

MINUTES

**UTAH
PHARMACY
RULES HEARINGS
AND
BOARD MEETING**

June 24, 2008

**Room 474 – 4th Floor – 9:00 A.M.
Heber Wells Building
Salt Lake City, UT 84111**

RULES HEARINGS:

1st HEARING

CONVENED: 9:04 am

Conducting Rules Hearings:

Judge Steve Eklund, Department of Commerce,
Administrative Law Judge

Controlled Substance Act Rules Hearing re:
CS Database Amendments

Judge Eklund conducted the Rules Hearing. A
transcript of the hearing may be obtained through
Judge Eklund's Office.

2nd HEARING

CONVENED: 10:15 am

Pharmacy Practice Act Rules Haring re:
Wholesaler/Distributor Amendments

Judge Eklund conducted the Rules Hearing. A
transcript of the hearing may be obtained through
Judge Eklund's Office.

Bureau Manager:

Noel Taxin

Bureau Manager:

Diana Baker

Board Secretary:

Karen McCall

Board Members Present:

Roger B. Fitzpatrick
Derek D. Garn
Betty Yamashita
Dominic DeRose, Jr.
David C. Young
Edgar Cortes

Board Members Absent:

Marty Val Hill

Guests:

Jaime Peterson, Walgreens
Katrina Young, Sav-On
Mike Sulzbach, Super Valu
Brittany Woodhouse, Super Valu
Christian Larsen, Super Valu
Naida Sehovic
Bassam Haddadin, Super Valu
Brady Green, Lee's Pharmacy
Michael Wood, Omnicare
Reid L. Barker, UPHA
Greg Jensen, Target
Dave Davis, Utah Food Industry/Retail Merchants
Jim Olsen, Utah Food Industry/Retail Merchants
Shawna Hanson, Sav-On
Dave Cheney, Sav-On
Charlie Curtis, Wal-Mart
Gerry Hassell, Wal-Mart
Ann Stout, USN, South Jordan
Frank Pagnanelli, Medco
Kirt Wray, Eagle Gate College
Rylee Weston, Eagle Gate College
Monica Kanyon, Eagle Gate College
Chelsie Hunt, Eagle Gate College
Alisa Nelson, Eagle Gate College
David Kendall, Eagle Gate College
Melissa Archer, University of Utah
Faith Stapley
Mark Harward, Pharmacy Student
Ric Sykes, Associated Foods
Ann Stout, University of Southern Nevada, College of
Pharmacy

DOPL Staff Present:

Mitchell Jones, AG
Ray Walker, Division Regulatory and Compliance
Officer
Thad Lavar, Department of Commerce, Deputy
Director
Diana Baker, Bureau Manager
Karl Perry, AG
Kent Barnes, Sr. Business Analyst

BOARD MEETING:

CONVENED: 10:45 A.M.

ADJOURNED: 5:40 P.M.

TOPICS FOR DISCUSSION

ADMINISTRATIVE BUSINESS:

MINUTES:

DECISIONS AND RECOMMENDATIONS

The minutes from the May 27, 2008 Board meeting were read.

Mr. DeRose made a motion to approve the minutes with minor revisions. Mr. Cortes seconded the motion. **The Board vote was unanimous.**

APPOINTMENTS:

10:45 am

Compliance Unit Update

Ms. Call introduced Ronda Trujillo as a new member of the compliance unit.

Ms. Call updated the Board regarding the compliance or non-compliance of probationers.

Ms. Call reported that **Andrew Buckley** is currently in compliance. She explained that he has submitted all required reports, has phoned in everyday during his 3 years of probation and has not had any positive UA tests. She stated that Mr. Buckley has changed his lifestyle and received only 1 non-compliance letter when his employer was late submitting a report. Ms. Call stated that Mr. Buckley will be requesting early termination of his probation today.

Ms. Taxin commented that Mr. Buckley submitted a summary for the Board to review.

Ms. Call reported that **Cameron Tolley** was to meet today but due to the 2 Hearings that were scheduled and number of appointments, Mr. Tolley's appointment was postponed until August 2008. She stated that Mr. Tolley asked if he could work alone for one day and she approved his request.

Ms. Call reported that **Diann Millikin** is currently out of compliance as she has not called the agency each day regarding her drug tests and the AA and 12 step documentation were submitted late. She stated that she will hand Ms. Millikin a non-compliance letter when she meets today.

Ms. Taxin commented that Ms. Millikin made 2 appointments to meet with a Psychologist for therapy and did not appear for either appointment. She stated that Ms. Millikin has chosen to meet with another therapist. Ms. Taxin informed the Board that she would recuse herself from Ms. Millikin's meeting and Ms. Baker would manage her case.

Ms. Call reported that **Rich Wright's** license was suspended for 3 months. She explained that he was to obtain a neuropsychological evaluation within 90 days of signing the Stipulation and Order and have that evaluation submitted to the Division for his file. Ms. Call stated that she provided Mr. Wright with Tom Schenkenburg's information to conduct the evaluation.

Ms. Call reported that **Sheryl Ledet** is currently in compliance with her Stipulation and Order.

Ms. Taxin commented that Ms. Ledet sent her an e-mail requesting her controlled substance license be reinstated as she is seeking licensure in another State and has found finding employment without a CS license difficult.

Ms. Call reported that **Isaac White** is out of compliance with his Stipulation and Order. She recommended the Board discuss his drug testing.

Ms. Call reported that **Rebecca Burton** is out of town at this time and will be rescheduled for August, 2008.

Ms. Call reported that **Michael Hodges** is in compliance with his Stipulation and Order as his employer reports, therapy report and the 12 step attendance information have been received. She stated that Mr. Hodges called to inquire how strict the Board would be regarding locations where he will be working and she informed Mr. Hodges that the Board recommended he be employed full-time at 1 or 2 locations only.

Ms. Call reported that **Stapley Pharmacy, Evan Stapley**, is currently out of compliance with the

Stipulation and Order. She stated that all the information was due June 3, 2008 and nothing has yet been received.

Ms. Taxin commented that Mr. Stapley would be in compliance if he brings his information today as this is only his second appointment with the Board.

Ms. Call reported that **San Rafael Chemical Services, Ralph Meibos**, is currently out of compliance with the Stipulation and Order. She stated that this will be Mr. Meibos initial interview with the Board. She stated that a report is due monthly regarding drugs analyzed or not analyzed and no report has been received.

11:00 am to 12:00 pm

Thomas Strebel, Reinstatement of License

Mr. Strebel met regarding reinstatement of his license.

Ms. Taxin reminded the Board that Mr. Strebel surrendered his Pharmacist and Pharmacist Controlled Substance licenses. She stated that Mr. Strebel is now requesting consideration for reinstatement of his licenses and he submitted a complete renewal application, letters of recommendation, and documentation as the Board requested. She asked the Board to review the information to determine if Mr. Strebel meets reinstatement requirements and if the licenses should be reinstated.

Ms. Taxin reminded Mr. Strebel and the Board that the meeting may be closed if the Board determines the discussion may be personal in nature.

Mr. Strebel thanked the Board for meeting with him and stated that he would like to have his license again. He stated that he does not plan to practice in Utah but needs the Utah license before he can apply for a license in Nevada.

Mr. Fitzpatrick asked Mr. Strebel what he has been doing to prepare himself to go back into the profession.

Mr. Strebel responded that he has completed some on-

line courses and could provide documentation of completion. He stated that he was scheduled to attend the St. George conference but was unable to attend.

Ms. Taxin commented that Mr. Strebel has had some criminal action taken. She asked him what he understands regarding the final disposition and his understanding of the type of license he would have if the Board determines he should be allowed to practice.

Mr. Strebel responded that he was indicted on fraud, a felony, and it ended as a misdemeanor. He explained that he was in the process of negotiations when the Division became involved. He stated that he had a 2 year probation and received a letter stating that after February 28, 2008 he could reapply for his license. He stated that he has paid back the outstanding debts.

Following additional discussion, Ms. Taxin asked Mr. Strebel if he has met the CE requirement of completing 30 hours.

Mr. Strebel responded that he has not completed the requirement of 30 hours of CE.

Mr. Fitzpatrick asked Mr. Strebel what kinds of things he believes the Board considers in making the decision to recommend the licenses be reinstated. He explained that the Board is charged to protect the public. He voiced concern that Mr. Strebel has been out of the profession for 2 years and expects to step right back into the pharmacy and be in charge without understanding the current practices. Mr. Fitzpatrick recommended Mr. Strebel take and pass the NAPLEX and MPJE again to show that his knowledge is current enough to be working in a pharmacy safely.

Mr. Strebel responded that he is aware of someone else who had his license reinstated without having to retake the examinations. He stated that he believes he deserves the same consideration. Mr. Strebel stated that he believes the CE requirement is appropriate but not retaking the examinations.

Mr. Fitzpatrick asked Mr. Strebel what he expected to be the outcome of his meeting today with the Board.

Mr. Strebel responded that he believed the Board would request updated CE, which he would complete and then meet again with the Board and have his license reinstated. He stated that he did not intend to leave the meeting with a license.

Karl Perry, AG, asked Mr. Strebel to explain how he can ensure the Board that a similar incident that happened with IHC would never happen again.

Mr. Strebel responded that a similar incident would not happen again. He explained that he would train the technicians on how claims were entered for insurance and then back out the information. He stated that he forgot to back out a claim. Mr. Strebel stated that he noticed it 6 months later and still did not take the time to correct the problem. He stated that when he contacted IHC to correct the problem it was too late and DOPL was then made aware of the problem.

Mr. DeRose commented that there appears to be some underlying issues that have not been brought up by Mr. Strebel. He stated that Mr. Strebel failed to correct an issue with IHC in a timely manner and then tried to sell his Pharmacy without having the legal papers signed with notarized signatures and without having the legal documents identify specific inventory, liabilities and financial documentation, who would be responsible to pay the debts and, if the new owner defaulted, who would take over the Pharmacy.

Mr. Strebel responded that Mr. DeRose is incorrect. He voiced that his concern was only to keep the pharmacy open. He stated that the sale, transferring of accounts, etc. was all legal and above board.

Mr. DeRose voiced concern that Mr. Strebel would imply that Mr. DeRose is accusing him of conducting a shady deal.

Mr. Strebel responded that he was not implying that Mr. DeRose was accusing him of conducting a shady deal. He stated that the contracts may not meet Mr. DeRose's standards but all parties were present and wrote the contracts together.

Mr. DeRose commented that if Mr. Strebel worked for him he would search the National Data Base and if Mr. Strebel's name was listed in that data base he could not allow Mr. Strebel to dispense any federal payment prescriptions.

Ms. Yamashita asked Mr. Strebel where he would work if he is on the National Data Base.

Mr. Strebel responded that he would not bill any federal agency. He stated that he understands that being on the data base will restrict him but he would rather have the restrictions than no license.

Mr. Fitzpatrick commented that there are others on probation that are on the National Data Base list and are unable to locate any employment. He stated that the Board is having a difficult time understanding how Mr. Strebel is competent to practice pharmacy at this time. He stated that Mr. Strebel has met with the Board without having prepared himself with documentation of completing CE or documentation of competency. He stated that Mr. Strebel informed the Board that he has been in contact with IHC and others but has not submitted any documentation to confirm the contact. Mr. Fitzpatrick informed Mr. Strebel that the Board would need to see a plan on how he is going to prepare himself to be a safe practitioner and a date for completion of his plan. He asked Mr. Strebel to submit a written practice plan for the Board to review.

Mr. Strebel responded that he will work on CE, prepare a written plan for the Board to review and then make an appointment to meet again with the Board.

Ms. Yamashita asked Mr. Strebel what he would recommend if he was a Board member and someone came before him requesting reinstatement

of their license. She asked what he believed the person would need to know or present to convince the Board that he was competent to practice and to ensure to the Board that a similar incident would not happen again.

Mr. Strebel responded that he would review the person's record. He stated that he worked 35 years without any problems prior to this incident.

Ms. Taxin stated that Mr. Strebel applied for reinstatement of his license in February 2008 and that it is still pending. She stated that the Division cannot hold a pending application for an indefinite period of time. Ms. Taxin stated that an option is for his application to be withdrawn and reapply at a later date when he has completed the things the Board has asked of him. She asked him to contact her regarding his decision.

Mr. Strebel responded that he would contact Ms. Taxin after he reviews his options.

Mr. Fitzpatrick asked Mr. Strebel how many CE hours he is planning to complete.

Mr. Strebel asked how many the Board wants him to complete.

Mr. Fitzpatrick asked Mr. Strebel how many CE hours are required to renew a license.

Mr. Strebel responded that he did not know how many hours are required to renew a license.

Mr. Fitzpatrick commented that Mr. Strebel needs to review the Laws and Rules and be familiar with the requirements of licensure.

Ms. Taxin summarized that the Board is requesting Mr. Strebel to submit the following prior to meeting again with the Board:

- 1. Submit a plan of the CE he will be taking to ensure he is safe to practice.**
- 2. Submit a letter of explanation, conclusion and recommendation for licensure from**

Darrell Bell, AG.

- 3. Submit a letter of explanation and recommendation from Wendy Johnson.**
- 4. Submit a letter of recommendation from his attorney.**
- 5. Check to see if he is on the OIG list.**

Mr. Strebel responded that he understands what he must complete and submit in order to be considered for reinstatement of his license.

12:00 pm to 1:00 pm

LUNCH

1:00 pm

Stapley Pharmacy, D Evan Stapley,
Probationary Interview

Mr. Stapley and his wife met with the Board for the Stapley Pharmacy probationary interview.

Board members and Division staff were introduced.

Mr. Fitzpatrick conducted the interview.

Mr. Fitzpatrick requested Mr. Stapley to briefly explain to the Board why Stapley Pharmacy is on probation and what is required of Mr. Stapley to meet the requirements of the probation.

Mr. Stapley responded that a man named Ray Beasley conducted an inspection audit, gave him a copy and said he would forward a copy to the Division. He gave a copy to the Board.

Ms. Taxin commented that the Division did not receive a copy of the inspection.

Ms. Call informed Mr. Stapley that she will now track his paperwork and notify him if information has not been received by the first day of the month when it is due. She stated that the Division has not yet received the required audits.

Mr. Stapley responded that he no longer does any sterile compounding.

Mr. Fitzpatrick asked that Mr. Stapley write and submit a note that states he has done no sterile compounding. Mr. Fitzpatrick stated that the

audit inspection report appears to be in order and documents no sterile compounding and no equipment for sterile compounding. He stated that Mr. Beasley has noted that he will conduct audits as required.

Ms. Call asked if the auditor is an independent auditor.

Mr. Stapley responded that she is correct. He stated that he will no longer need to have an audit on a branch pharmacy as he no longer has a branch pharmacy.

Mr. Fitzpatrick reminded Mr. Stapley that his inspection reports are due every 6 months and the next report is due in October. He asked Mr. Stapley if he has the required policies and procedures manual for the Board to review today.

Mr. Stapley responded that he has been working on 3 different manuals. He stated that he has contacted NCPA and received their guidelines to review, he contacted PCCA for their guidelines for compounding and DME as he needs to be DME accredited. He stated that he will incorporate some of the information he has received into his manuals. Mr. Stapley submitted the 3 manuals and informed the Board that they are still a work in progress. Mr. Stapley explained that he contracts with Rite-Aid to prepare the prescriptions and their label is on the prescriptions. He stated that he is the delivery service for Rite-Aid and he delivers the prescriptions to the home. He stated that he bills for the transaction and pays Rite-Aid when they pick up the prescriptions. Mr. Stapley stated that once he is again recertified with DME then the process will change.

Mr. Young asked if Mr. Stapley logs the prescription into his pharmacy log and then does the transfer to Rite-Aid.

Mr. Stapley responded that he retains a log of what and when prescriptions are received and when they are transferred.

Mr. Fitzpatrick asked if Mr. Stapley has something in writing for the Board to review.

Mr. Stapley responded that he did not bring anything for the Board to review but could.

Mr. Fitzpatrick asked the Board to respond regarding the 3 policy and procedures books.

Mr. DeRose responded that Mr. Stapley has a good start on the books.

Ms. Taxin requested Mr. Stapley to update the Board with copies of additions and/or changes in his policies and procedures books in the future.

Mr. Stapley commented that it would be beneficial for someone to give a presentation on what is required for a branch pharmacy.

Mr. Fitzpatrick responded that it would make a good workshop at a conference and maybe include an investigator to assist with the presentation.

Ms. Yamashita commented that it might even be a good workshop for those who currently run branch pharmacies. She then stated that it is apparent that Mr. Stapley has put a lot of work and thought into the policies and procedures since he last met with the Board.

Ms. Taxin commented that hopefully Mr. Stapley found the process beneficial.

The Board determined Mr. Stapley is currently in compliance with his Stipulation and Order.

An appointment was made for Mr. Stapley to meet again September 23, 2008.

Ms. Call reminded Mr. Stapley to submit his reports the first of the month as they are due. She stated that he could fax a copy of the independent audits.

Ms. Taxin recommended Mr. Stapley frequently

review his Stipulation and Order to be sure he is meeting all requirements.

1:20 pm

Sheryl Ledet, Probationary Interview

Ms. Ledet met for her probationary interview.

Mr. Young conducted the interview.

Mr. Young requested Ms. Ledet update the Board regarding her employment, PIR and 12 step meetings and her therapy.

Ms. Ledet responded that she is working at Pharmacy Solutions in the call center in an unlicensed position. She stated that she attends 12 step meetings and sees a counselor through her medical physician's office. Ms. Ledet stated that the Board requested her to obtain a statement from her therapist regarding a recommendation to be released from aftercare. She stated that she is choosing to continue seeing her counselor twice a month and will continue the 12 step meetings twice a month. She reported that she received notification that OIG has reinstated her. Ms. Ledet stated that she is continuing to apply for employment without any success. She stated that she believes that pharmacies will not hire her while she is on probation as she is unable to dispense products. Ms. Ledet stated that she is also looking at positions in New Mexico and Arizona but is unsure of the process of applying in other States. She stated that she also has an application in at Albertson's.

Ms. Taxin asked the Board to address Ms. Ledet's request for reinstatement of her CS license.

Discussion took place regarding options and concerns.

Ms. Call commented that for December and January there were some faxing problems but Ms. Ledet has been in compliance with her Stipulation and Order, she has called in for the drug testing every day and has not missed any tests.

Mr. Fitzpatrick asked Ms. Ledet how she is handling her pain.

Ms. Ledet responded that she is doing ok with the pain problem. She stated that her physician has set a date in July for her to go through detox and she has scheduled time off work to go through the program.

Following further discussion Ms. Yamashita made a motion to lift the suspension on Ms. Ledet's Controlled Substance license and, when employed, submit a practice plan that includes a Controlled Substance inventory, continue the random drug testing and submit supervision reports.

Mr. Garn seconded the motion.

Mr. Fitzpatrick, Ms. Yamashita, Mr. Garn, Mr. DeRose and Mr. Young voted in favor of the motion. Mr. Cortes abstained from voting. The motion passed with a majority of votes.

Ms. Taxin reminded Ms. Ledet that all other requirements of her Stipulation and Order would remain as written.

Ms. Yamashita and Ms. Taxin stated that inventory reports will be required monthly until the Board recommends they be submitted quarterly.

Mr. Fitzpatrick commented that having an inventory of the pharmacy when Ms. Ledet starts working in a pharmacy and continuing that inventory report protects her as a probationer.

The Board determined Ms. Ledet is currently in compliance with her Stipulation and Order.

An appointment was made for Ms. Ledet to meet again in October and then she will be back on her regular quarterly schedule.

1:35 pm
Andrew Buckley, Yearly Probationary
Interview

Mr. Buckley met for his yearly probationary interview.

Board members and Division staff were introduced.

Mr. Cortes conducted the interview.

Mr. Cortes asked Mr. Buckley to update the Board regarding his employment, drug testing and general supervision.

Mr. Buckley responded that he calls every morning regarding his drug tests, he attends regular meetings and his employment is 7 days working and 7 days off. He explained that in the past he did not cope well but has now learned not to bottle things up. He stated that he has learned his limits and finds himself saying that there are some things he cannot do. He stated that many of the stresses before his addiction have been resolved and he is now at a maintenance place. He stated that he has now been off the drugs for about 3 years. He explained that his ex-wife still has anxieties about his use of drugs and has requested that he continue the drug tests. He stated that if she is willing to pay for the tests then he is willing to test 4 times a year as requested.

Mr. Cortes commented that the Board received and reviewed Mr. Buckley's letter requesting early termination of his probation. He stated that Mr. Buckley is the only probationer who has not missed a day calling and has had all negative tests on his drug tests.

Mr. Fitzpatrick commented that traditionally the Board does not recommend early termination of probation if at least half has not been completed even if the probationer is in compliance. He recommended the Board consider reducing the requirement of attending meetings to one meeting a week and decrease the required reports to quarterly.

Following additional discussion the Board requested Mr. Buckley to meet again in 6 months.

Ms. Taxin asked Mr. Buckley to submit a letter of recommendation for termination from his sponsor and one from his employer.

The Board found Mr. Buckley in compliance with his Stipulation and Order.

An appointment was made for Mr. Buckley to meet again December 16, 2008.

1:50 pm

Diann Millikan, Probationary Interview

Ms. Taxin recused herself from this appointment based on a possible conflict of interest.

Diana Baker, Bureau Manager, met during this appointment.

Ms. Yamashita conducted the interview.

Ms. Yamashita asked Ms. Millikan to update the Board and address the time she took off her employment to work on herself.

Ms. Millikan responded that she is taking a position July 8 at Carefirst Pharmacy. She explained that they are a closed door pharmacy. Ms. Millikan stated that she will be working 2 days a week with another pharmacist and 2 days doing consulting in a nursing home. Ms. Millikan asked the Board for guidance regarding what she should include in her practice plan.

Mr. Fitzpatrick asked Ms. Millikan if she will have any access to medications in the nursing home.

Ms. Millikan responded that she will not.

Ms. Yamashita asked if she will have a supervisor the 2 days she is consulting in the nursing home.

Ms. Millikan responded that she will have a supervisor.

Ms. Yamashita stated that Ms. Millikan's practice plan should include an inventory when she starts her employment to protect herself and then a quarterly inventory. She stated that there should be a policy regarding how they reconcile any discrepancies, and a schedule regarding the days she works at the closed door pharmacy and the days she works at the nursing home. Ms. Yamashita stated that the UA's will continue. She then asked Ms. Millikan to explain why she missed

calling in for the UA's a few times. She reminded Ms. Millikan that it is a requirement to call every day. She recommended Ms. Millikan put something in place to remind her to call each day.

Ms. Millikan responded that there was no excuse regarding why she did not call everyday.

Ms. Yamashita asked Ms. Millikan to update the Board regarding the required therapy.

Ms. Millikan responded that she made an appointment with Dr. Kathleen King, a Psychologist, but they did not see eye to eye on some issues so she did not keep her appointments. She stated that she went back to the therapist she had been seeing. Ms. Millikan stated that since then she has talked with Dr. King who said she could come back if it was ok with the Board. She stated that she attends 2 or 3 meetings a week and has counseling once a week. She stated that she is committed to recovering.

Ms. Baker responded that she believed it would be good for Ms. Millikan to go to Dr. King again as Dr. King will assist her in facing some of her issues.

Mr. Fitzpatrick reminded Ms. Millikan that some of her probation time will not count as she was not employed in the field of pharmacy. He stated that her new employer is required to submit a letter confirming they have read the Stipulation and Order and are willing to assist Ms. Millikan in being successful in her probation and that they are willing to submit the required monthly reports and do the inventories.

Ms. Yamashita stated that the letter and reports may be faxed into Ms. Call.

Ms. Call reminded Ms. Millikan that her reports are due the 1st of the month.

The Board found Ms. Millikan out of compliance with her Stipulation and Order based on her lack of calling the UA's each day.

An appointment was made for Ms. Millikan to meet again September 23, 2008.

2:10 pm

Isaac White, Probationary Interview

Mr. White did not appear for his appointment.

2:25 pm

San Rafael Chemical Services, Ralph Meibos,
Probationary Interview

Mr. Meibos met for the probationary interview.

Board members and Division staff were introduced.

Mr. Garn conducted the interview.

Mr. Garn requested Mr. Meibos to briefly explain what brought him before the Board.

Mr. Meibos responded that he received a letter requesting him to meet and keep the appointment.

Mr. Garn reminded Mr. Meibos that he signed a Stipulation and Order which means that he agreed that the facts were correct and he agreed to the requirements of probation.

Mr. Meibos responded that he signed a document, but believes the fully signed document returned to him had been altered from the one he signed and agreed to.

Mr. Garn reviewed the requirements of the Stipulation and Order.

Mr. Meibos stated that he never tested people on steroids. He stated that he does steroid analysis only. He stated that he does not know about the information regarding the steroids.

Ms. Taxin asked if Mr. Meibos still has a DEA license.

Mr. Meibos responded that the DEA requested the license be surrendered and he surrendered it.

Mr. Garn continued reviewing the Stipulation and Order requirements. He asked Mr. Meibos if he has paid the required \$2,000.00 fine. He also reminded Mr. Meibos that his report is due

quarterly and has not yet been received.

Mr. Meibos responded that he is making payments on the fine. He stated that his reports are due quarterly and it has not yet been 3 months. He asked what the Board wants on the reports.

Ms. Taxin responded that the reports should document the date entries of analysis, who requested the analysis and the results of the analysis. She stated that the Board would review the reports. Ms. Taxin suggested he also write on the reports that he is not advertising for steroid analysis.

Ms. Call stated that the quarterly report is due June 27, 2008 and then again by September 1, 2008.

Mr. Meibos commented that he talked with Sandy Hess, Investigator, regarding the language of the last paragraph. He stated that he would never have signed anything with the language of his agreeing that he was involved in unprofessional conduct.

Ms. Taxin asked Mr. Meibos if he was saying that he signed a document with other signatures already on the document.

Mr. Meibos responded that Mark Shurtleff had signed.

Ms. Taxin stated that Mr. Shurtleff would not have signed the document. She stated that there had to be some type of unprofessional conduct or the Division could not have taken any action.

Mr. Meibos asked Ms. Taxin if she has read the Utah Code. He stated that the State of Utah does not want him testing steroids any more.

Ms. Taxin commented that she believed Mr. Meibos talked with the Board secretary, Ms. McCall stating he had an issue but he did not contact her. She stated that if Mr. Meibos believes the Stipulation and Order is a fraudulent document

then she will take it to the AG's office to review. She stated that she did not believe anyone would make changes to the document after it had been signed by Mr. Meibos as all revisions are made prior to anyone signing.

Mr. Meibos again stated that he believes an unrevised version was put through for signatures after he signed.

Ms. Taxin stated that as long as Mr. Meibos works on the requirements quarterly then he will be in compliance.

Mr. Meibos asked why a testing lab is clumped with Pharmacy.

Ms. Taxin explained that the Class E Pharmacy is a testing lab.

Sandy Hess, Investigator, arrived in the meeting.

Ms. Taxin explained Mr. Meibos allegations.

Ms. Hess responded that she could not take out the language regarding unprofessional conduct as the steroid testing was unprofessional conduct.

Mr. Meibos again stated that he would never have signed the Stipulation and Order with the unprofessional conduct language written in. He stated that he was afraid that the document would be changed after he signed it. He asked why Ms. Hess would not allow him to make a copy of the document after he signed it.

Ms. Hess responded that she believed he had made a copy after he signed. She reminded him that he had another person with him in the office that day when he took a copy.

Ms. Taxin asked if Mr. Meibos has ceased and desisted advertising for testing for steroids.

Ms. Hess commented that there were websites that advertised for him. She stated that Mr. Meibos was informed to contact the websites and have the

advertising stopped. She stated that Mr. Meibos has said that he did contact the websites and there is no longer any advertising for his company doing testing of steroids. She stated that there is also criminal action being taken regarding Mr. Meibos testing and she cannot address any other issues at this time.

Ms. Taxin again stated that the action falls under unprofessional conduct. She stated that if Mr. Meibos is unwilling to abide by the Stipulation and Order requirements he should let her know or he can accept the document the way it is written and move on with his probation. She asked Mr. Meibos to submit the analysis documentation, submit a statement that he is not advertising for testing steroids and continue to pay on his fine.

The Board found Mr. Meibos out of compliance based on his failure to submit the required analysis report and the statement of not advertising.

An appointment was made for Mr. Meibos to meet again September 23, 2008.

2:45 pm to 3:15 pm
Mitchell Melling, MD, Utah
Biopharmaceutical Laboratories

Dr. Melling and Doug McClain met with the Board to discuss their application for a Pharmacy license.

Ms. Taxin explained that Dr. Melling submitted an application for a Manufacturing Pharmacy license in order to produce his product. She stated that she allowed Dr. Melling to withdraw his application but he requested to meet with the Board to explain what he is doing at Utah Biopharmaceutical Laboratories. She explained that Dr. Melling's company uses processed goat serum to help MS patients and other types of autoimmune diseases. She explained that the company does not currently have an FDA number and approval to produce the product for human use and she would have had to deny their application.

Dr. Melling explained that he treats MS patients in Beaver, Utah. He stated that Beaver area has the

highest MS numbers in the world. Dr. Melling explained that Dr. Erickson, in Texas, was using this medication with a Texas waiver and there is a Dr. Morales in Mexico that distributes 3 month supplies of the medication to U.S. citizens who were going there to obtain the medication and bringing it back to the U.S. He explained that he facilitated some patients receiving the medication from Mexico. Dr. Melling stated that Gary Herbert, the Lt. Governor of Utah, has stated that if there was a Utah company manufacturing and distributing the medication prior to FDA approval it would be a great thing for the State. He then explained the manufacturing process. Dr. Melling stated that his application would have been denied based on the lack of FDA registration so he requested the application be withdrawn. He explained that his attorneys have stated that he does not need the FDA registration and he is waiting to see what determination the Division attorneys will make. He stated that his goal is to treat his patients who have MS and have failed in the traditional therapy for the disease.

Mr. McClain stated that the testing is in Phase I right now.

Dr. Melling stated that they anticipate moving into Phase II after they receive Orphan designation. He stated that the product is now being manufactured in Texas by Iso-Tex and he has a letter from Iso-Tex that they have the approval of Texas to manufacture. He stated that currently the product is being manufactured in Boston, is sent to Wales and then to Texas. He stated that if the Board would approve the product it would be manufactured in Boston, sent to Wales and then directly to him for his patients.

Mr. Cortes asked if Dr. Melling would follow the same quality control and the same formula for the drug.

Dr. Melling responded that he would.

Ms. Taxin stated that she was informed that the facility in Texas is a nuclear facility. She asked if Dr. Melling has any documentation regarding the

type of facility that is in Texas.

Dr. Melling responded that he does have the documentation regarding the type of facility that is in Texas.

Mr. Fitzpatrick asked how the distribution in Texas will affect the FDA trials.

Dr. Melling responded that there are enough physicians involved in the testing that it would not be overlapped.

Mr. McClain commented that they are now in the process of obtaining the FDA approval.

Ms. Hess commented that some States allow distribution of drugs by Physicians. She stated that Utah does not. Ms. Hess stated that Dr. Melling would be preparing the medication and the patients would take it home to use.

Ms. Taxin asked if the drug is not FDA approved then is it appropriate to manufacture the product.

Mr. Cortes commented that if they were in Phase II testing they could use the product on humans.

Dr. Melling responded that there are many medicines used that are not FDA approved. He stated that he will be meeting with the Physician's Board in July and will be asking for a waiver from that Board. He stated that he receives many phone calls each week requesting information on obtaining the medication. Dr. Melling stated that he refers patients to Dr. Morales in Mexico.

Ms. Taxin asked Dr. Melling how he knows the medication given out by Dr. Morales is what it is proposed to be.

Dr. Melling responded that he does not know if it is what it is suppose to be as the medication arrives in unlabeled bottles, but that it is expensive and there is a no return policy so they use the medication.

Mr. Perry, AG, commented that Dr. Melling has

called numerous times to be sure he is not doing something he should not be doing.

Dr. Melling responded that he has called for guidance.

Ms. Taxin asked the Board if they believed the Division made an error in their decision that Dr. Melling does not meet requirements for a Manufacturing Pharmacy.

The Board responded that the Division did not error as Dr. Melling would need an FDA number.

Mr. Perry, AG, asked for clarification regarding how Iso-Tex obtained an FDA number if the drug is still pending and has not completed the trials.

Dr. Melling responded that Iso-Tex was given a compassionate waiver but it is not on Orphan status yet.

In conclusion, Ms. Taxin informed the Board that Dr. Melling would be meeting with the Physician's Board on July 9, 2008 and then the Division would make a final decision based on that appointment.

3:15 pm to 3:30 pm

Warren RX Enterprises, Inc, Brent Warren,
Probationary Interview

BREAK

Brent Warren met for the Warren RX Enterprises, Inc. probationary interview.

Board member and Division staff were introduced.

Mr. DeRose conducted the interview.

Ms. Taxin informed the Board that Mr. Warren has not met with the Board for awhile. She stated that he is not required to meet regularly, he paid the \$2,000.00 fine and wrote the required letter to the Board. She stated that if the Board determines Mr. Warren has met the requirements of his probation they should consider terminating his probation.

Mr. Fitzpatrick and Mr. DeRose responded that prior to making a decision to terminate probation

another inspection should be conducted to be sure all deficiencies have been corrected.

Ms. Taxin asked Mr. Warren to explain where he is with completing the requirements of the Stipulation and Order and to address if he believes he is in compliance by correcting all the Pharmacy issues.

Mr. Warren responded that he is currently working on the CE requirements. He stated that he needs to complete 3 more hours.

Ms. Taxin stated that when Mr. Warren completes the CE he should send copies of the completion certificates to Ms. Call and then she will schedule an investigator to go out to re-inspect the Pharmacy. Ms. Taxin also requested Mr. Warren submit a letter requesting early termination and describing what he has learned from the process.

The Board determined Mr. Warren is currently in compliance with the Stipulation and Order.

An appointment was made for Mr. Warren to meet again August 19, 2008.

4:00 pm to 4:30 pm
Intern/Extern Ratio and Practicing After
Graduation Discussion

Ms. Taxin explained that the Division has received many phone calls regarding how many Pharmacy Interns or Externs the Pharmacist may supervise. She stated that the Law is very clear and reads 1 paid Pharmacy Intern or 2 unpaid Pharmacy Externs. Ms. Taxin read the Law to the Board.

Mr. Perry, AG, stated that the Law is also very clear regarding the unpaid Pharmacy Externs are observational and are not to be doing any Pharmacy work and the hours would not count for intern licensing.

Ms. Taxin stated that the way the Rules are currently written is how they are currently being enforced. She stated if the Board wants to amend the current language then that would be a possible solution to some of the questions being asked.

Mr. Young commented that he will get in touch with Ms. Taxin regarding changing the language.

Ms. Taxin stated that there is also an issue regarding practicing after graduation without a license. She stated that the Board and Division have to be fair and treat graduates of all programs the same. It would be unfair to allow U of U students to practice without a license and require out of State or other students to be licensed.

Mr. Perry commented that the licensing requirement is in the Law and not the Rule. He stated that the Board cannot change the Law as that is done by the Association and Legislature.

Ms. Taxin recommended further discussion at the next scheduled meeting.

APPLICATIONS:

Craig Boody, Review for MPJE Approval

Ms. Taxin explained that Mr. Boody submitted an application to be approved for the MPJE examination.

Upon completion of reviewing the application the Board recommended Mr. Boody be approved to sit for the MPJE.

DISCUSSION ITEMS:

Agenda Items

Ms. Taxin commented that the Board has not covered all items on the agenda today. She asked if the Board wants the items put on the next agenda or have another meeting.

The Board recommended a meeting be scheduled on July 8, 2008 from 1:00 pm to 4:00 pm and another meeting be scheduled on August 12, 2008 from 1:00 pm to 4:00 pm to complete any left-over July agenda items.

Board Members Answering Questions Outside Board Meetings

This item was deferred to the July 8, 2008 Board meeting.

Review and Discuss 58-17b-602(4)(b),
Pharmacist changing day amount with or
without Dr. approval

Mr. Perry, AG, explained that there are Physician's writing prescriptions for 3 refills. He stated that the Pharmacist asks if the patient wants a 90 day supply as it would save them money.

Mr. Garn commented that the logic takes away the professional judgment of the Pharmacist as the Pharmacist would still have to contact the Physician if he was giving the patient a 7 day fill to try out the prescription.

Following additional discussion, the Board recommended Ms. Taxin ask the Physician's Board for a recommendation.

Update from Mr. Fitzpatrick regarding the
District Meeting

Mr. Fitzpatrick updated the Board on the District Meeting. He requested all Board members to fill out the registration information and get the forms to him to submit to the Division for payment and hotel registration. Mr. Fitzpatrick reminded the Board that the Division will cover the economical rooms but not the deluxe. He stated that there are other conventions being held at the same facility and he did not anticipate the response that he has received. He recommended the Board get their information submitted as soon as possible in order to secure their rooms.

Ms. Taxin asked who will be delivering the welcome as noted on the agenda.

Mr. Fitzpatrick responded that he will deliver the welcome.

Ms. Taxin asked if the State would be involved.

Mr. Fitzpatrick responded that the State could be involved.

FYI

Ms. Taxin informed the Board that a name for a new Board member has been submitted but the Governor's office has not yet notified the Division of approved names. She stated that a new Board Chairperson will be determined when there is a full Board.

FYI

Ms. Taxin informed the Board of Cody R. Beaumont

surrendering his license. **No Board action was taken.**

Update from Joyce McStotts regarding
Pharmacy Training Program Issues

This item was deferred to the July 8, 2008 Board
meeting.

CORRESPONDENCE:

Request for Southwood Apothecary Shop
Pharmacy Technician Education Program
review

The information was given to Mr. Cortes to review.

International Journal of Pharmaceutical
Compounding, May/June 2008

This item was deferred to the July 8, 2008 Board
meeting.

NASPA Announcement of New E-prescribing
CQI Initiative

This item was deferred to the July 8, 2008 Board
meeting.

Ric Sykes Letter requesting approval to change
Pharmacy Technician Program

The information was given to Mr. Cortes to review.

PTCB Update, June 6, 2008

This item was deferred to the July 8, 2008 Board
meeting.

BUSINESS FROM PREVIOUS MEETING:

Gatlin Education Services Pharmacy
Technician Education Program Review

Mr. Cortes reviewed the education program and
determined the education is deficient in the following
areas:

1. (a) The didactic training program must be approved by the division in collaboration with the board and must address, at a minimum, the following topics:
2. (i) legal aspects of pharmacy practice including federal and state laws and rules governing practice; **The Utah Law section or unit needs to be included.**
3. (ii) hygiene and aseptic technique; **A unit needs to be added in the program.**
4. (vi) filling of orders and prescriptions including packaging and labeling; **The program is deficient in this area.**
5. (vii) ordering, restocking, and maintaining drug inventory; **The program is deficient in this area.**
6. (viii) computer applications in the pharmacy; and **The program is deficient in this area.**

7. (ix) non-prescription products including, but not limited to, cough and cold, nutritional, analgesics, allergy, diabetic testing supplies, first aid, ophthalmic, family planning, foot, feminine hygiene, gastrointestinal preparations, and pharmacy care over-the-counter drugs. **This criteria needs to be included in the program.**
8. (b) This training program's curriculum and a copy of the final examination shall be submitted to the division for approval by the board prior to starting any training session with a pharmacy technician in training. The final examination must include questions covering each of the topics listed in Subsection (3)(a) above. **A copy of the examination must be submitted for review and there must be 100 or more questions on the examination.**
9. (d) The training program must require at least 180 hours of practical training supervised by a licensed pharmacist in good standing with the division and must include: **Utah requires 180 hours.**
10. (i) written protocols and guidelines for the teaching pharmacist outlining the utilization and supervision of pharmacy technicians in training that includes: **Submit the protocols and guidelines for the didactic and practical training and supervision.**
11. (A) the specific manner in which supervision will be completed; and **Submit the protocols and guidelines for the didactic and practical training and supervision.**
12. (B) an evaluative procedure to verify the accuracy and completeness of all acts, tasks, and functions performed by the pharmacy technician in training. **Submit the protocols and guidelines for the didactic and practical training and supervision.**
13. (e) An individual must complete an approved training program and successfully pass the required examinations as listed in Subsection R156-17b-302(3) within one (1) year from the date of the first day of the training program, unless otherwise approved by the division in collaboration with the board. **This is not**

specified in the program.

The Board concurred.

Mountain West Apothecary Pharmacy
Technician Education Program Review

Mr. Cortes reviewed the education program and determined the education is deficient in the following areas:

1. (a) The didactic training program must be approved by the division in collaboration with the board and must address, at a minimum, the following topics:
2. (i) legal aspects of pharmacy practice including federal and state laws and rules governing practice; **The module or block for the Utah Law must be included in the program.**
3. (b) This training program's curriculum and a copy of the final examination shall be submitted to the division for approval by the board prior to starting any training session with a pharmacy technician in training. The final examination must include questions covering each of the topics listed in Subsection (3)(a) above. **The final examination did not include all the topics listed in Subsection (3)(a). Also, add additional questions to the examination to be a minimum of 100 or more.**
4. (d) The training program must require at least 180 hours of practical training supervised by a licensed pharmacist in good standing with the division and must include: **Explain the protocols and guidelines for the practical training or externship.**
14. (B) an evaluative procedure to verify the accuracy and completeness of all acts, tasks, and functions performed by the pharmacy technician in training. **Submit the protocols and evaluation procedures.**
5. (e) An individual must complete an approved training program and successfully pass the required examinations as listed in Subsection R156-17b-302(3) within one (1) year from the date of the first day of the training program, unless otherwise approved by the division in collaboration with the board. **This is not specified in the program.**

The Board concurred.

Kamas Foodtown Pharmacy

Mr. Cortes reviewed the requested examination and determined the examination meets requirements. The program was approved. **The Board concurred.**

NEXT MEETING SCHEDULED FOR:

July 22, 2008

ADJOURN:

The time is 5:40 pm and the Board meeting is adjourned.

Note: These minutes are not intended to be a verbatim transcript but are intended to record the significant features of the business conducted in this meeting. Discussed items are not necessarily shown in the chronological order they occurred.

July 22, 2008
Date Approved

(ss) Roger B. Fitzpatrick
Chairperson, Utah Pharmacy Licensing Board

July 17, 2008
Date Approved

(ss) Noel Taxin
Bureau Manager, Division of Occupational &
Professional Licensing