

**KANSAS STATE BOARD OF PHARMACY
MINUTES OF THE MEETING**

June 8 & 9, 2004
AmeriSuites
6021 SW 6th Ave.
Topeka, Kansas

Tuesday, June 08, 2004

MEMBERS PRESENT: Frank Whitchurch, RPh., Vice President; Merlin McFarland, RPh., Jeff Thompson, RPh.; JoAnne Gilstrap, RPh.; Max Heidrick, RPh.

ABSENT: Howard Paul, Public Member.

STAFF PRESENT: Debra Billingsley, Executive Secretary; Jim Kinderknecht, RPh., Pharmacy Inspector; LaTonyua Rice, Pharm.D., Pharmacy Inspector; Reyne Kenton, Compliance Officer; Randy Forbes, General Counsel and Karen Hollon, Administrative Officer.

OTHERS PRESENT: See attached listing.

MEETING CALLED TO ORDER: Frank Whitchurch called the meeting to order at 9:00 am.

INTRODUCTION OF NEW BOARD MEMBERS: Mr. Whitchurch introduced new board member Max Heidrick of Beloit, Kansas. Mr. Heidrick replaced Michael Hurst. Merlin McFarland was reappointed to serve another term. Both Heidrick and McFarland will serve a term of three years.

APPROVAL OF AGENDA: A motion was made and seconded to accept an amended agenda by adding discussion regarding license classifications of pharmacists and pharmacies. (Thompson/McFarland) Motion carried 4-0.

APPROVAL OF MINUTES: A motion was made and seconded to accept amended March minutes whereby the second paragraph of page seven reads as follows, "Ms. Gilstrap also requested clarification as to whether a PA and ARNP from another state should be required to have the practitioner's name on the RX along with their own when their practicing state does not require this. The Board concluded that they must follow Kansas law and have the physician's name on the RX along with their own." (Heidrick/Gilstrap) Motion carried 4-0.

DISCUSSION, CONSIDERATION, AND POSSIBLE ACTION REGARDING RENEWAL OF CONTRACT WITH KPhA TO IMPLEMENT CIPP PROGRAM: Jenith Hoover, Associate Director of KPhA, and Nancy Corkin, Chairman of the CIPP Program, presented a summary report of the past year's program and the 2004 Final

Expense Report. The Board discussed that they will make a determination next year as to whether to add technicians to the CIPP contract. This will give the board an opportunity to look at the numbers and statistics involving technicians.

Mr. Whitchurch also introduced and welcomed the new KPhA Executive Director, John Kiefhaber.

A motion was made and seconded to approve the contract with KPhA to implement the CIPP program for the July 1, 2004 through June 30, 2005 period. (Thompson/McFarland) Motion carried 4-0.

ADMINISTRATIVE PROCEEDINGS:

JEFFREY HODGSON #1-13251

Jeffrey Hodgson appeared in person and with legal counsel, Steve Schwarm. Marty Snyder, Assistant Attorney General represented the Board. The parties advised the Board that Mr. Hodgson was charged with violating K.S.A. 65-1627(a)(4) in that the licensee has had an addiction to alcohol or drugs to such a degree as to render the licensee unfit to practice pharmacy. This was evidenced by Respondent's diversion of Tussionex and hydrocodone from his employer for his own use. The Respondent also violated K.S.A. 65-1637(a) by failing to fill a prescription in strict conformity with the directions of the prescriber. This was evidenced by a prescription filled a prescription incorrectly with purinethol 50 mg when the prescription was for P.T.U. 50 mg. The parties presented a proposed settlement agreement reference the allegations. A motion was made and seconded that the Board go into executive session until 10:05.a.m. to discuss a report generated as part of the impaired provider program which is therefore confidential." Those present in executive session were the Respondent, Steve Schwarm, Marty Snyder, Randy Forbes, Debra Billingsley and Jim Kinderknecht. (Gilstrap/McFarland) Motion carried 4-0.

RECONVENE: The Board meeting reconvened at 10:05 a.m. with all members present as previously stated. After hearing further statements of counsel a motion was made that the Board recess for ten minutes followed by an executive session not to exceed 20 minutes for deliberation. Those present in executive session were Randy Forbes and Debra Billingsley. (Heidrick/Thompson) Motion carried 4-0.

RECONVENE: The Board meeting reconvened at 10:35 a.m. A motion was made to accept the proposed agreement with specific modifications. The effective date of the agreement would be June 8, 2004. (Thompson/McFarland) Motion carried 4-0. The parties were directed to draft the modifications in the form of an Order and to provide signed copies to the Board in a timely manner.

STEVEN R. BRAMLET #1-09647

Steven R. Bramlet appeared telephonically and without counsel. Marty Snyder, Assistant Attorney General appeared on behalf of the Board. The State filed a Petition to Revoke, Suspend or Otherwise Limit the license of the Respondent based on a license

revocation out of the State of Texas. The State submitted certified Texas Orders #K-02-009, #K-00-004 and #G-03-003. The Respondent requested that the Board consider copies of CEU's completed, letters of support from Patrick James Pang, R.Ph.; Eleanor L. Lanquin, CPhT; a professional employment agreement with restrictions and drug testing; a copy of last three pages of Texas Board order showing that the license was inactive at the time of revocation. After hearing arguments from both parties the Board advised Respondent that they would deliberate later in the day and would call him back when they came back into open session.

RONALD A. TERRY #1-09055

Ronald Terry did not appear. Marty Snyder, Assistant Attorney General, appeared on behalf of the Board. Ms. Snyder advised the Board that the Respondent had signed a Consent Agreement and Order with Kansas that was based on action taken in Oklahoma. Oklahoma had charged the Respondent with substituting generic for name brand and charging it as the brand name. A motion was made to approve the Consent Agreement and Order (McFarland/Thompson) Motion carried 4-0.

RECESS: The Board recessed for lunch until 1:20 p.m.

RECONVENE: The Board meeting reconvened at 1:20 p.m. with all members present as previously stated.

BUDGET:

A budget presentation was provided by Julie Thomas, Budget Analyst assigned to Board of Pharmacy. Ms. Thomas gave a handout of the budget process and went through the procedures necessary for state budget approval. She discussed the fee fund sweep that will occur at the end of 2005 fiscal year, which will leave a balance of \$200,000. Ms. Thomas discussed whether the Board should raise or reduce fees at this time and she advised that it would be better to get some history with the collection of pharmacy technician registrations before any action is taken.

RECESS: The Board took a five-minute break.

RECONVENE: The Board reconvened the meeting at 2:05 p.m. A motion was made to go into executive session for deliberation regarding Steven Bramlet. Those included in the executive session were Randy Forbes and Debra Billingsley. (McFarland/Thompson) Motion carried 4-0.

RECONVENE: The Board reconvened at 2:25 p.m. The Board took up the case of Steven Bramlet and Mr. Bramlet appeared telephonically and without counsel. No one represented the Board at this juncture. A motion was made and seconded to revoke Steven Bramlet's license in Kansas based on the revocation of license out of Texas. (Thompson/McFarland) Motion carried 4-0.

DISCUSSION, CONSIDERATION, AND POSSIBLE ACTION REGARDING REQUEST OF USP TO SUPPORT FEDERAL FUNDING:

The Board discussed the USP's request that the Board assist in generating support in Congress for funding an initiative to complete monographs for 200 of the most commonly prescribed compounded drugs. USP would test the preparations at various laboratories located at key universities nationwide. Standards would be established over a five year period for up to one thousand products that are currently compounded and USP would create national standards for quality, purity, and strength for ingredients and final products that are provided to consumers. The proposal was based on concerns over recent deaths and injuries caused by contaminated and subpotent compounded prescription drugs. After discussing the issue the Board requested that the Executive Director find out whether the NABP has taken a position on this issue. The Board took no action at this time.

DISCUSSION REGARDING FEDERAL VETERINARY COMPOUNDING ACTIVITIES:

The FDA sent correspondence to State Boards requesting assistance in determining the extent of illegal veterinary compounding activities in each state. The Center for Veterinary Medicine was issuing inspection assignments to FDA field offices to inspect certain pharmacies and they wanted State Board participation. Ms. Billingsley advised the Board that she had contacted the FDA and was told that there would be no inspections conducted in Kansas because they did not consider Kansas to be a problem. They indicated that they had not received any complaints regarding Kansas compounding activities. The Board advised Ms. Billingsley that the staff should assist the FDA if assistance is requested.

UPDATE REGARDING BOARD COMPOUNDING REGULATIONS:

Jeff Thompson gave an update and advised the Board that he has almost completed the next draft of the Compounding regulations. He has continued to receive phone calls from interested persons with either suggestions or questions regarding our proposed requirements. He hasn't made any substantive changes based on these conversations but has made improvements to the language. We should be able to put these in regulation format soon and he will send them out via email when the next draft is completed.

DISCUSSION, CONSIDERATION, AND POSSIBLE ACTION REGARDING K.A.R. 68-20-17 AS IT RELATES TO ELECTRONIC TRANSFERS OF DEA 222 FORMS:

The Board received an inquiry from the National Association of Chain Drug Stores regarding an interpretation of K.A.R. 68-20-17 and whether the regulation in its present form would follow any changes made federally. The DEA will soon be publishing their final regulations on electronic controlled substances ordering systems. The regulations will permit completion of DEA form 222 to be submitted electronically. The Board determined that a regulation change would be necessary since our current regulation adopts the old version of 21 CFR 1305. The Board recommended that staff begin working toward amending our regulation so that when the federal regulation becomes final we can move forward on adopting the new version.

DISCUSSION, CONSIDERATION, AND POSSIBLE ACTION REGARDING USE OF MEDICAL DEVICE CALLED THE AUTOJECT.

Randy Forbes advised the Board that he had been contacted by a law firm requesting a formal opinion as to whether a pharmacist may counsel a patient on the use of an autoject device. Currently, nurses are training patients how to use the device but it would be more feasible for a pharmacist to do this if it does not violate the Pharmacy Practice Act. Mr. Forbes indicated that he had reviewed the law and this would be part of the counseling process permitted by law. The Board agreed with their legal counsel's assessment of the law. A motion was made and seconded that instruction given by a pharmacist to patient of the autoject device was part of the practice of pharmacy as it related to counseling and consulting patients in the proper use, storage, and maintenance of a prescription device. (Heidrick/Thompson) Motion carried 4-0. The Board directed the Executive Director to write a letter advising the attorney of the board's opinion.

BOARD DISCUSSION:

K.A.R. 68-1-3a

Randy Forbes advised the Board that he had received correspondence from the Attorney General's Office regarding the Board's submission of an amendment to K.A.R. 68-1-3a. The A.G.'s Office had advised Mr. Forbes that they were not approving the amendment to the regulation because the Board did not have the statutory authority to make the change they were attempting to make. Specifically, the Board was attempting to exert authority over preceptors and the A.G. did not believe that the statute granted this authority. After discussing the issue the Board directed Mr. Forbes to review the statutes to see if there was authority elsewhere in the Pharmacy Practice Act.

DISCUSSION, CONSIDERATION, AND POSSIBLE ACTION REGARDING AMENDING CONTROLLED SUBSTANCE ACT TO INCLUDE KHAT AS A SCHEDULE I DRUG.

At the March meeting Jim Kinderknecht had informed the Board of a criminal case he had testified in regarding possession of the drug Khat. The defendant used the defense that Khat was not a scheduled drug and therefore it was not illegal to possess. The Board directed the Executive Director to ask the Kansas County and District Attorney's Association whether this was something that was a problem in Kansas. The Board received a response from Lyon County requesting that the drug be placed on the Schedule I list. The Board had also received information, which indicated that the KBI might have some other drugs that they would like added to the list also. The Board requested that this item be moved to the September 2004 agenda so that the KBI could provide a complete list of drugs that they would like submitted for a legislative change.

DISCUSSION, CONSIDERATION, AND POSSIBLE ACTION REGARDING PLACEMENT OF RESTRICTIONS ON PURCHASE OF DECONGESTANTS THAT CONTAIN PSEUDOEPHEDRINE:

The Board had been approached by several interested parties regarding enactment of a law in Kansas that would be similar to a new law that just passed in Oklahoma. Specifically, the law in Oklahoma would list pseudoephedrine-based drugs as a Schedule V substance that can only be sold at licensed pharmacies. A photo identification and

signature would be required to buy the products. In addition, the law limited the amount of pseudoephedrine tablets purchased over a 30-day period to no more than nine grams, or the equivalent of 12 boxes of cold pills. The Board discussed this issue but was advised that there was some opposition to the measure. The Board received a letter from the Consumer Healthcare Products Association asking the Board to consider all aspects and impact of the Oklahoma legislation prior to placing this restriction on the citizens of Kansas. The Board requested that this issue be placed on the September Board agenda so that interested parties could attend the meeting and provide input.

ELECTRONIC PRESCRIPTIONS/SIGNATURES:

The Board received a request from Olathe Medical Center asking that a formal opinion be issued regarding their use of electronic prescriptions and signatures. Specifically, the hospital's system prints the name of the physician over the prescription signature line with the term "E Sig" in parenthesis behind the name. The computer system assures that the electronic signature belongs to the appropriate physician by use of a password. In view of the security features that are built into this system the board agreed that the pharmacy could use in the system in class III through V controlled medications and for non-controlled medications so long as the identifying information was on the prescription. The Board also discussed the interpretation of "intervening person or entity" as it relates to electronic prescriptions. The Board stated that it has been their position that a prescription can be sent by facsimile or through a computer so long as no human intervention possible. Therefore, software that sends through another computer is acceptable so long as there are safeguards from human intervention regarding the prescription.

RECESS: The Board took a ten-minute break.

RECONVENE: The Board reconvened at approximately 4:30 p.m.

ANNUAL ELECTION OF OFFICERS:

A motion was made and seconded that Jeff Thompson be nominated as President of the Board of Pharmacy. (McFarland/Gilstrap). Ms. Gilstrap also noted that she held a proxy of Howard Paul and that he voted for Jeff Thompson as President. Motion carried 5-0.

A motion was made and seconded that Frank Whitchurch be nominated as Vice-President of the Board of Pharmacy. (McFarland/Thompson) Ms. Gilstrap also noted that she held a proxy of Howard Paul and that he voted for Frank Whitchurch as Vice-President. Motion carried 5-0.

INVESTIGATIVE REPORTS:

Frank Whitchurch reported to the Board that a total of 23 complaints had been received by the Board in 2004. Four cases had been referred to the Attorney General for discipline. Two cases are currently under investigation and four cases have been investigated but are awaiting additional information. Eleven cases had been officially closed. Mr. Whitchurch provided the board with the specifics of the confidential closed cases.

SPECIAL PRESENTATION TO MICHAEL HURST, R.Ph.

The Board presented Michael Hurst with a plaque in their appreciation of his unselfish service to the profession of pharmacy. Mr. Hurst was a member of the Board of Pharmacy and was President during the 2004 fiscal year.

ADJOURNMENT:

The Board adjourned until 8:00 a.m., June 9, 2004.

Wednesday, March 9, 2004

MEMBERS PRESENT: Frank Whitchurch, R.Ph., Vice-President; Jeff Thompson, R.Ph., President-Elect; Merlin McFarland, R.Ph.; JoAnne Gilstrap, R.Ph.; Max Heidrick, R.Ph.

STAFF PRESENT: Debra Billingsley, Executive Secretary; Jim Kinderknecht, R.Ph.; Pharmacy Inspector; LaTonyua Rice, Pharm. D., Pharmacy Inspector; Reyne Kenton, Compliance Officer; Randy Forbes, General Counsel and Karen Hollon, Administrative Officer.

OTHERS PRESENT: See attached listing.

MEETING CALLED TO ORDER:

Jeff Thompson, President-Elect called the meeting to order at 8:05 a.m.

DISCUSSION, CONSIDERATION AND POSSIBLE ACTION REGARDING PHONE-IN PRESCRIPTIONS:

The Board discussed problems that pharmacists are having with untrained persons calling in prescriptions from a physician's office. There have been instances when the person calling does not have the correct drug name or dosage and it places an incredible burden on the pharmacist to determine what the doctor wanted the patient to have. The Board determined that it would be helpful to collect some specific examples of problems and then to discuss this issue with the Board of Healing Arts to see if they can assist in combating this problem.

CANADIAN PHARMACY ISSUE:

The Board discussed what they viewed as continued violations in Kansas of the Pharmacy Act. Specifically, there are businesses throughout the state that are unlawfully providing pharmaceuticals and are using unlawful designations as part of their signage and advertising. The Board had previously requested that the Attorney General prosecute violators of Kansas law. Further, the Board had requested that the legislature permit the Board to encumber \$500,000 of their funds to use toward prosecuting these unlicensed businesses. The legislature indicated that the Board should request assistance from the Attorney General rather than seek funds for this issue. Therefore, the Board directed the Executive Director to make an official request to the Attorney General asking that these businesses be prosecuted to the full extent of the law.

DISCUSSION INVOLVING PHARMACIST/PHARMACY CLASSIFICATIONS:

The Board discussed whether it would be helpful to licensing and the inspection process to have pharmacies classified. There are several other states that have license classifications. This would require a statutory change. Board staff was directed to research what other states' laws require. This can be reviewed at the November meeting.

BOARD REPORTS:

Jeff Thompson discussed an issue regarding wholesale distributors being required to have a Pedigree for all drugs they have distributed. The NABP has model rules regarding distributors maintaining Pedigrees. Mr. Thompson wondered whether the Board would like to look at this issue. He indicated that the Board had received correspondence from the Pharmaceutical Distributor's Association asking that the Board work within a framework that would not destroy small businesses. The Executive Secretary was directed to place this issue on the next agenda.

Merlin McFarland shared a postcard that was from the Texas State board giving information on how to renew online. The information indicated that as a cost saving measure the Texas Board was asking all pharmacists to apply online. Mr. McFarland indicated that this might also be a cost saving measure that Kansas could use.

Merlin McFarland raised the issue of pharmacy technician registration. He requested that the Board consider giving some type of incentive to pharmacy technicians who are nationally certified. The junior colleges have been encouraging this training and it would be helpful if the Board also encouraged that technicians seek advanced training. The Board discussed the technician test that has been approved. Some of the questions are ambiguous and it was suggested that the Board review some of the questions that have been approved and see if they need changed or updated. The Board also discussed a question that the investigators had been getting about whether a hospital needed to register nurses as a pharmacy technician if they were going into the pharmacy and doing work that was generally considered technician duties. The Board stated that the nurse did not need to be registered as a technician.

Max Heidrick stated that he was glad to be back to serve 3 more years on the Board. He complimented the staff on the jobs they were doing. He stated that the turnaround time on renewals was very good. Mr. Heidrick suggested that the Board consider getting new software to track disciplinary cases especially with the addition of regulating technicians.

RECESS: The Board recessed until 9:50 a.m.

RECONVENE: The Board meeting reconvened at 9:50 a.m. with all members present as previously stated.

STAFF REPORTS:

Debra Billingsley discussed legislative issues that may be of concern in the next year. There has been an interest that with the registration of technicians that the ratio can be raised. Ms. Billingsley advised the Board that she had heard from some legislators that they would have a concern with the ratio being raised and that they would want a careful study before a change is made.

Ms. Billingsley also advised the Board that she had received information that there was still an interest in drug repository legislation. It would be helpful if the Board took a proactive approach and came up with language that would provide the safety mechanisms that were not present in the earlier legislation. Ohio has a bill and we need to see how their legislation is working for them.

There is legislative interest in the Pseudoephedrine bill that was passed in Oklahoma. We talked about this issue yesterday. Even if the Board doesn't take action on this type of legislation it will be raised by law enforcement. We have moved this to September and should have more information on whether the Board will want to take a position on this.

The Board staff is in the middle of renewals right now. Things are going pretty smoothly although we have had a few computer glitches. We are going to make an effort to get the retail dealers registered. If they sell more than 12 OTC products they must be registered. There has been no real push to see that they have complied and we are going to see what needs to be done to get them all registered.

District VI meeting will be in Galveston September 23-25, 2004 after our September board meeting. KPhA has a meeting the weekend before our meeting. Any Board members interested in attending should try and give Ms. Billingsley notice so that she can turn in an estimate of how many will attend.

We have been reviewing statutes and regulations. There are currently no regulations on institutional drug rooms. We may need to start working on these or include this issue in our discussion of pharmacy classifications. There is also a renal dialysis law that states that these facilities are to be licensed. Staff has noted that we haven't licensed any in Kansas. There are also no regulations written although the statute indicates that there should be some regulations. Jim Kinderknecht went through some of the history behind the renal dialysis legislation. The Board suggested that staff go through Medicare and inform them that these facilities should be licensed since they also license the same facilities. Ms. Billingsley also discussed exemptions from paying license fees and CE approvals by the Board. The Executive Director may use discretion in these matters.

Jim Kinderknecht reported that the staff continues to struggle with definition of medical devices and there is still a question as who should be licensed. Mr. Kinderknecht advised that he had divided the 3 inspector areas into 4 so Melissa Martin has her own area. Melissa is taking part of Jim's area and LaTonya Rice's area.

Reyne Kenton welcomed Max Heidrick back to the Board and she stated that Western Kansas was happy that they had representation.

LaTonyua Rice advised the Board that there were continuing questions about the CII diet drug statute. This is a Board of Healing Arts law and we get quite a few calls about its interpretation.

Randy Forbes reported that John Kiefhaber, the new Executive Director of KPhA, had contacted him. Randy said that John had requested Randy's assistance in two areas. John had asked Randy to review and update the KPhA law book. He had also asked Randy if he could give a recommendation for an attorney. The Board discussed both of these issues and advised Randy that there was no conflict in his providing assistance to John in these two areas.

Mr. Forbes advised the Board that he had received a signed agreement from Pam Stoddart. She had agreed to sign the document at the last meeting but had failed to do so. He sent a letter to Ms. Stoddart and she then agreed to sign the document. This case is now completed.

In reviewing the disciplinary proceedings conducted yesterday Mr. Forbes suggested that we get some procedures in place on how to conduct a hearing. Marty Snyder is very capable but may need direction in what the Board is expecting from her. Further, Mr. Forbes recommended that the Board get a court reporter if the hearing is contested or if the matter is an emergency. Ms. Billingsley was asked to provide the meeting chair with an outline of hearing procedures so that more guidance may be given to the attorneys during the hearing process. This would help things go smoother and would prevent appeals.

A motion was made and seconded to go into executive session for the purpose of discussing unclassified personnel matters until 11:15 a.m. The closed session was restricted to board members only (McFarland/Heidrick) Motion carried 4-0.

RECONVENE: The Board reconvened at 11:25 a.m. A motion was made and seconded to reappoint Debra Billingsley as Executive Secretary for the next year (Heidrick/Gilstrap) Motion carried 4-0.

APPROVAL OF NEW LICENSES/REGISTRATIONS:

A motion was made and seconded to approve the new pharmacists and pharmacies licensed. (Heidrick/Whitchurch) Motion carried 4-0.

Jeff Thompson reminded the Board that the next meeting would be held in Lawrence at the School of Pharmacy. The parking will probably be at the parking garage near Allen Fieldhouse. Staff would check and make sure that the Board received information on parking and accommodations.

BOARD SCHEDULE:

The Board scheduled the next meetings as follows:
September 21-22, 2004 – Lawrence, KS
November 30-December 1, 2004 – Topeka, Kansas
March 8-9, 2005 – To Be Announced
June 7-8, 2005 – To Be Announced
September 20-21, 2005 – To Be Announced
December 6-7, 2005 – To Be Announced

ADJOURNMENT: The Board adjourned the Board meeting at 11:30 a.m.