacist Committee (IPC), to include a drug counselor if indicated; submission of a signed release for medical records; AA or NA no less than three (3) times per week; submission to the Board of written quarterly reports of all AA/NA meetings; submit to random observed urine/blood drug screens; not ingest any mood altering substance whether legend or nonlegend medications and including alcoholic beverages; notification to the Board of all legend and nonlegend drugs taken within 10 days; shall keep Board informed of place of employment; Board or Board President’s approval of all employers; obtain all prescriptions and those of family members at pharmacy designated in writing to the Board; shall not dispense any drugs for himself or his family members; shall be subject to biannual inspections by the Board at all places of employments, cost not to exceed \$500 per inspection; attendance at the University of Utah School on Alcoholism and Other Drug Dependencies or the Southeastern Pharmacist Recovery Network meeting within one year; provide the Board or the IPC with a monthly written self-performance evaluation; and shall make any and all appearances before the IPC as requested. Order on Reinstatement to be drafted and forwarded to Mr. Weigel for his signature and upon its return to be signed by President Armstrong. Mr. Naseman seconded, and the motion passed unanimously.

**Alicia Bernardo.** Ms. Bernardo appeared before the Board to petition for reinstatement of her Kentucky pharmacist’s license. Ms. Bernardo was placed under oath by Ms. Toole, Court Reporter. Ms. Bernardo had surrendered her pharmacist’s license to Mr. Fingerson in June 2004 and gave an overview of the cause that lead to the surrendering of her pharmacist’s license. After a brief discussion, Ms. Thornbury moved to consider Ms. Bernardo’s petition for reinstatement at the January 5, 2005, Board meeting, after she has demonstrated at least six months of sobriety. Ms. Cooper seconded, and the motion passed unanimously.

**MINUTES:**

On motion by Ms. Kindall Jones, seconded by Mr. Edwards and passed unanimously, the Minutes of September 12, 2004, were adopted.

**BOARD REPORTS:**

**President.** President Armstrong welcomed Mr. Burleson as the new Executive Director of the Kentucky Board of Pharmacy and wished him the best of luck. He thanked Dr. Osman and Mr. Losch for serving as Interim Executive Directors.

1. Board Retreat. President Armstrong encouraged all pharmacists to attend the Board Retreat November 13-14, 2004, in Bowling Green, Kentucky. Joel Thornbury, President of the Kentucky Pharmacists Association (KPhA), announced that KPhA was sponsoring a

- continuing education program on November 12, 2004, as well as the Retreat. Mr. Thornbury presented the proposed agenda for the Retreat. Topics of discussion include pharmacy technician issues, electronic environment in pharmacy, continuing professional development, and medication error issues. He also invited all pharmacists to attend the retreat. Ms. Thornbury recognized Dr. Bouvette for his hard work on the Retreat.
2. January 2005 Board Exam. The Board Staff has a verbal agreement from the University of Kentucky College of Pharmacy to hold the January 2005 examinations at that facility. The finished exam needs to be at the Board office by the December 8, 2004, Board meeting.
  3. Board Room Renovation. There are five options regarding office space:
    - a. The Board staff has received a bid of \$15,164 to enlarge the Board meeting room; a bid of \$31,000 was received to renovate the entire office space with carpet, ceiling tiles, and paint.
    - b. Option to explore office space to rent or lease outside of Frankfort, for example in Lexington.
    - c. Option to build a building.
    - d. Option to hold the Board meetings in another building but keep the office where it is.
    - e. Option to stay as is.

Assistant Attorney General and Board Counsel Lalonde-Mooney directed Mr. Burluson to get more information. Ms. Thornbury requested a comparison on rent at available spaces.

**Members.** All Board members welcomed Mr. Burluson as the new Executive Director. Ms. Cooper requested that an article on USP 797 be in the December Board Newsletter.

Ms. Thornbury gave an update on the Board Manual that she and Ms. Lalonde-Mooney are assembling. A student has offered to help Ms. Thornbury and Ms. Lalonde-Mooney with the Manual. Ms. Thornbury will present the Board Manual at the Retreat.

Mr. Naseman volunteered to personally review the Board of Pharmacy regulations and bring any regulation that needs updating to the Board for action.

**Executive Director.** Mr. Burluson stated that he was privileged and honored to be serving as Executive Director.

1. Mr. Burluson provided the Board with the past three months of expense and income reports.
2. Mr. Burluson presented the Board with the state letter of agreement from the National Association of Boards of Pharmacy regarding the North American Pharmacist Licensure Examination and the Multistate Pharmacy Jurisprudence Examination. Mr. Edwards moved for Mr. Burluson to sign the agreement. Mr. Naseman seconded, and the motion passed unanimously.
3. The office computer system has been updated. The hardware was purchased for \$15,032.72, staff was able to save approximately \$1000. The programmers cost was \$20,565 which was over budget by approximately \$3500. The software was purchased for \$7,855.20. Mr. Burluson thanked Dr. Bouvette and Ms. Lalonde-Mooney for all their help.
4. A cleaning crew has been hired and started October 1, 2004.
5. The Board had a brief discussion regarding the need for a court reporter at Board meetings. No decision will be made until an Executive Secretary is hired.

6. Board portraits will be made at the December 8, 2004, Board meeting.
7. Mr. Burluson thanked the entire staff for their helpfulness during the first days of his employment.
8. The Board staff is in the process of hiring two employees, a Pharmacy and Drug Inspector and Executive Secretary.

**Staff.** Dr. Osman and Mr. Losch welcomed Mr. Burluson as the Executive Director. Mr. Fingerson discussed the budget of the Impaired Pharmacist Committee (IPC). By statute, the Board is allowed to collect \$10 per pharmacist's license to finance the IPC. Mr. Fingerson was given a raise, therefore almost the entire budget of the IPC will be used to pay his salary, resulting in IPC being over budget.

**CURRENT/PENDING CASES: Office of Attorney General/Cheryl Lalonde-Mooney.**

1. The Office of Attorney General has issued an opinion that the Case Review Committee of the Kentucky Board of Pharmacy is viewed as a public agency, therefore, it is subject to the open meetings law. As a public agency the Case Review Committee is an open meeting unless it is closed due to an exception of the open meetings law. As an open meeting the Case Review Committee meetings must be posted as to time and place of meetings and minutes must be taken and approved at the meetings.
2. As directed by the Board at the August 11, 2004, meeting, Ms. Lalonde-Mooney has written a letter of response to the Ethics Commission regarding the Ethics Accountability for Board and Commission Members, stating that the Kentucky Board of Pharmacy already has protocols in place.
3. The Board discussed KRS 315.035 (4), regarding permit renewal. The statute is open to interpretation, being silent on the penalty for renewing a permit after August 1. Historically, the Board has fined permit holders \$500, not for renewing late, but for operating without a valid permit if the permit is not renewed by June 30. The Board decided to uphold this decision and directed Mr. Naseman to work with Ms. Lalonde-Mooney to make the language very clear on KRS 315.035 (4).
4. Ms. Thornbury moved to authorize the Board to buy a \$168 subscription of Monthly Licensing Report. This is a report that gives a synopsis of different issues affecting all types of licensing agencies. Ms. Kindall Jones seconded, and the motion passed unanimously. Ms. Lalonde-Mooney volunteered to summarize a case or two per month for the Board.

Mr. Edwards moved for acceptance and entry of the proposed Agreed Orders as written. Ms. Kindall Jones seconded, and the motion passed unanimously.

**Case No. 02-0137A; Case No. 03-0044; Case No. 03-0131; Case No. 03-0135A; Case No. 03-0150; Case No. 04-0001; Case No. 04-0041A; Case No. 04-0046A; Case No. 04-0046B; Case No. 04-0069A; Case No. 04-0069B; Case No. 04-0069C; Case No. 04-0069D; Case No. 04-0070A; Case No. 04-0070B; Case No. 04-0070C; Case No. 04-0070D; Case No. 04-0070E; Case No. 04-0070F; Case No. 04-0070H; Case No. 04-0070I; Case No. 04-0070K; Case No. 04-0070L; Case No. 04-0070N; Case No. 04-0070P; Case No. 04-0070Q; Case No. 04-0070R; Case No. 04-0070S.**

## **CASE REVIEW COMMITTEE**

Ms. Thornbury moved for acceptance of the Committee recommendation for the following case reports.

**Case No. 01-0135A.** Pharmacy permit holder employed a pharmacist that allegedly engaged in unprofessional and unethical conduct by refusing to fill a written prescription presented to him by a consumer of the Commonwealth. The Board office received a written complaint from the consumer on November 29, 2001. The consumer lives two hours from the pharmacy and presented the prescription for OxyContin. The pharmacist refused to fill the prescription because it was not legible. The identity of the pharmacist could not be identified and the complainant could not be contacted. Alleged violation of law: KRS 315.121 (2)(d). CRC recommendation: case is dismissed. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 01-0135B.** Pharmacist allegedly engaged in unprofessional and unethical conduct by refusing to fill a written prescription presented to him by a consumer of the Commonwealth. The Board office received a written complaint from the consumer on November 29, 2001. The consumer lives two hours from the pharmacy and presented the prescription for OxyContin. The pharmacist refused to fill the prescription because it was not legible. The identity of the pharmacist could not be identified and the complainant could not be contacted. Alleged violation of law: KRS 315.121 (2)(d). CRC recommendation: case is dismissed. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 03-0148A Revisit.** Pharmacy permit holder allegedly sold a misbranded drug as the result of selling prescription drugs without authorization from a licensed practitioner. The pharmacy was selling non-patient specific compounded legend drugs to an Ohio hospital as well as compounding prescriptions that were commercially available (at the time these drugs were compounded they were unavailable from the manufacturer). The Ohio Board of Pharmacy had scheduled a hearing in April 2004. The Settlement Agreement between the Ohio Board of Pharmacy and the permit holder was signed August 3, 2004. The major terms of the Agreement are a one month suspension of the pharmacy license and a \$4000 fine. The FDA also fined the permit holder \$1000. Alleged violations of law: KRS 217.065, KRS 315.121(2)(f), and Section 505 of the Food, Drug, and Cosmetic Act. CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 03-0148B Revisit.** Pharmacist-in-charge engaged in unprofessional conduct by selling prescription drugs without authorization from a licensed practitioner. The pharmacy was selling non-patient specific compounded legend drugs to an Ohio hospital as well as compounding prescriptions that were commercially available (at the time these drugs were compounded they were unavailable from the manufacturer). The Ohio Board of Pharmacy had scheduled a hearing in April 2004. The Settlement Agreement between the Ohio Board of Pharmacy and the permit holder was signed August 3, 2004. The major terms of the Agreement are a one month suspension of the

pharmacy license and a \$4000 fine. The FDA also fined the permit holder \$1000. Alleged violations of law: KRS 315.121(2)(f), and Section 505 of the Food, Drug, and Cosmetic Act. CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 03-0148C.** Pharmacist engaged in unprofessional conduct by selling prescription drugs without authorization from a licensed practitioner. The pharmacy was selling non-patient specific compounded legend drugs to an Ohio hospital as well as compounding prescriptions that were commercially available (at the time these drugs were compounded they were unavailable from the manufacturer). The Ohio Board of Pharmacy had scheduled a hearing in April 2004. The Settlement Agreement between the Ohio Board of Pharmacy and the permit holder was signed August 3, 2004. The major terms of the Agreement are a one month suspension of the pharmacy license and a \$4000 fine. The FDA also fined the permit holder \$1000. Alleged violations of law: KRS 315.121(2)(f), and Section 505 of the Food, Drug, and Cosmetic Act. CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0011A Revisit.** Permit holder was allegedly manufacturing drugs when the health of the animal is not threatened, manufacturing drugs in commercial size lots, compounding drugs where there is a manufactured alternative, compounding without a valid veterinarian relationship, and compounding with bulk drugs. The pharmacy was inspected by a Food and Drug Administration (FDA) compliance officer. An FDA-483 warning letter was issued to the pharmacy regarding whether the entity's scope was that of a pharmacy or a manufacturer. Update: Kentucky Board of Pharmacy inspector and FDA inspector have inspected pharmacy permit holder. FDA issued a seizure warrant for the compounded products at the permitted site and the permit holder filed an order to claim the compounded products. The matter is being litigated in federal court. Alleged violations of law: 21 CFR 530.13(a), 21 CFR 530.13(b)(2), 21 CFR 530.13(b)(1) and (b)(3), and KRS 315.121 (1)(h). CRC recommendation: there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0011B Revisit.** Pharmacist-in-charge was allegedly manufacturing drugs when the health of the animal is not threatened, manufacturing drugs in commercial size lots, compounding drugs where there is a manufactured alternative, compounding without a valid veterinarian relationship, and compounding with bulk drugs. The pharmacy was inspected by a Food and Drug Administration (FDA) compliance officer. An FDA-483 warning letter was issued to the pharmacy regarding whether the entity's scope was that of a pharmacy or a manufacturer. Update: Kentucky Board of Pharmacy inspector and FDA inspector have inspected pharmacy permit holder. FDA issued a seizure warrant for the compounded products at the permitted site and the permit holder filed an order to claim the compounded products. The matter is being litigated in federal court. Alleged violations of law: 21 CFR 530.13(a), 21 CFR 530.13(b)(2), 21 CFR 530.13(b)(1) and (b)(3), and KRS 315.121 (1)(h). CRC recommendation: there is insufficient evidence of a violation to

warrant disciplinary action and the case is closed without prejudice. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0029A.** Pharmacy permit holder allegedly sold a misbranded drug as the result of a medication error. A prescription was presented and left to be filled for Zithromax suspension. There was some difficulty in locating the prescription once the caregiver returned to the pharmacy to pick it up. The prescription was dispensed without being reconstituted. The caregiver returned the medication, retrieved the prescription, and had it filled at another pharmacy. Alleged violation of law: KRS 217.065(1). CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0029B.** Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. A prescription was presented and left to be filled for Zithromax suspension. There was some difficulty in locating the prescription once the caregiver returned to the pharmacy to pick it up. The prescription was dispensed without being reconstituted. The caregiver returned the medication, retrieved the prescription, and had it filled at another pharmacy. Alleged violation of law: KRS 315.121(2)(d). CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0044.** Pharmacy permit holder allegedly sold a misbranded product as the result of a medication error in the form of incorrect number of tablets in the vial. Additionally, it is alleged that an unauthorized person was allowed to pick up a prescription. The Board office received a written complaint from a consumer on February 11, 2004, alleging that his prescription for hydrocodone/acetaminophen 10/325 mg tablets, quantity of 112, had been shorted by 12 tablets. Also, when he arrived at the pharmacy he was informed that the prescription had already been picked up the previous day. Alleged violations of law: KRS 217.065(1) and 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0045A.** Pharmacy permit holder allegedly sold a misbranded product as the result of a medication error. Patient had prescription refilled for metformin XR 500 mg. Prescription was filled with metronidazole 500 mg but labeled as metformin XR 500 mg. Patient took the metronidazole for approximately 2 weeks and experienced uncontrolled blood glucose levels and a rash. Alleged violation of law: KRS 217.065(1). CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0045B.** Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. Patient had prescription refilled for metformin XR 500 mg. Prescription was filled with metronidazole 500 mg but labeled as metformin XR 500 mg. Patient took the metronidazole for approximately 2 weeks and experienced uncontrolled blood glucose levels and a rash. Alleged violation of law: KRS 315.121(2)(d). CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0050A.** Pharmacy permit holder allegedly sold a misbranded drug as the result of a medication error. Patient presented prescription for Percocet 5 mg tablets and allegedly received a mixture of generic Percocet 5 mg and aspirin 325 mg tablets. The patient experienced unrelieved pain symptoms. Alleged violation of law: KRS 217.065(1). CRC recommendation: there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0050B.** Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. Patient presented prescription for Percocet 5 mg tablets and allegedly received a mixture of generic Percocet 5 mg and aspirin 325 mg tablets. The patient experienced unrelieved pain symptoms. 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0051A.** Pharmacy permit holder allegedly sold a misbranded product as the result of a medication error. Patient presented prescription for Fiorinal #3 but was filled and labeled as generic Fiorinal, without the codeine. The patient took the entire prescription, had it refilled and had consumed the refill before the error was detected. The patient experienced unrelieved pain symptoms. Alleged violation of law: KRS 217.065(1). CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0051B.** Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. Patient presented prescription for Fiorinal #3 but was filled and labeled as generic Fiorinal, without the codeine. The patient took the entire prescription, had it refilled and had consumed the refill before the error was detected. The patient experienced unrelieved pain symptoms. Alleged violation of law: KRS 315.121(2)(d). CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0053A Revisit.** Pharmacy permit holder allegedly sold a misbranded drug as the result of a medication error. A prescription was presented for Keppra 500 mg. The prescription was filled with Cipro 500 mg. The patient experienced seizure activity and was hospitalized for 3 days. Alleged violation of law: KRS 217.065(1). CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0053B Revisit.** Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. A prescription was presented for Keppra 500 mg. The prescription was filled with Cipro 500 mg. The patient experienced seizure activity and was hospitalized for 3 days. Alleged violation of law: KRS 315.121(2)(d). CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0070G Revisit.** Pharmacy permit holder failed to renew permit in a timely manner and continued to operate as a pharmacy. Alleged violation of law: KRS 315.035. CRC recommendation to uphold the original recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0071A.** Pharmacy permit holder allegedly sold a misbranded drug as the result of a medication error. Patient presented a prescription for prednisone 10 mg tablets. The prescription was labeled as prednisone 10 mg tablets, however, the prescription vial contained promethazine 25 mg tablets. The patient took the promethazine for 2 days before the error was detected. The patient could not eat, exhibited flu-like symptoms, had an exacerbation of arthritis, had a swollen knee, and had symptoms of withdrawal. Alleged violation of law: KRS 217.065(1). CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0071B.** Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. Patient presented a prescription for prednisone 10 mg tablets. The prescription was labeled as prednisone 10 mg tablets, however, the prescription vial contained promethazine 25 mg tablets. The patient took the promethazine for 2 days before the error was detected. The patient could not eat, exhibited flu-like symptoms, had an exacerbation of arthritis, had a swollen knee, and had symptoms of withdrawal. Alleged violation of law: KRS 315.121(2)(d). CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0073A.** Pharmacy permit holder allegedly sold a misbranded product as the result of a medication error. A prescription was telephoned to a pharmacy for a dog for NPH insulin. The prescription was filled and dispensed as Novolin Regular (R) insulin. The dog received the R insulin for several months before the error was detected. The dog experienced uncontrolled diabetes and is now blind. Alleged violation of law: KRS 217.065(1). CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0073B.** Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. A prescription was telephoned to a pharmacy for a dog for NPH insulin. The prescription was filled and dispensed as Novolin Regular (R) insulin. The dog received the R insulin for several months before the error was detected. The dog experienced uncontrolled diabetes and is now blind. Alleged violation of law: KRS 315.121(2)(d). CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0074.** Pharmacist allegedly engaged in unprofessional conduct by embezzling at least \$25,000 from the pharmacy at which she was employed. Pharmacist has admitted to the embezzlement and has paid restitution to the pharmacy. It is probable that a grand jury indictment will be requested in October. Alleged violation of law: KRS 315.121(1)(a). CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0077A.** Pharmacy permit holder allegedly refilled a non-controlled substance prescription longer than the allowable one year limit. The Board office received a written complaint from a physician's office regarding a prescription. The physician's office alleged that the last prescription for this patient for Glucophage was written on August 6, 2002, with 11 refills. Pharmacist telephoned a refill request for the patient on June 23, 2004. Therefore, the patient had been receiving the Glucophage for approximately 11 months past the expiration of the last prescription. It was discovered that the physician had issued a prescription on March 17, 2003, with 12 refills. The prescription was originally filled at one pharmacy on March 17, 2003, then transferred to pharmacy permit holder on June 19, 2003. The transferred prescription was entered into the computer with an original issuance date of June 19, 2003, with 12 refills remaining, instead of the correct original issuance date of March 17, 2003, with 9 refills remaining. Therefore, the prescription was actually filled for approximately 16 months. Alleged violation of law: 201 KAR 2:185, Section 3. CRC recommendation: there is sufficient evidence of a violation, however, the

penalty shall be the issuance of a Letter of Reprimand. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0077B.** Pharmacist allegedly refilled a non-controlled substance prescription longer than the allowable one year limit. The Board office received a written complaint from a physician's office regarding a prescription. The physician's office alleged that the last prescription for this patient for Glucophage was written on August 6, 2002, with 11 refills. Pharmacist telephoned a refill request for the patient on June 23, 2004. Therefore, the patient had been receiving the Glucophage for approximately 11 months past the expiration of the last prescription. It was discovered that the physician had issued a prescription on March 17, 2003, with 12 refills. The prescription was originally filled at one pharmacy on March 17, 2003, then transferred to pharmacy permit holder on June 19, 2003. The transferred prescription was entered into the computer with an original issuance date of June 19, 2003, with 12 refills remaining, instead of the correct original issuance date of March 17, 2003, with 9 refills remaining. Therefore, the prescription was actually filled for approximately 16 months. Alleged violation of law: 201 KAR 2:185, Section 3. CRC recommendation: there is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0078A.** Pharmacy permit holder allegedly relocated the pharmacy without a prior inspection by the Board. Pharmacy permit holder signed and dated application for permit to operate a pharmacy in Kentucky – change of address/location on August 13, 2004. The Board office received the application and accompanying letter on August 22, 2004. The Board office mailed an acknowledgement to the permit holder on August 23, 2004. The pharmacist-in-charge contacted the inspector for an inspection on August 26, 2004. The pharmacy had relocated on August 18, 2004. Alleged violation of law: KRS 315.035(1) and (5). CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0078B.** Pharmacist-in-charge allegedly relocated the pharmacy without a prior inspection by the Board. Pharmacy permit holder signed and dated application for permit to operate a pharmacy in Kentucky – change of address/location on August 13, 2004. The Board office received the application and accompanying letter on August 22, 2004. The Board office mailed an acknowledgement to the permit holder on August 23, 2004. The pharmacist-in-charge contacted the inspector for an inspection on August 26, 2004. The pharmacy had relocated on August 18, 2004. Alleged violation of law: KRS 315.035(1) and (5). CRC recommendation: there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0079.** Wholesaler permit holder allegedly relocated prior to notification and inspection by the Board. The Board inspector conducted a routine inspection of the permit holder. The permit holder had moved to a new building next door to the old location without filing a change of address/location application with the Board. Alleged violations of law: KRS 315.03691) and 201

KAR 2:050 Section 1(13). CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0083A.** Special limited medical gas pharmacy permit holder allegedly moved without notifying the Board of the move and was not inspected prior to the move and failed to renew permit in a timely manner and continued to operate as a special limited medical gas pharmacy. Alleged violation of law: KRS 315.035. CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0083B.** Pharmacist-in-charge of a special limited medical gas pharmacy allegedly allowed permit holder to move without notifying the Board of the move and without being inspected prior to the move and failed to renew permit in a timely manner and continued to operate as a special limited medical gas pharmacy. Alleged violation of law: KRS 315.035. CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

**Case No. 04-0084.** Pharmacist is allegedly impaired. Alleged violation of law: KRS 315.121(2)(f). CRC recommendation for Complaint with the Executive Director to attempt to resolve 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. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Cooper was unavailable at the time of the vote.

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

**Chad Reynolds.** The Board reviewed Mr. Reynolds's request for reinstatement of his Kentucky pharmacist's license. After a brief discussion, Ms. Kindall Jones moved to reinstate Mr. Reynolds's Kentucky pharmacist's license provided he successfully completes the MPJE. Mr. Edwards seconded, and the motion passed unanimously.

#### **CORRESPONDENCE/COMMUNICATIONS:**

**Telepharmacy Solutions, Inc./Richard Slone.** The Board reviewed the correspondence regarding remote automated dispensing pharmacy services to be used in a rural community. Mr. Slone provided regulations from states that allow this type of technology, as requested by the Board. At the March 6, 2002, Kentucky Board of Pharmacy meeting, the Board moved and approved proceeding with adopting an administrative regulation with the Notice of Intent being filed to use this technology. After a brief discussion, Mr. Naseman directed the Executive Director to draft the

regulation and present to the Board for review by the December 8, 2004, or January 5, 2005, Board meeting.

**Mission Frankfort Pharmacy/Larry Hadley.** Mr. Hadley appeared before the Board to request exemptions to 201 KAR 2:090 Section 2(1) for the charitable pharmacy, Mission Frankfort Pharmacy. Mr. Hadley was placed under oath by Ms. Toole, Court Reporter. After a brief discussion, Ms. Kindall Jones moved that an exemption be granted to Mission Frankfort Pharmacy waiving the equipment requirements of a prescription balance, weights, graduates, mortar and pestle, filtration funnel with filter papers, heating unit, and ointment slab or paper. Additionally, granting an exemption for a sink with hot and cold running water to be located in the pharmacy since a sink is available for pharmacy use approximately 21 feet from the pharmacy. Mr. Naseman seconded, and the motion passed unanimously.

**PharMerica/Joseph Buganski.** The Board reviewed the correspondence regarding the request for a waiver from 201 KAR 2:170 Section 1(8), pharmacists signing the end of day prescription reports and instead utilizing a daily pharmacist's signature log as documentation of verifying the accuracy of the pharmacist's work. After a brief discussion, Ms. Thornbury moved to provide Mr. Buganski with the information that a pharmacist's signature log was acceptable as long as the hard copy of the end of day prescription reports were printed and available for review and verification. Ms. Kindall Jones seconded, and the motion passed unanimously.

**hospice pharmacia/David Kupperman.** The Board reviewed the correspondence regarding a proposed pilot collaborative practice program with the Hospice and Palliative Care of Louisville. After discussion, the Board directed Mr. Burleson to communicate with Dr. Kupperman requesting more information.

#### **LEGISLATION/REGULATIONS:**

Dr. Bouvette informed the Board that the Kentucky Legislature has a special session starting October 8, 2004. House Speaker Jody Richards is expected to present a resolution asking the Food and Drug Administration for an exemption for Kentucky to import prescription drugs from Canada. After a discussion, Ms. Kindall Jones moved for Dr. Bouvette, American Pharmacy Services, Inc.; Jan Gould, Kentucky Retail Federation; Mike Mayes, Kentucky Pharmacists Association; and Mike Burleson, Executive Director of the Kentucky Board of Pharmacy to create a strong position statement on Canadian importation to be presented to appropriate members of the Legislature. Ms. Thornbury seconded, and the motion passed unanimously. Once the position statement is written, it is to be disseminated to all Board members for their approval. Mr. Burleson was directed to research and compile any documentation of public harm from the importation of drugs into the United States of America.

#### **CONTINUING EDUCATION:**

Mr. Edwards moved to accept the continuing education programs 04-30 through 04-35 as recommended. Ms. Kindall Jones seconded, and the motion passed unanimously.

**OLD BUSINESS:**

Katie Busroe gave a brief update on the Kentucky Board of Pharmacy website which should go live in the first part of 2005.

**NEW BUSINESS:**

The November hearing dates were tabled by President Armstrong.

Governor Fletcher has appointed Pete Orzali to serve a term on the Kentucky Board of Pharmacy from January 1, 2005, until December 31, 2008. Governor Fletcher reappointed Patricia Thornbury to serve her second term from January 1, 2005, until December 31, 2008.

**ADJOURNMENT:**

On motion by Ms. Kindall Jones, seconded by Mr. Naseman and passed unanimously, President Armstrong adjourned the meeting at 5:30 p.m. The next Board meeting is scheduled to begin at 9:00 a.m. on December 8, 2004, at the Board office in Frankfort.

MB:nkb

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Mike Burlison, Executive Director