South Carolina Department of Labor, Licensing and Regulation

Before the South Carolina Board of Pharmacy

September 14, 2011

BOARD MINUTES

This meeting is being held in accordance with Section 30-4-80 of the South Carolina Freedom of Information Act by notice mailed to the State Newspaper, Associated Press, WIS-TV and all other requesting persons, organizations or news media. In addition, notice was posted on the bulletin boards at the two main entrances of the Kingstree Building, Columbia, South Carolina.

Board Members:

Dan Bushardt, Chairman
Dock Henry Rose, Vice Chairman
J. Addison Livingston
Dr. Leo Richardson
Robert C. "Rob" Hubbard
Carole Russell
Rebecca Long

Lee Ann Bundrick, Administrator

Dean Grigg, Advising Counsel

Pat Hanks, Assistant General Counsel

HEARING REPORTED BY KATHRYN J. LINDLER

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MR. BUSHARDT: I would like to call the South Carolina Board of Pharmacy Board meeting to order please. This meeting is being held in accordance with Section 30-4-80 of the South Carolina Freedom of Information Act by notice mailed to The State Newspaper, Associated Press, WIS-TV and all other requesting persons, organizations or news media. In addition, notice was posted on the bulletin boards at the two main entrances of the Kingstree Building.

I would like to apologize first for starting a few minutes late. Since this is my first meeting I'm trying to get everything done right with legal counsel. From now on we will try to start exactly on time. If we could stand now and have the Pledge of Allegiance and then Rob Hubbard is going to give our invocation.

Pledge of Allegiance.

Invocation by Rob Hubbard.

MR. BUSHARDT: Let's start with introducing ourselves to each other so we will know who we are. Why don't we start with Leo Richardson.

DR. RICHARDSON: I'm Leo Richardson. I'm the lay member of the board. I'm from Columbia and I'm a member at large.

MR. HUBBARD: I'm Rob Hubbard. I'm from Clemson and I represent the Third Congressional District.

MR. ROSE: My name is Dock Henry Rose and I

represent the Fourth Congressional District.

MR. BUSHARDT: I'm Dan Bushardt, I'm from Lake City and I represent the Fifth Congressional District.

MR. GRIGG: I'm Dean Grigg, I'm advice counsel for the Board.

MR. LIVINGSTON: I'm Addison Livingston from Swansea and I represent the Second Congressional District.

MS. RUSSELL: Carole Russell from Charleston representing First Congressional.

MS. LONG: I'm Rebecca Long. I'm from Columbia, but I'm the at-large member appointed by Governor Nikki Haley.

PUBLIC AUDIENCE: Thomas Phillips with CVS and South Carolina Association for Chain Drug Stores. Clelia Sanders, Board Pharmacy staff. Lee Ann Bundrick, Administrator Board of Pharmacy. Marilyn Crouch, Board of Pharmacy staff. Ernie Shuler, Board of Pharmacy staff. Robert Spires, Health Systems pharmacist. Christy Pettit, Target. Eric Ridings, Fred's Pharmacy. Chris Isgett, attorney from Columbia, here on behalf of Scott Padgett. Scott Padgett, Script. Lora Crouch RPH. Rosemary Boguski, Board of Pharmacy staff. Shannon Amerison from Capital Information Affiliates. Amy Hughes, pharmacy student. Elizabeth Probst, pharmacy student. Catherine Wheeler, pharmacy student. Jessica Brunson, pharmacy student. Jess

Manuel. Ed Vess, pharmacy consultant.

MR. BUSHARDT: I noticed today that I don't draw quite as big a crowd as Bobby Bradham usually draws, but I'll try to do better. I am the new chairman this year and I just have a few remarks I want to make. I'm going to be open and I will be free if anyone in pharmacy needs to get in contact with me. My information is available. I don't try to hide my identity or my e-mail address or my telephone numbers. It is available. You can call the Board here and get it. I will work with you on any information or any issue that you might have. Just feel free to get in touch with me.

The Board also will allow the audience to provide information during this meeting if it pertains to the subject matter. Just wait until we call on you and then you may speak. We hope to have more students to come join us, because I think it's so important for the future of pharmacy to have our young people come to see what's going on in pharmacy and to help protect the future of pharmacy. Let's get started with the meeting. We will start with the approval of the minutes for the June 15/16 meeting. Are there any additions or corrections to the minutes?

Mr. Rose makes a motion to approve the minutes. Seconded by Dr. Richardson.

Mr. Livingston has some changes to make to the minutes. The page numbers are referenced by the number in the upper right hand corner. Page Number 19, Line Number 6 has MALTAGON as multi guide. Next page is actually page 31, that's at the bottom right hand corner, line 7, change Ray Crocker to Ray Trotter. Page 72, that page number comes from the upper right hand corner, line 11 and 12, it says during this time frame when they didn't have a PIC, they did have a pharmacist and the grammar is misworded there. Page 72, upper right hand corner, line 11 and 12 should say during this time frame when they didn't have a PIC, they did have a pharmacist. Next one I have is page number 103, that page number comes from the bottom right-hand corner. This is actually me speaking some of my not so good grammar. Starting at line 3 it says I have one more question before he leaves. The statement should say if he goes through this pathway, hopefully he'll be applying for an intern license and does not have to come back before us is what we are trying to say there. So the gentleman would not have to come back before I think was the end result of that. And the last thing was page number 165 and this page number comes from the bottom right-hand corner line number 13 and there is, the word nothing should be added before the word wrong with that. That's all that I have.

Mr. Rose had one correction in the introductions on the June 15 minutes. Page 6 says Larry Grant is listed as a part-time investigator and it should say full time.

No further corrections were made.

Mr. Rose makes a motion to accept the corrections. Seconded by Mr. Livingston. Mr. Bushardt called for approval of the minutes. Minutes are approved.

APPROVAL OF RECIPROCITY CANDIDATES FOR LICENSURE:

Mr. Bushardt thanks Board Members for taking time out of their busy schedule to interview these candidates. A motion is made for acceptance by Mr. Livingston and seconded by Mr. Hubbard. There is no discussion. Mr. Bushardt asks those in favor to raise right hand. Opposed likewise. Reciprocity candidates are approved. Mr. Rose asks the question when candidates receive their large license certificate if the certificate has the word reciprocity on it now or not or did it ever have that on it. Ms. Bundrick replies that it did have that and it was changed. Ms. Crouch said there was discussion about it a year or more ago, but doesn't know if it's been changed back. Ms. Bundrick will check on that. Mr. Rose said I think it's important, because it's not fair to people that have their primary registration in South Carolina and

reciprocity candidates have the same. Mr. Livingston remembers it being discussed also. Both Mr. Livingston and Mr. Rose thought it happened while OLC was doing the licensing and it was changed back. Ms. Bundrick will double check and let the Board know. She will ask Sally.

ADMINISTRATOR'S REPORT: Lee Ann Bundrick Good morning, Mr. Chairman and Members of the Board. I am pleased to announce that the staff had an exhibit booth at the South Carolina Pharmacy Association's annual convention June 23 through the 26th in Hilton Head, South Carolina. This was an excellent opportunity for staff to improve public awareness of the Board and its duties and responsibilities. I would also like to thank Mr. Carmelo Cinquaconchay and his staff at the Association for working with us and making this possible.

LLR is in the process of scheduling a Board Member orientation. Please keep October 11, 2011 available to attend. More information will be forthcoming.

The Board of Pharmacy has a vacancy for the Fifth Congressional seat due to the resignation of Mr. Hugh Mobley. The term of the Fifth Congressional seat expires June 30, 2013. Information on the requirements was in the August newsletter. The following individuals have submitted their biographies and petitions to run for this seat. Ms. Deborah Bowers, Mr. Marvin Hyatt and Mr. Larry

Meek.

The Board of Pharmacy will conduct an election for the Fourth Congressional District seat which expires June 30, 2014. Information on the requirements was in the August newsletter. The following individuals have submitted their biographies and petitions to run for this seat. Mr. David Banks, Mr. Fred Bender, Mr. John Doug Harmon and Mr. Eric Ridings.

After receiving the biographies and petitions, the Board Administrator will prepare and mail ballots by October 15 to all pharmacists who certified on their last renewal application that they reside in the Fifth Congressional District and all pharmacists who certified on their last renewal application that they reside in the Fourth Congressional District and certify as true and valid all ballots postmarked before November 15 and received by the Board office before November 25.

The Board will certify in writing to the Governor the names of the three candidates receiving the most votes in the election along with the name of the person who the nominee replaces on the Board after the election results are tabulated.

As of this report we have approximately 2,815 active state certified pharmacy technicians and 4,726 active registered pharmacy technicians. We have 7,211

active licensed pharmacists. We have 3,874 permitted facilities and three electronic prescribing routing companies.

The pharmacist inspectors have conducted 349 inspections since the last Board meeting. 140 were pharmacy permit inspections. 144 were non-dispensing drug outlet permit inspections. 23 were EMS permit inspections and 42 were medical gas/DME permit inspections. Of the 349 inspections 75 were new permits. No citations have been issued since the last Board meeting.

The Board of Pharmacy has continued to serve as a site for pharmacy students on clinical rotations from the South Carolina College of Pharmacy USC campus. During the month of August Ms. Tara Chamblee was on rotation with the Board office.

Mr. Eddie Durant, temporary pharmacist investigator, resigned effective July 26.

Ms. Cle Sanders, Mr. Wilbur Harley and I completed the MPJE state specific law review the week of August 16 through 22. We reviewed approximately 4,000 questions to determine if they were appropriate questions to be in compliance with state and federal laws.

My staff and/or I have participated in the following meetings since the June Board meeting: Mr. Bobby Bradham, Mr. Henry Rose, and I attended the House of

Delegates at the South Carolina Pharmacy Association annual meeting on June 24. Ms. Cle Sanders presented a CE program Compliance in the Art of Compounding at the South Carolina Pharmacy Association's annual meeting on June 24.

We had a USP 797/795 compounding task force meeting on July 8. Staff attended customer service excellence training for the agency. We had a telephone IRC with Mr. Turner on July 12. Ms. Cle Sanders and I attended the Physical Therapy Board to discuss non-dispensing drug outlet permits as related to their profession on July 14. I attended SCEIS training for the agency on July 18. Staff attended a follow-up meeting regarding the assigning of the answering of telephone calls to the program staff on July 26 to discuss ways to be more efficient and to work smarter. I met with Director Templeton on July 26 to discuss the pharmacy program. Ms. Sally Green and Mr. Michael Rowland attended the NABP program review and training August 27 through the 28th in Chicago, Illinois. Ms. Cle Sanders and I met with Mr. Matt Faile in the IT Department regarding improvements to reports in MiForms and ReLase. We also discussed the new inspection software program that the pharmacy program will be converting in the near future. We met on July 28.

Mr. Hugh Mobley and I attended the Board of Medical Examiners meeting on August 1 to discuss

e-prescribing in regards to public safety. On August 1 I had a staff meeting with the pharmacist inspectors. On August 2 I had an office staff meeting. On August 4 I attended an administrator's meeting for the agency. On August 5 I attended a legal meeting for the agency. Mr. Henry Rose, Dr. Leo Richardson, Ms. Carole Small Russell and I attended the NABP/AACP District 3 annual meeting in Biloxi, Mississippi, August 6 through 10. The pharmacist inspector/investigator staff attended a drug diversion training on August 9. On August 12 I met with Mr. Grant Gillespie, Director of Business and Government Affairs, as a meet and greet to discuss legislative issues related to the Board. We had a USP 797/795 compounding task force on August 19. Mr. Ray Trotter and I met with legal to review investigations on August 23. We had a telephone IRC with Mr. Turner on August 25. Mr. Ray Trotter and I met on August 29 and 30 to coordinate cross training of the pharmacist inspectors in regards to investigations and sterile and non-sterile compounding. We had a telephone IRC with Mr. Turner on August 29. We had a pharmacy practice committee on August 30. Ms. Cle Sanders and I gave a presentation to the Presbyterian College first year pharmacy students tips to be an excellent pharmacy intern on August 31.

I met with Chairman Bushardt on September 6

to discuss the upcoming year and go over Board meeting information. We had a telephone IRC with Mr. Turner on September 7. Ms. Cle Sanders met with IT to determine what information they need to move forward with the new inspection software program on September 8. I attended a criminal background check meeting on September 9 presented by SLED. We had a telephone IRC with Mr. Turner on September 9. On September 13 I met with the pharmacist inspectors to begin cross training for investigations and compounding. The pharmacist inspector/investigators have been assigned territories and will be responsible for all aspects of inspecting and investigating for their territories. This will allow us to be more efficient and cost saving.

The deadline for the fourth quarter Board of Pharmacy newsletter to NABP is quickly approaching. If you have any suggestions for articles, please let me know. We have been sending this information to you for your review and comments. If you have any problems receiving it, please let me know.

Handouts for your review that are under the Administrators tab are in front you that may be of interest. I have a letter to the Institute for Safe Medication Practices from Carmen Catizone at NABP requesting additional information for presentation to the

boards of Pharmacy on national advertising campaigns for pharmacy and pharmacy services and prescription time guarantees that impact public safety as well as the letter to NABP from the Institute for Safe Medication Practices. An e-mail from NABP stating that President Malcolm Broussard of NABP has appointed me to serve as a member of the task force on pharmacy practice technology systems scheduled for November 1 and 2 there is also a letter, brochures and information from Purdue Pharma in regards to the new drug application for Butrans Transdermal System control substance three being approved by the FDA and the confusion between the legal requirements and restrictions concerning buprenorphine-containing products specifically indicated for use in treating opioid dependence, also referred to as opioid addiction, suboxone, subutex and gerneics and Butrans which is indicated only for analgesic use and is not approved for the use in the treatment of opioid addiction. There's a folder in front of Mr. Bushardt that has all that information. I did not copy it for everybody. So if you would all pass it around. If you have any questions, let me know.

I would like to thank the Board for their continued support of me and the rest of the staff in the office. We always appreciate the encouragement and support that you give us and I would respectfully answer any

questions that you might have at this time.

Dr. Richardson had a question on the telephone system training. Ms. Bundrick explained they had a meeting to look at the progress since the new director came in. She sent all the calls back to the program areas instead of the customer care center and had a meeting to look at how the staff could be more efficient and work smarter in the phone system. Dr. Richardson went on to further say he asked that question regarding the system that NABP talked about in May that's supposed to be part of a national type thing. Ms. Bundrick explained that's CE, continuing education, which is different. Mr. Livingston asked about how many technicians did not renew. Ms. Bundrick said there was about 3,000 that did not renew and cease and desist letters were sent out to all of them. She said they received a lot of phone calls from technicians freaking out that they didn't renew. She said all they have to do is renew, reinstate their license, but to reinstate, you must pay a fine and have proof of their continuing education. Mr. Bushardt asked if a letter is also sent to the employer or just to the person. Ms. Bundrick responded the letter was just sent to the person. Dr. Richardson asked why is it so many, 3,000. Ms. Bundrick said that's why we sent cease and desist letters out. She doesn't know if there was confusion because OLC

did a two-year renewal last time and there might have been some confusion between the one and the two years or if they just forgot. A lot of technicians move and don't notify the Board and don't intend to practice, but 3,000 is a lot out of the total number that. Mr. Livingston said of the 3,000 cease and desist letters sent out, any guestimate of how many people have since then been reinstated. Ms. Bundrick said she could find that out. She said based on this report here we've reinstated 31 pharmacy technicians since the last Board meeting and four state certified and that is as of yesterday. That's not a lot, but that's based on the statistics out of Relay. Mr. Livingston commented that it might be a good idea to put in the newsletter about technicians renewing. Ms. Bundrick said they could also send an e-blast out on the e-mail addresses that are on file in the computer system. There was an e-blast sent out on the hurricane and she doesn't know if the Board Members received that. Mr. Rose responded he received it. Mr. Livingston said pharmacists-in-charge need to be looking for those. Dr. Richardson said he had a concern because Ms. Bundrick stated she does not know the reason for the renewal and we need to find out what happened to that, if it's something we should have done that we didn't do then we can fix that, but I do think we need to find out why we have so many. Ms. Bundrick said

some pharmacy techs are now interns. They called and told us that and we saw that and deleted the CND, because they were actually not practicing. They did have their license as an intern. Mr. Livingston said he expects there's a large portion of those that don't need to be renewed, but it is hard to believe there's been 3,000 people who either left their job. He thinks there's probably a great number of them still out there practicing. Ms. Bundrick said that was an alarming number for us too as staff. Ms. Bundrick said I think probably a lot of the ones that did not renew was probably due to the confusion between the two years and one year licensing. Mr. Rose commented that all technicians received a letter at their last known address about their renewal and if they have not let the Board know what their change of address is, that's not the Board's fault, it's their fault. They're supposed to do that within ten working days. It's not the Board's fault they didn't renew, it's their fault and all the PICs in this state need to realize if they have a technician working that has not renewed that's a violation and it's going to be an expensive violation when inspectors come around and they should have all those renewals in one place where they can be seen by the public. Dr. Richardson wanted to know what kind of impact that would have on pharmacists throughout the state in terms of number, that each

pharmacist is supposed to have two to three techs. Ms. Bundrick responded it depends on the ratio according to law. Dr. Richardson wanted to know what kind of impact is it going to have on the ratio that's required by the Pharmacy Act. Mr. Livingston responded the best way to figure that out is how many active technicians did we have in March or April if that can be determined. Ms. Bundrick said she could get the statistics from her last report. She reports it looks like based on the statistical information we are going to go over after awhile, it looks like we have 9,597 active and we had about 12,000. So basically a fourth did not renew. So it could have a large impact. Dr. Richardson said that should be our concern. Mr. Livingston said it has to be concern, but he also think you have to take some responsibility for maintaining your job in some form or fashion. Mr. Bushardt said it is the PIC's responsibility to make sure that they all keep their license up. However, he doesn't know if they shouldn't be involved in the renewal process, maybe they should be notified that some of their techs did not renew, because they're responsible. They're the ones that are supposed to make sure that they are and they get in trouble if inspectors come in and there is an invalid technician registration on a wall. Even though that's their responsibility, to be totally fair with them, he doesn't

know that the Board shouldn't send some type of notice to the PIC saying this tech has not renewed and they might could write back and say this tech no longer works for me or whatever and maybe we'll have a little better idea of what we should do and what we shouldn't do.

Robert Spires asked all technicians had to renew for one year. Ms. Bundrick told him that's correct. Mr. Spires said he would make sure that all directors of pharmacies at hospitals have been informed today to check their staff to make sure they are current. Mr. Phillips informed Mr. Livingston that the chains had been sent an e-blast about renewals and e-mailed Ms. Bundrick that he had done so.

Mr. Livingston asked what is our involvement in the three routing companies, that he is seeing more and more prescriptions come to him in electronic format that are very very confusing, they have some ambiguity, directions have some ambiguity, in strength, and he sees it as a real hazard to the people that we are serving, because it's very, very easy to make a mistake and he doesn't know if the process could be improved by the routing company or be improved by the software that physicians have. He just doesn't know the Board's involvement in that particular process. Ms. Bundrick replied according to statute they are supposed to notify us, we do not give them a license, a permit or anything. They just have to notify us that they

are a routing company. She said we could send a letter if that's what you would like. As Mr. Livingston said, you're not real sure which end it would be for improvement. Mr. Livingston said he's thinking it may be something that the Practice Committee could look into. He could provide the Board with examples, because he gets them and it's not black and white, you need clarification. Ms. Bundrick said the e-prescribing is not actually in our statute, it's in 44 for all practitioners. Mr. Hubbard said what I think would help us would be able to see what the menu looks like from these different companies, because when he calls the doctor's offices about these errors, they say they have a drop-down menu and what happens is they punch the first drug that looks like what they were on and so we're getting a lot of different dosages and the first thing we do is call them about did you mean to change Customer X to a different dosage and they say no we wanted to renew what they had been on. He continues, if we could just see what kind of screen that they have. Mr. Livingston said it would be important for us to see their screen, but it would be nice for them to see what we are getting on our end as well and he doesn't know if that could be done through some work with the Medical Board as well, because they are driving electronic prescriptions. Ms. Bundrick and Mr. Mobley met with the Medical Board of Examiners and they

asked us to submit them information that they could put in their newsletter about e-prescribing in regards to public safety and she has the information to give to Mr. Duke for them to get that into their newsletter that would hopefully help improve some of this on their end. Mr. Livingston thinks that would be beneficial because he sees it as a real potential for some problems, that it's very easy to make a mistake.

Mr. Livingston also stated when he does the reciprocity interviews, he asks for feedback on the whole process and he continually gets responses that the NABP side of things are somewhat lengthy. He wants to know is that something that NABP welcomes feedback on. Ms. Bundrick said we could give them feedback on it, but they have to go by a process through NABP and then NABP notifies us and then we have to approve them to send them an authorization to test. We can't do anything until NABP sends the information to us. Mr. Livingston said from his interviews recently everyone has been very complimentary of the staff here, it's just getting to the point that they can deal with the staff here that's been somewhat difficult. Ms. Bundrick said she could check with Carmen and those at NABP and see if anything has changed on their end.

Mr. Richardson informed the Board that he

too had been appointed to a task force on control and accountability of prescription medication. The first meeting will be October 26 and 27.

REPORTS:

OFFICE OF INVESTIGATION AND ENFORCEMENT: No one was present to give a report.

OFFICE OF GENERAL COUNSEL: Pat Hanks

Mr. Hanks handed out his report. There is 26 open cases, nine of those are pending work in the Office of General Counsel. Ten of those are pending either consent agreement or a memorandum of agreement. Seven of those the Board is going to see in a disciplinary hearing. Since January of 2010 61 new cases were closed. After this session nine pharmacy cases will be pending, but that's always changing, because you will have IRC approval and you'll approve probably 20 formal complaints today, but it gives you a ball park. Mr. Bushardt asked if it was a number that they could handle at a regular meeting. Mr. Hanks replied that he believes so, that you should again after this process have approximately 10 to 12 cases pending. From history the Board typically held about 90 to 100 cases and typically have about 40 to 50 pending and we're down to the teens. Mr. Livingston wanted to know the pending hearings that we have are from relatively recent cases or do you have any idea how old they are.

Mr. Hanks replied that most cases are relatively recent cases. Mr. Rose asked about a case that was supposed to come before the Board probably two years ago that was going to last two days and it's been continued since that time, is that case ever going to come before the Board or is it just continued forever. He thought the chairman of the Board of Pharmacy had to okay it each time. Mr. Hanks said the case actually went backwards into OIE and the way he understands it there were some issues with the federal government and us going forward and the federal government has a criminal case pending, that at some point the Department of Justice will give us the okay, but they haven't at this time. The case that Mr. Hanks would have is back in OIE and he said what he did as a result of that is that he took as stringent an action as he could to take care of the public safety issue. Those people are restricted as severely as they can be restricted at this point pending the Department of Justice letting him know he can go forward with the prosecution.

Mr. Richardson said as a point of order, there are seven of us around the Board and we do know that the process is in place to replace two people, either Mr. Rose and Mr. Mobley and in the mean time Mr. Rose is continuing to serve until he's been replaced, but Mr. Mobley's position has not been filled, can Mr. Mobley

continue on the Board unless there is some statute saying that he can't continue until he's replaced on the Board. Mr. Bushardt responded that he can't serve on two state boards at the same time and he's serving on another state board and so he wouldn't be able to vote on this Board.

Mr. Bushardt also said as a point of order here we were talking about three day meetings, three day meetings would put too much of a hardship on the pharmacists serving on this committee. The Board will only have two day meetings, but if a third day is needed, it will be a separate day, that we can work one day, but it's hard for us to work three in a row. The Board would be glad to work with everyone if a third day is needed to have a hearing. That's why he asked Mr. Hanks if that would be within the time of regular meetings and Mr. Hanks replied yes.

OFFICE OF INFORMATION SERVICES:

Ms. Bundrick handed out a handout entitled Board Meeting Report and this is the statistical information since the last board meeting in regards to the number of licenses, registrations and certifications that have been issued, reinstated and/or renewed online and total active number of credentials 20,540.

FINANCE REPORT:

Ms. Bundrick reported there is a handout on the back of

number 3 that has a sticky on it. This is for your information. Mr. Livingston had a question on the immigration OSHA $100,000 expense. Ms. Bundrick replied that is taken out according to proviso 65.8 and 65.7, it has to do with the proviso and she thinks they took it out of everybody's budget for it. Mr. Livingston asked OLC had an expenditure of $161,501 for 2011 and had $193,853 for 2010 and 2010 was a complete year and at some point we got out of OLC or OLC department got out of our business in 2011 in March. Ms. Bundrick said reorganization took place April 1. Mr. Bushardt said Dr. Richardson is going to take over finance.

COMPLIANCE AND INSPECTORS REPORT:

Ms. Crouch passed out a handout to the Board for August 25. Ms. Bundrick reported we have eight cases that are recommended for dismissal. They were reviewed as a group and voted on as a group. Mr. Rose wanted to know if some of these generated a formal complaint. Ms. Bundrick replied the dismissals did not, but further back we have formal complaints and letter of caution, but we're only looking at the eight dismissal cases right now. Mr. Rose commented like the first one is a pharmacy owner who is the permit holder is no longer there and so he would have been a formal complaint later, is that not true. Ms. Bundrick said we don't have jurisdiction over a permit

holder if they're no longer a permit holder. Mr. Rose said that may not have been a pharmacist is that what you are saying. Ms. Bundrick said it was not a pharmacist. Mr. Hanks said I think what we could possibly look at is dealing with the permit itself, because if the permit is still there, but there may have been a reason why they didn't deal with that permit number even if they did try to do the egg shell game on us, that Lee Ann might know why we didn't, but he thinks what they are talking about is conduct that occurred while he was the permit holder. Ms. Bundrick agrees that it was while he was the permit holder, but could not do anything to the permit holder, we have to do something to the permit and the permit holder is no longer there, they have a new permit holder and owner. Mr. Rose moves to accept the dismissals. Mr. Livingston seconds the motion. There was no further discussion. Mr. Bushardt asks for the vote by raising right hand, opposed the same way, and motion passes.

MS. BUNDRICK: The next case is a dismissal. We issued a cease and desist, and that would be for your information.

The next set are formal complaints and there are 14. We ask that you approve these for us to move forward. That means the Board will see them later in a consent order, MOA or a hearing. So you will see these again.

This just give us approval to move forward with starting on those processes.

MR. BUSHARDT: On 2011-7, was there a patient harmed in that one, the next to last one?

MS. BUNDRICK: If there was a formal complaint, it was probably something to the patient. You will see it later when it comes before you.

Mr. Livingston makes a motion to accept these. Second by Dr. Richardson. There was no further discussion. Mr. Bushardt calls for the vote by raising your right hand and opposed the same way and motion carries.

MS. BUNDRICK: The next two cases are letters of caution. These were investigated by a pharmacist and reviewed by me in order with the Resolution Guidelines.

Mr. Livingston makes a motion to accept. Second by Mr. Rose. There was no discussion. Mr. Bushardt calls for the vote by raising right hand and opposed by the same way. Motion passes.

MR. HANKS: Chairman and Members of the Board, the first set of items we are going to deal with is four cases that are coming before you where individuals have decided not to go forward and challenge their disciplinary action, but to relinquish permanently their authorization to practice. Case number 2011-45, this is a case where a

technician was calling in for prescriptions for herself and others and was arrested as a result of that in Pickens County. Rather than go through the disciplinary process, she has advised that she wishes not to practice as a pharmacy technician anymore, to forevermore relinquish her right to practice as a technician in this State.

MR. LIVINGSTON: We are going to do these as a group, Pat?

MR. HANKS: Yes. The second case is 2011-60. This individual diverted Hydrocodone and Clonazepam while employed as a tech. She also surrendered her authority to practice. Third case is 2011-62. This individual diverted some Lortab for her own personal use while working at a CVS in Greenville. She too agrees to forever give up her registration to practice. And then finally case number 2011-69 this individual diverted Oxycodone while acting as a technician down in Bennettsville and like the other individuals this individuals does not wish to practice as or act as a technician at any point in the future.

MR. LIVINGSTON: These are relinquishments?

MR. HANKS: Yes.

MR. LIVINGSTON: They would have no bearing on any legal action that's taking place?

MR. HANKS: Criminal action, no bearing on the criminal action.

MR. LIVINGSTON: I move that we accept these.

MR. HUBBARD: Second.

MR. BUSHARDT: Any discussion? Those in favor raise your right hand. Opposed the same way. Motion passes.

MR. HANKS: Mr. Chairman, the next set of issues you are looking at are just five cases of voluntary surrenders. These don't require your action. These individuals have surrendered, but they have not surrendered in any kind of permanent fashion. So you are going to have to deal with the cases at some point. So rather than being temporarily suspended, these individuals voluntarily gave up their ability to act as a pharmacist or tech.

MR. BUSHARDT: We accept this as information only?

MR. HANKS: Yes, sir. And then finally start dealing with the consent orders. If we could, if we could start with the two handouts that we have as consent orders. You should have two cases that were given as handouts. The first matter is a permit. You may want to take a little time to look at permit case number 600-10218, the OIE case number should be 2011-78. This case has come before you all before. Again this is permit number 600-10218. This case has come before you before. Essentially what happened in this case is we got an out of state permit holder. The

out of state permit holder has appeared before the Board pursuant to an application hearing. That application hearing issue was tabled and then they reapplied and the application has been determined to be complete with the exception of them obtaining a sterile compounding permit in the State of California. As you can see in the findings of fact that issue has been dealt with under finding of fact number 3. They have obtained a sterile compounding permit in the State of California. But there are also issues with the fact that this individual's authorization to ship into this State expired in October 2009 and they continued to ship in this State until they voluntarily ceased in June of 2011. So it was a period of approaching two years of continuing to ship into here. They received a cease and desist in June of 2011. So, of course, the continued conduct was an issue that we discussed with the Investigative Review Committee and as any consent order situation, Members of the Board, it's up to you to approve what IRC has recommended. In this case IRC is recommending for the Board to consider that this permit be issued in a probationary status for a period of five years and also that they suffer a fine of $75,000 and that they provide a copy of the permit issued for sterile compounding in California and I understand that there is a finding of fact issue in finding of fact number 4. We understand that they

lapsed and according to your licensing order they would have always lapsed in June rather than October of 2009 just as any permit would lapse in June of the renewal period. But I don't think that takes away from the situation. Basically what we are saying is it was not in October when they lapsed, it was June when they lapsed. The central issue is that the Board understands that this matters was pending before pursuant to an application and the issues of the continuing to ship into this State were looked at by the IRC and the IRC, if you accept this matter, you then take away your issue to deal with the application. I don't know if that's a good thing or bad thing, but the application would be granted. They would be able to be reinstated as long as they meet all other requirements and they would be on probation for a period of five years and they have agreed to remit the sum that's listed in the consent order.

MR. GRIGG: Mr. Hanks, I just want to make sure of a few things real quick. First of all I understood that Mr. Dayhoff would be present. Is he in fact here? I just want to note that for the record.

MR. DAYHOFF: Yes, thank you, I'm here.

MR. GRIGG: You're the attorney for General Home Pharmacy, correct?

MR. DAYHOFF: That's correct.

MR. GRIGG: The second thing is, Mr. Hanks, number 4 you're saying it should be changed from October to June.

MR. HANKS: That would have been the period in which.

MR. GRIGG: Does either party have a problem with amending that on the record here today?

MR. DAYHOFF: That's fine.

MR. ROSE: Should we have a motion then, Mr. Hanks?

MR. HANKS: I don't know, Dean, if you all want to do this one a little different than the others.

MR. HUBBARD: Mr. Chairman, I move that we go into executive session.

MR. LIVINGSTON: Second.

(Executive Session.)

MR. ROSE: Make a motion that we come out of executive session.

MR. LIVINGSTON: Second.

MR. BUSHARDT: Any discussion? All in favor signify by saying aye. I want to just say that no motions were made and no votes were taken while we were in executive session.

MR. LIVINGSTON: Mr. Chairman, in the matter we are considering I make a motion that we accept this consent

order that's before us.

MR. HUBBARD: I second it.

MR. BUSHARDT: Any discussion? All in favor signify by raising right hand. Opposed likewise. Motion passes.

MR. HANKS: Mr. Chairman, if you could next consider 2010-90 which was also a handout.

MR. GRIGG: Mr. Hanks, the one we just finished up, wasn't there potentially something scheduled for later this afternoon?

MR. HANKS: There is.

MR. GRIGG: Do we need to mark that off so they know not to come? Was it actually on the agenda?

MS. BUNDRICK: Yes. I think it's S.

MR. HANKS: If we could, Dean, and Mr. Chairman, if we could consider the other handout case before we start with the cases that are listed in your book. If we could look at case 2010-90. In this case we have an individual that has, as the document states, he surrendered his license in December of 1999 incident to another event and his most recent surrender was September 2010. This individual diverted some Hydrocodone syrup from a Walgreens. It was a prescription that wasn't picked up by a patient. Thereafter he continued to divert from pharmacy stock. He diverted approximately $600 worth and all of

this was in an effort to self-medicate for back pain. This individual had the same issue with trying to self-medicate back in January of 1999 to November of 1999 which resulted in his appearance before the Board at that time. As I stated he surrendered his license in December of '99 incident to that event. The respondent's recovery efforts is thus. Respondent went to Cornerstone, he did some recommended treatment from 6 June of 2010 to basically the end of July 2010. And then he reentered August 24 for about seven or eight days to September 1. Respondent has also completed intensive out-patient program by LRADAC. He completed some relapse prevention programs. He's enrolled in Script and caduceus and 12-step programs and he's in counseling with Dr. Michael. However, it's important to note that the Respondent at this point is not in compliance with RPP and should you accept this order he won't be reinstated until such time as RPP says he's in full compliance. These efforts that you have in paragraph number 5 are efforts that he has underwent, but those efforts are not in compliance and consistent with the RPP program at this time. But the Respondent has indicated his willingness to come back to the RPP process should it be the Board's decision to accept this consent order. As I say prior to him being reinstated from this most current September 2010 surrender, he would have to come into

compliance with RPP contract and have RPP's recommendation that he be able to return to work. If able to return to work, his license would be suspended indefinitely. Now I'm on page 2 down at the bottom paragraph 1. His license would be suspended indefinitely, stayed and the conditions to that would be again that RPP recommends his return to work he will be under a typical RPP contract, he has to remain drug and alcohol free and only take any medications that are prescribed by his physician for a legitimate medical purpose. He will be subject to random drug screens. Also the Respondent will pay a fine of $500. His ability to be a permit holder or a pharmacist-in-charge would be negated indefinitely also. Respondent also has to have any employment of greater than seven days approved by the Board. Now the other catch on this consent order is that if the Respondent violates any terms of this consent order, his license could be revoked which is not a situation where we are going to deal with a suspension any disciplinary action. The intent of this consent order is that if there are any additional problems that his license could be revoked. So it's a period of indefinite probation, RPP, can't be PIC or permit holder indefinitely and he can't have any job over seven days unless approved by the Board. It will run from Lee Ann to the Board chairman or whoever the chairman is at the time he's

applying, any correspondence relating to his application have to be in writing, $500 fine and again revocation in the case of non-compliance.

MR. ROSE: I move to approve the consent agreement.

MR. BUSHARDT: Hear a second?

MR. HUBBARD: Second.

MR. BUSHARDT: Any discussion?

MR. LIVINGSTON: You said he's not compliant with RPP right now. If we were to approve this, how long typically would it take for him to become compliant with RPP? Is it a three month process?

MR. HANKS: Under the agreement he has to show his active participation agreement within 30 days of this agreement. I'm assuming that the Respondent did read that. Thirty days after the effective date of the agreement he has to send something back to Lee Ann showing that he signed the contract and is an active participant in RPP. So that's going to lock in his time frames.

MR. LIVINGSTON: I guess my question is suppose he does sign that contract, we're basically giving RPP the authority to let him go back to work from what I understand here. He has to do more than simply sign a contract, is that not correct?

MR. HANKS: That's correct. He has to be an

active participant in the contract. That's to say he's signed up and he's an active participant in RPP. That's within 30 days of this agreement becoming effective.

MR. SHEHEEN: Generally in these situations we would ask that they be three to six months 100 percent compliant before we would make a recommendation.

DR. RICHARDSON: Repeat that.

MR. SHEHEEN: We would ask three to six months of 100 percent compliance before we would make a recommendation.

MR. HANKS: He's talking about a track record.

MR. BUSHARDT: Any other discussion?

MR. HANKS: This is counsel for that individual.

MR. ISGETT: Mr. Chairman and Members, I'm Chris Isgett, here on behalf of the Respondent. We have some documents in which Pat was kind enough to accept via e-mail that shows Respondent's work to date toward recovery and his willingness to continue to work. I made copies for the Board to review. If you would like to see them now, I don't know if they were printed out. We worked to late hours with Pat to get this ready so I don't know if it's in your material now. The Respondent is also available for any questions or comments you may have.

MR. HANKS: As I understand, he's documenting the things that are in paragraph 5 on top of page 2. It's the

same recovery efforts --

MR. ISGETT: It's just in depth of what he has done and shows the compliance.

MR. GRIGG: Mr. Hanks, do you have any problem with those being handed up?

MR. HANKS: No.

MR. ISGETT: May I approach. This is the original and those are copies. I think there's enough. I may have miscounted.

MR. HANKS: As we see the crux of the whole matter is that the Respondent has not been compliant with the RPP program. He has done a number of things. We have to give him credit for that, but as Frankie stated, Frankie is going to want to see some sort of track record.

MR. GRIGG: Sir, you may have said it and I missed it, you are the Respondent's attorney?

MR. ISGETT: Yes, Chris Isgett.

MR. ROSE: Mr. Chairman, can I ask the RPP representative one question?

MR. BUSHARDT: Sure.

MR. ROSE: When you have a case like this where a person has failed to comply and they're going back through the program, would your testing be more intensive than normal? Early on it's more intensive anyway than it is later in the program, is that correct?

MR. SHEHEEN: Yes, sir, it is.

MR. ROSE: During the first maybe six months they probably have a lot more drug screens than they would have in the successive period?

MR. SHEHEEN: What we do is 26 a year upon enrollment and that would be the level and that's with the first two years. After that it's 100 percent compliance, the number goes down. We normally don't do more. We may ask for a hair test within the first month to verify what's happened. In this case, he's not enrolled with RPP currently, but I have had documentation and conversations with drug court and know that he's had all negative tests there since he's been in drug court. We would want to test him for several months with us before we could attest his safety to practice, because drug court, their tests are not the same proficiency as the ones that we have and they can't test for the same panel, same number of chemicals that we can test for. They don't test for the same number. We would want our drug test to be performed for a while. It's a higher level of testing, more expensive too, but a higher level of testing.

MR. ROSE: The expense would be borne by the client in any case?

MR. SHEHEEN: Yes, sir.

MR. LIVINGSTON: Under this consent agreement

this information basically becomes irrelevant. RPP is the program that will have to be and all parties agree to that?

MR. HANKS: Exactly.

MR. LIVINGSTON: I make a motion we accept.

MS. BUNDRICK: We got a motion and a second.

MS. LONG: Second.

MR. BUSHARDT: We got two motions and two seconds. Any more discussion since you've read? All right. Let's go ahead and vote. All in favor signify by raising right hand. Opposed likewise. Motion passes.

MR. ISGETT: Thank you, Mr. Chairman.

MR. HANKS: Mr. Chairman and Members of the Board, under I believe your tab 5 we have additional consent orders. 2008-98. In this case this individual, this is one of those cases that Mr. Livingston was concerned about. This is a case where the facts occurred back in 2006/2007 and we're now getting to deal with the issue where this individual was reprimanded by the State of North Carolina for not properly supervising a technician in North Carolina. As you can see the amount of diversion was over a hundred thousand dosage units of Alprazolam and a quantity of Xanax also, but again the conduct occurred in North Carolina. She was disciplined by the North Carolina Board in 2008 and our typical guideline policy on the case is to mirror whatever the other state did and so IRC is

recommending at this point that we reprimand this individual. There would be no compliance issues with the North Carolina Board, because of course they did not take any action other than reprimand her.

MR. BUSHARDT: Do I hear a motion?

MR. LIVINGSTON: So moved.

MR. ROSE: Second.

MR. BUSHARDT: Discussion? All those in favor signify by raising your right hand. Opposed likewise. The motion passes.

MR. HANKS: Next case is a 2010-62. We've had a series of these cases in the past and I believe this is the last in that series. In this case again we are dealing with a non-resident pharmacy who shipped in this case one prescription here prior to the Drug Utilization Review being conducted as a result of a software error and they determined that there was no patient safety issues here, new prescriptions were secured in other cases and there was no complaint that resulted from a member of the public. IRC nonetheless saw fit to put the permit on probationary status for a period of one year and for them to suffer a $500 fine.

MR. LIVINGSTON: Motion to accept.

MS. RUSSELL: Second.

MR. BUSHARDT: Discussion? All those in favor

signify by raising right hand. Opposed likewise. Motion passes.

MR. HANKS: Next case 2010-138. This matter involves a pharmacy technician who is non-certified. She transferred a prescription for insulin. She gave the incorrect strength and she also gave incorrect directions. That information was cleared up by a physician on a different day. This Respondent also transferred a prescription for Pepcid. IRC's recommendation in this case is for the registration to be placed in a probationary status for one year and for her to suffer $500 fine.

MR. BUSHARDT: Motion?

MR. LIVINGSTON: I make a motion we accept.

MR. HUBBARD: Second.

MR. BUSHARDT: Do I have any discussion?

MR. ROSE: I have one thing. This is a continuing problem in South Carolina where the non-state certified techs are doing this and it's a problem and it's -- I think that even some of the PICs probably don't know that they can't do this and it's probably something that needs to go in a newsletter. I know we've done it before, but I think we need to do it again, what the state's certified techs only can do. We also had in Pharmacy Practice on the 30th another thing that came up that we only want state certified techs to do. We need

some way to stop this kind of a problem. I don't know what we can do to do it, but this is certainly a danger to the health and well being to citizens of South Carolina.

MR. BUSHARDT: Any other discussion? All in favor signify by raising right hand. Opposed likewise. Motion passes.

MR. HANKS: In the matter of 2010-156. In this case we had an individual who was acting as PIC at a pharmacy up in Rock Hill. They filed a forged prescription for Allegra and various other antibacterial medications as well as Vigamox. DHEC took some action against this individual as to the Allegra. IRC looked at the situation and they're recommending that this individual's license be put in a probationary status and suffer $1,000 fine and that they not practice as a permit holder or PIC during that one year period that their license is going to be on a probationary status.

MR. BUSHARDT: Motion?

MR. ROSE: Motion to accept consent agreement.

MS. LONG: Second.

MR. BUSHARDT: Discussion?

MR. LIVINGSTON: What kind of action did DHEC take against on the Allegra prescription?

MS. LORA CROUCH: That would be me. They submitted jail and PTI and it's gone off my record.

MR. BUSHARDT: Any other discussion? All in favor of the motion raise right hand. Opposed likewise. Motion passes.

MR. HANKS: Mr. Chairman, the final cease and desist is just for your information. Likewise as to the TSO.

DR. RICHARDSON: Mr. Chairman, just a point that I think we should emphasize particularly the last, not the last one, the previous one that Mr. Rose made in terms of, during the question period, in terms of those suggestions as to how to fix the problem. I hope we don't take those recommendations likely.

MR. BUSHARDT: I'm going to talk to Ms. Bundrick about that.

DR. RICHARDSON: Make sure that we follow through on those, because we do have solutions and sometimes these things keep coming back to us and if we could just follow through on those recommendations, I think it would enhance the problem, I mean delete some of the problems that we do have.

MR. HANKS: I think in that very case both the technician and the PIC was unaware.

MR. BUSHARDT: I have some ideas about that and I will talk with Ms. Bundrick about that.

(Break.)

MR. BUSHARDT: Request Release from Order, Jess Manuel, Jr. This is your time that you can express to the Board what you would like to tell us.

MR. MANUEL: I'm here on an unfortunate circumstance, but I've grown enough that I feel I'm ready to go back to practice. I just need your courtesy.

MR. BUSHARDT: Can you tell us a little bit about your history. It says that your license should be reinstated. You've done everything that you're supposed to have done through RPP?

MR. MANUEL: Yes, sir.

MR. BUSHARDT: As of October 19, 2011, you would have completed everything that you were supposed to have completed, is that correct?

MR. MANUEL: With the exception of intern, a thousand intern hours.

MR. BUSHARDT: How about your CEs?

MR. MANUEL: Done all the CEs that are required plus some more.

MR. BUSHARDT: Lee Ann, with a thousand hours, would that be, instead of October 19, would that be after the 1,000 hours?

MS. BUNDRICK: Yes, sir. He would have to get the thousand hours, but he couldn't have any kind of

license until October 19. Come October 19, we can issue him the intern certificate if you approve.

MR. BUSHARDT: Does the Board have any questions of Mr. Manuel? Do I have a motion for release of order?

MR. LIVINGSTON: So moved.

MR. BUSHARDT: Is there a second?

MS. LONG: Second.

MR. BUSHARDT: Discussion?

DR. RICHARDSON: Mr. Chairman, I was out, I didn't read this so I want to make sure I understand what happened in the meeting, because I was out. I want to make sure I vote correctly.

MR. BUSHARDT: He has completed everything asked of him as of October 19, 2011. So at that point in time then we can reinstate. So he has done what he was supposed to have done. Any other discussion? All in favor signify by raising your right hand. Opposed likewise. Motion passes. We grant his request. Good luck in the future. .

MR. BUSHARDT: Request Modification of Order Patrick Hill. Is Mr. Hill present? (Ms. Crouch looks in the hallway for Mr. Hill unsuccessfully.) What he's asking for is request to allow him to perform as a PIC and it looks like it's early.

MR. LIVINGSTON: He signed an order for five years to prevent him from being a PIC and now he wants to be a PIC basically two years after he signed an order.

MR. BUSHARDT: Right.

MR. LIVINGSTON: Make a motion to deny.

MR. BUSHARDT: What we can do here -- I got a motion and a second. Do I have a second?

MS. RUSSELL: Second.

MR. BUSHARDT: What we can do, we can either deny or we can either delay it until the next meeting and let him tell his side of the story.

MR. GRIGG: Now that you got a motion on the table, you got to address that first.

MR. BUSHARDT: Okay. Any discussion? All in favor of denying the request raise your right hand. Motion passes, request is denied.

MR. BUSHARDT: Old Business Board of Pharmacy Investigations.

MR. LIVINGSTON: Mr. Chair, I think there was some discussion as to how the investigations were going to be handled in this department and part of those discussions was with two of our prior Board members. I make a motion that we go into executive session with those previous Board members and our attorney and get some legal advice.

MR. BUSHARDT: Do I hear a second?

MR. ROSE: Second.

MR. BUSHARDT: We'll go in executive session.

(Executive Session.)

MR. BUSHARDT: We're back in session. Do I hear a motion to come back in session?

MR. LIVINGSTON: I make a motion we come back in from executive session.

MR. HUBBARD: Second.

MR. BUSHARDT: Discussion? All in favor raise your right hand. Opposed likewise. We're back in session. It may be said that there were no motions made or votes taken while we were in executive session.

MR. LIVINGSTON: Mr. Chairman, because the Board of Pharmacy has had some concerns with how investigations have been handled by the LLR staff, I want to put in the form of a motion a request to LLR of some things that I

would like to see taking place around here so that we can comply with statute. There are actually three specific requests that I have written here so if you would indulge me.

In regards to licenses, permits and registrations issued by the Board of Pharmacy when a disciplinary issue occurs including diversion that those issues be immediately reposted to the Board of Pharmacy for logging into a data base within a specified period of time determined by an administrator of the Board to be assigned to a pharmacist slash or investigator slash inspector to determine the best course of investigation using the resources within the LLR agency.

Second request that I have is we request that the administrator divide the State into regions for the purpose of efficient management of the region by pharmacist inspector slash investigator and be trained as necessary to accomplish investigations and inspections within that region. We want our State broken up into different regions and our inspectors also be investigators for that region.

Then the third request is that the agency provide a resource staff within the Board of Pharmacy to assist with training and assistance in inspections slash investigations and cross train them. We want a person or

staff members to be assigned to the Board to help us to make sure that we train our staff in both investigations and inspections so that they can adequately do both jobs.

MR. GRIGG: Just to clarify. That is in the form of a motion, three-part motion?

MR. LIVINGSTON: Right, three-part motion.

MR. ROSE: I second that.

MR. BUSHARDT: Any discussion? All in favor of the motion signify by raising your right hand.

MR. LIVINGSTON: I would like to ask that the excerpt of this part of the minutes be prepared and delivered to the administrator of LLR or the director of LLR and also the legal staff here at LLR as soon as possible.

MS. BUNDRICK: I do have one question. You said licenses, permits?

MR. LIVINGSTON: And registrations. Anything that we --

MS. BUNDRICK: You need to put certificates also then.

MR. LIVINGSTON: I would like to amend to include certificates.

MR. ROSE: That's okay with me.

MR. BUSHARDT: Second on that.

MS. LONG: Second.

MR. BUSHARDT: We'll vote again. Any further discussion? All in favor signify by raising your right hand. Opposed likewise. Motion as amended passes.

NEW BUSINESS:

UNIVERSITY COMPOUNDING PHARMACY

MR. BUSHARDT: Request approval of non-resident pharmacy application, University Compounding Pharmacy John Grasela. Let's see. On your application you had a couple of yes answers. Would you like to say something about those yes answers?

Thereupon,

JOHN GRASELA,

being first duly sworn to tell the truth, the whole truth and nothing but the truth, as hereinafter certified, testified as follows:

MR. GRASELA: About 20 years ago I contacted hepatitis C and I was under the care of a physician at Scripts Institute in San Diego and I was on Interferon and what was prescribed for me was failing and I was starting to get liver damage and he suggested I go on Ribavirin which was not available at the time and I could not get into a study that was going on in San Diego. They told me I could get it in Mexico which I did. Then I also found out I could buy the chemical and compound it, the medication, and took a verbal order from him. What happened is I saved my receipts for six months, turned them into the insurance company, they wouldn't pay for it, that it wasn't a FDA approved drug. They turned me into the

Board of Pharmacy. Board of Pharmacy came for an inspection, asked the doctor whether he prescribed it and the doctor said no even though it was in his chart with all of his changes. At that time they were receiving grant money from Shearings (phonetic) so he didn't want to bite the hand that feeds him. So as a result I got a violation of taking an antiviral drug without a prescription.

MR. BUSHARDT: That was the only thing that --

MR. GRASELA: That's the only thing I've ever had. And that was back like 10-15 years ago.

MR. ROSE: You said you compound for clients all over the United States, is that correct?

MR. GRASELA: Only states that we have -- no, not physicians, for patients only unless the physician is administering the drug in the office. I do not resell to physician offices. Definitely no.

MR. BUSHARDT: Have we had anybody to look at this particular information that has been sent to us?

MS. SANDERS: Yes, I have reviewed it. I guess the first thing that I would bring forth as I was doing the reviewing is Joseph Grasela is noted as the pharmacist-in-charge, and you'll note, I think it's in your packet, there's a letter that states that he lives in Nevada 250 miles away with a different address.

MR. GRASELA: No, that's me.

MR. LIVINGSTON: Joseph is a brother I assume?

MR. GRASELA: Yes, he's my brother. He lives in San Diego a mile from the pharmacy. I live in Nevada.

MR. LIVINGSTON: What you are referring to is another inspection that has you listed as the PIC and that particular inspection is 7/15/10. In the letter that you wrote us you tell us basically that you have had no involvement in that particular pharmacy and have not filled a prescription in over ten years and that you're only a passive stockholder, but yet you're listed on an inspection report as the pharmacist-in-charge and also you're listed on another list of pharmacists that are employed by this particular company.

MR. GRASELA: I am not the pharmacist-in-charge. You're talking about the State of California inspection record?

MR. LIVINGSTON: Yes.

MR. GRASELA: There must be an error on their part. What happens is people call me Joe and John and you get to know inspectors and people in general and I just answer yes to Joe and I think that's probably what happened, but I've never been the -- Joe has been the pharmacist-in-charge ever since the pharmacy's inception for 20 years.

MR. LIVINGSTON: I think they have you listed and

your license number and also in the list that you gave us of the pharmacist's names and their license numbers that you included in your package. You have John, Carol Grasela with your license number 32430, is that you?

MR. GRASELA: That's correct.

MR. LIVINGSTON: You have it listed on here, but you're saying you're only a passive stockholder?

MR. GRASELA: I do not fill prescriptions. All I do is come to meetings.

MS. SANDERS: The main contact when it came to policies and procedure, et cetera, he told me he was like a supervisor was a Thomas Freeman at that pharmacy. He is the one who has mainly provided the information that I requested. I believe also in your packet there is a portion from their web site about the advertising and also about the prescription that's online that I felt that the Board Members would want to look to in conjunction with 40-43-86-CC2E about the advertising of compounded medications.

MR. GRASELA: May I address that?

MR. BUSHARDT: Certainly.

MR. GRASELA: In our pharmacy software you have the ability, you know, through your IDR, you're ordering refills, but not for ordering any new prescriptions. It's only for physicians to look at patient's profile or for

patients to reorder their prescription drugs, but never would I process a new prescription over the internet. That would be crazy.

MS. SANDERS: Also I don't have a full understanding about their beyond use dating versus their expiration dating products since they are doing testosterone and Metrodin progesterone, capulate (phonetic), maybe you could give us the full process on that.

MR. GRASELA: What we do is take random samples, about 24 random samples a month, different drugs, whether it's Estradiol or Vias (phonetic) or Ketoprofen and they're sent to Eagle Labs in Colorado for quantitative testing. Also we are certified by P-Cap which requires testing. They just were in for our relicensure here about a month or two ago. We do a lot of beyond use dating. We spend probably about $4,000 a month for beyond use dating testing and I got a binder this thick that we use and the only time we put a beyond use dating that is longer than what is recommended in USP is only if we can prove that it's beyond that date.

MS. SANDERS: The other question would be how do you track back, I'm looking at prescription labels that were provided to me, how do you track back the compound that is made to the actual prescription?

MR. GRASELA: We use PCCA's PK software and in there each ingredient is listed, each lot number is listed, everything is bar coded and it's very traceable through the whole process from the time it comes off the shelf as a pure product to the final entity and if anyone who has that software, you're nodding your head there, I'm assuming...

MR. ROSE: I've seen that. Actually it's -- it also includes when you weigh out the powder it tells you how many grams or whatever powder you use.

MR. GRASELA: The nice thing about it is it almost prevents 99 percent of the errors, because if the stock is not bar coded correctly, the scale won't, it will tell you that you haven't weighed the correct amount, you don't have the right ingredient and then the capsules when they're tested -- it's amazing how it's eliminated errors with the PK software.

MS. SANDERS: I understand that part. I'm asking as to that if you make batch number 1234 of product ABC and you make 20 of them and you dispense 5 to Mr. Brown, how do you track the 5 out of that 20 went to Mr. Brown and 5 went to Ms. Smith and 5 went to --

MR. GRASELA: By their prescriptions. So you can just do a drug usage report for a time period. So let's say for the last month you want to find out you could do a drug usage report by typing in that drug, it will tell you

every prescription, whatever quantity, whatever lot number that's assigned to it.

MS. SANDERS: It's just the labels weren't given a lot number so I couldn't tell how it was being traced back.

MR. GRASELA: It's all in the software.

MR. LIVINGSTON: Couple other questions. You said this physician had written this Ribavirin, but in this complaint we have an excerpt that came from a physician's record and it says in review the patient, you said that he wrote that prescription for you?

MR. GRASELA: What I did is I took a verbal order from him and he noted it in the chart on three different occasions because he had to adjust the dose.

MR. LIVINGSTON: He has in his records or in this accusation I guess, formal accusation, it says in review the patient is a compounding pharmacist that has the ability to access his own medications and he creates his own regimented therapy. Although I do not condone this current treatment, his combination therapy, I have agreed to monitor his laboratory tests and at the end warn him about possible adverse effects of the treatments.

MR. GRASELA: Yeah, that was his response after the Board of Pharmacy inspector visited him and like I said Scripps Institute is a big research center and there's a

lot of money coming from Shearing due to studies and he's not going to bite the hand that feeds him, but in the chart, I mean he gave me a verbal order, he made adjustment in dosing. So as a pharmacist I take a verbal order and I transcribe it. And again this is an antiviral agent. We're not talking about narcotics here or trafficking. I was on the verge of very close to dying and I made sure that I took that medication in a comprehensive basis and I was under his direct supervision with monthly visits to monitor. There's no drug abuse here on my part. I'll urine test any time you want.

MR. LIVINGSTON: That's the only issue that you've had against you or --

MR. GRASELA: Correct.

MR. LIVINGSTON: What about the -- I have an accusation here again that speaks to unsupervised pharmacy technician and staff in the pharmacy while there was no pharmacist there.

MR. GRASELA: That's not mine. Oh, what happened was in one of our pharmacies, a pharmacist did not show up for work that day. The technician who had the key which was supposed to be kept in an envelope opened the door to call the supervisor to let them know that the pharmacist wasn't there and lo and behold guess who walks in at that moment, Board of Pharmacy inspector for a routine

inspection, but that was not anything to do with -- you asked me about anything having to do with me and that did not deal with me.

MR. LIVINGSTON: But that was a pharmacy that you own.

MR. GRASELA: That we own.

MR. LIVINGSTON: So in essence it does have to do with you.

MR. GRASELA: I understand that, but even with CVS you can't control what all your pharmacists do. Ultimately you are responsible, but you can't sit there and baby sit them with whatever action you're taking. You just have to deal with the issue when it arises and do the correct thing.

MR. ROSE: Is that the one that was withdrawn? There was an accusation that was withdrawn. Is that the one you are talking about? State of California withdrew an accusation against Medical Center Pharmacy.

MR. GRASELA: Medical Center, right.

MR. ROSE: They didn't actually have any kind of --

MR. GRASELA: No, they withdrew that, because what happened was they were holding our licensure up, because our lease was expiring and we wanted to move to a new location and so they held that up and at that point

instead of me litigating it, it was easier for me to say I admit guilt and they would issue our pharmacy license and they just dropped the charges against that pharmacy, but that pharmacy has nothing to do with University Compounding Pharmacy. That pharmacy was owned 20 years ago.

MR. LIVINGSTON: What kind of products do you provide or will provide?

MR. GRASELA: The biggest thing is bio-identical hormone replacement. My primary job is education for physicians. Like tomorrow I'm going to be in Dallas. We have 384 physicians who are attending our three-day seminar on bio-identical hormone. We bring in some of the best speakers in the world and I moderate the seminars plus give a talk and one of the things I do in my talk is I emphasize the legality of what's involved in compounding, because there's so much problems with people reselling it. I make sure that everybody understands this and there are hormone issues. So I primarily do the teaching and most of our business is bio-identical hormone replacement, because we have taken the lead in educating physicians.

MR. BUSHARDT: Any other questions?

MR. LIVINGSTON: As far as marketing to our, I shouldn't say marketing, you will be hopefully I guess trying to get in contact with physicians in South Carolina?

MR. GRASELA: No, I don't have to do that. What

happens is by having these seminars, you got 384 doctors, people come from all over the United States and what we're about is relationship building. If you go out of your way to teach a physician the right way and you have a health desk where two pharmacists are there to answer questions for physicians and guide them in how to prescribe properly, you build a relationship. It's not about price. It's not about delivery. It's about building relationships. If you build a relationship with a doctor who can trust you, you're likely to get the business as opposed to going somewhere else. It's one of the things I emphasize. Go visit the pharmacy. Make sure they're Vcap certified, make sure they're doing things the right way. If you don't have the time to do it, you better make sure you build a relationship with the physician and at the end of three days that they spend with me, they have confidence in my ability and pharmacist's ability to take care of their patients, but I don't have to do any mailings and soliciting of physicians. We have physicians coming to us.

MR. BUSHARDT: Any other questions? Mr. Grasela, what we will do is we will hear all of New Business and then we will go into executive session. We can tell you later on today our decision.

MR. GRASELA: Do I have to be here, because I got a flight.

MR. BUSHARDT: No, you don't have to be here. You will be notified today or --

MR. GRASELA: That's okay.

MR. GRIGG: We will draft something in writing and it will be a couple of days.

MR. BUSHARDT: It will be coming shortly.

MR. GRASELA: Thank you very much.

MR. BUSHARDT: Request approval of non-resident pharmacy application Hartley Medical Center Pharmacy, Incorporated, William Stuart.

Thereupon,

WILLIAM STUART,

being first duly sworn to tell the truth, the whole truth and nothing but the truth, as hereinafter certified, testified as follows:

MR. BUSHARDT: Mr. Stuart, if you would tell us a little bit about your business and your request.

MR. STUART: Mr. Chairman and Members of the Board, I do appreciate this opportunity. I am a pharmacist. We've been established in Long Beach, California, since 1979 and at various practices. Currently at this time I'm primarily a sterile compounding pharmacist. My practice and scope is pain management and head movement disorders. We compound and dispense medications pursuant to prescriptions for patients suffering from chronic pain. Medications primarily are administered through the intrathecal route by implantable pumps. We do some epidural therapies for hospital clients. As I said we've been established since '79. It's a family business. My father was a pharmacist and I followed in his foot steps. We have a dedicated program and we've been

involved with this kind of practice for about 14 years, sterile compounding for pain management. We are in the process of trying to license in all the states that require licensure to comply with regulations. We have no business in this state at this time. I submitted an application and we answered yes to one question regarding a violation of statute and so I would like to kind of review those. I'll go line by line. Our first involved, we have a situation where we were cited by the State of California for dispensing medication beyond their expiration date and this medication, it was the excipients associated with compounding a topical preparation, specifically polysorbate 80 and then DSL and lavender oil and there was a complaint filed and the investigation, the investigator determined and actually observed that we utilized excipients beyond the manufacturer's recommendation or expiration date in the container. Because of my background and understanding of chemicals, I considered the excipients to be a minor factor not affecting the final product or the finished product and the clinical effect of this topical preparation. We contested this particular charge and we submitted these particular excipients to an outside lab for verification and the results a year after the expiration date on this showed both products to be within USP specifications. We presented this information to the California Board of

Pharmacy and they gave it a massive ten minutes and said no and they still issued the fine and so we decided not to take the issue any further. This topical preparation was anesthetic. It was made for a laser treatment center within a hospital, UC Davis, and it had an adverse reaction with a patient who had taken the topical preparation and introduced it into her eye unbeknownst to the health care worker supervising her and subsequently filed a complaint. The complaint was filed on behalf of the hospital. So in this situation it was my judgment that I considered the excipients to be acceptable and I had certain chemicals that I worked with over time and beyond the expiration date and we have submitted them in for quantitative and qualitative analysis and have found them to be with USP specification. In this particular case I chose not to try to overturn this any farther and I moved forward. Any questions on this?

MR. BUSHARDT: That's the only thing that you got against you there?

MR. STUART: On this situation. I have two other complaints. I'll just roll over to the next. We have a situation that occurred, also with a similar client, UC Davis, where we had an intrathecal preparation that was compounded and dispensed and administered to this patient. Subsequently was suffering from an adverse reaction, the

medication was withdrawn, submitted to a lab for quantitative analysis and came out as specifications. We reviewed the matter, both internally and I went to US Davis to speak with administration in the pain management department. We didn't have an answer for this one. All the documentation was in order, staff involved, everybody had been tested. This was not a new thing. It was an aberration so it seems. And then about a year later a similar compounding preparation was dispensed to the same patient and also an adverse reaction and this patient, we removed the solution. Quantitative analysis showed it outside specifications, outside the prescribed specifications. To this date I have no understanding of how this occurred and all the documentation orders, compounding documents, there's nothing that says technician error, pharmacist calculation error. One of those darn things is that I dispense roughly about 30,000 medications of this type of nature and so the same mistake happens to the same patient 30,000 prescriptions later, it does kind of boggle my mind. I don't have an answer for it. We changed procedures. We modified our techniques and we accelerated protocols and programs to prevent this from happening again. Can I tell you a little bit about that?

MR. BUSHARDT: Sure.

MR. STUART: In our particular pharmacy practice,

the prescriptions are received. They're entered into a computer system. We basically comprise a compounding document. It's quite extensive to review the calculations, everything that can be done to compound as accurately is then checked by a second individual and then is introduced into the compounding room, the sterile preparation area of which it is then reviewed by a third person and then a fourth person will then review calculations, label, finished product. So a technician or pharmacist may compound this and those documents are still checked. So after this occurred, I looked in the mirror and said how can we change this one more time. So we continued the same process of prescription received, compounding documents now done by computer, it's not done by hand anymore, those are then rechecked by a second person and then a third person will then stage, which means I take all the vials or whatever, excipients or whatever, drug additives I will use to compound that preparation and then we will stage everything to specification of the prescription meaning they will draw back on the syringes, place that syringe or whatever instrument is used for the additives for that and primarily I work with sterile compounding we use a syringe, if the prescription requires two cc's of a drug, it will be drawn up, placed next to the vial, each additive like a TPM formulation back in the days, everything gets cross checked

between that prescription and the compounding document and what the technician and/or pharmacist has done and everything is checked by a set individual prior to the final compilation of that prescription. The system seems to be working, because we haven't had a problem like that since this time. So I look at this situation. We were cited and fined. We changed our policies and procedures and at this time we have not had a repeat accident. This situation was also an unusual event considering that we compounded this type of preparation since 1996. Very unusual.

The last item was with the State of Colorado which seems I've had a string of these, been cited and fined, something that's not in my business plan. So in this situation we were delayed delinquent in submitting our prescription drug monitoring data to the State of Colorado. Every state has unique procedures, some require monthly, some require bimonthly. The State of Colorado the first and 15th data needs to be submitted, 16th and 25th. The individual who submits the data was ill, submitted it late and they cited us and fined us.

MR. BUSHARDT: That was a clerical error?

MR. STUART: Yes. An expensive clerical error.

MS. BUNDRICK: We do see a lot of that from Colorado.

MR. STUART: You probably have similar questions for me regarding our procedures.

MR. LIVINGSTON: When you had the solution that turned up so potent, were you using PK software or something of that nature?

MR. STUART: No.

MR. LIVINGSTON: Manual records?

MR. STUART: Yes.

MR. LIVINGSTON: Do you use PK software now?

MR. STUART: I don't. I don't trust it. I use Access Database and we actually have a programmer that does now all of our calculations. So it's similar to what other companies have done. Pk software, I don't think it's quite designed to sterile compounding.

MR. LIVINGSTON: I looked at some of your attachments and there's a formula you submitted to us. Do you have all that information?

MR. STUART: I do not.

MR. LIVINGSTON: There's one particular, it looks like compounding record, that has Baclofen, Guanidine, Morphine.

MR. STUART: That's a template. It's more or less a compounding document that is computer generated and I want to say this is how the format comes out, milligrams or micrograms and it automatically calculates our volumes

based on our batch solution.

MR. LIVINGSTON: You have on here and I noticed in one of your policies and procedures it says reconstitute with normal saline or sterile water injection. How do you determine which one you are going to use?

MR. STUART: Our policies and procedures instruct certain drugs can be mixed with normal saline to remain isotonic, but then other solutions can exceed, let's say Bupivacaine, exceeding 29 milligrams per ml, we will convert to sterile water.

MR. LIVINGSTON: So you never use a combination of the two to adjust isotonicity?

MR. STUART: I would like you to repeat that question.

MR. LIVINGSTON: You either use one or the other? You don't use a combination of the two?

MR. STUART: No, I do not. Correct.

MR. LIVINGSTON: Why not?

MR. STUART: These infusions are actually micro infusions. They're like 300 microliters a day. So if you talk about IV therapy, people are getting 100 cc's an hour, isotonicity is a fair amount. Regarding spinal infusions in its final state holds roughly 120 milliliters and when you're infusing 0.2 to 0.3 cc's in 24 hours, isotonicity would penetrate very little to the tissues. It's somewhat

not a major consideration versus parenteral or even intramuscular.

MR. LIVINGSTON: You're right, but you're familiar with keratin granulomas?

MR. STUART: I am.

MR. LIVINGSTON: And some data that would possibly support...

MR. STUART: The data doesn't support that actually.

MR. LIVINGSTON: There's some data that leans you to believe that isotonicity could cause the granuloma.

MR. STUART: No. If I may? I'm actually on a committee, Polyanalgesic Consensus Committee, which set up guidelines. I'm the only pharmacist on this committee. They published their guidelines in 2003, '07. New ones are coming out in November of '11. Granulomas are more considered to be chemical rather than isotonicity. I have not seen any data regarding that and if you have seen that --

MR. LIVINGSTON: In those guidelines you discussed, it has concentration guidelines in it.

MR. STUART: Yes, they do. Concentration of other chemicals. Actually there are studies done by like Morphine sulfate 15 milligrams per ml has a higher preponderance of granuloma formation than say Hydromorphone

or Fentanyl. More concentration with it even with beagles as well as pigs. Tony Axon (phonetic), University of San Diego, he specifically found that if you use 25 milligrams or more per amount, working safely, you will have a greater preponderance of granuloma formation in a shorter period of time than something less than that. And they also compared like ten milligrams per ml like giving 25 milligrams per day and found granulomas, and not only the concentration, but it was the dose. Hydromorphone not so much, Baclofen, Fentanyl. Baclofen I've seen a couple both with commercial product as well as compounding.

MR. LIVINGSTON: I guess my question to you really is, why not adjust if you can? Why not make an isotone?

MR. STUART: I'll research that. I don't have enough compelling for that because of the nature of the route.

MR. BUSHARDT: Any other questions? Mr. Stuart, we will go into executive session after we've gone over all the new business and we will make a decision and we will let you know within a day or two.

MR. STUART: I do appreciate your time. Have a good day. Thank you.

MR. BUSHARDT: Request approval of non-resident wholesale/distributor/manufacturer Medisca, Incorporated, Vanessa Verni and Anna DiNezza.

MR. GRIGG: Mr. Chairman, if I may. I understand Mr. Livingston and Ms. Long may be listed as customers for this company.

MS. LONG: That's correct. We are current customers.

MR. GRIGG: Mr. Livingston, you are not?

MR. LIVINGSTON: I am not, but I am on the list.

MR. GRIGG: Is there any reason why you all could not proceed in this matter in a fair and impartial manner?

MS. LONG: No.

MR. LIVINGSTON: No.

MR. GRIGG: Ms. Bundrick or you all, do you have any reason why you would not want them to remain on the Board to discuss this?

MS. VERNI: No.

MR. BUSHARDT: Tell us a little bit about your company and why you are here today.

MS. VERNI: I'm Vanessa Verni. Medisca has active and non-active pharmaceutical ingredients. We sell to compounding pharmacies within the US.

MR. BUSHARDT: I'm sorry, I got side-tracked.

You need to be sworn in.

Thereupon,

VANESSA VERNI AND ANNA DINEZZA,

being first duly sworn to tell the truth, the whole truth and nothing but the truth, as hereinafter certified, testified as follows:

MS. VERNI: As I was saying the reason we are here we applied for a non-resident application wholesale/distributor from our Texas facility and we answered yes to some of the disciplinary action questions. If you take a look at the disciplinary action report that we provided on the second page. It is entitled disciplinary actions and corrective action. It lists the disciplinary actions as well as the corrective action that we have implemented since then. The first one was actually in Florida in 2007. The violation was that we sold to a person not authorized to purchase. So the person that we sold to did not have the valid pharmacy license. We paid a fine of $250 to settle the agreement. And since then Medisca now only ships to clients that are authorized to purchase our products. So you must have a valid pharmacy license to purchase from Medisca.

The second violation was that Medisca shipped prescription drug to a client in Florida without holding a valid out of state prescription drug wholesaler permit.

And also did not provide a pedigree paper. Medisca paid a fine of $1500 to settle the agreement. The license was not valid during that time, because we did not have a designated representative. The person who was acting as a designated representative left the company suddenly so our license was invalid and an order was inadvertently shipped at that time. At this time now we have two designated representatives in each of our facilities as a back up in case.

MR. BUSHARDT: Your Florida license was okay?

MS. VERNI: Yes. We also implemented the pedigree procedure. It's attached to the corrective action report. So obviously there is a pedigree that's provided with each shipment to Florida.

The next violations were for a DEA inspection that occurred in 2007 at our Plattsburgh facility. There was a fine of $350,000 that was paid to settle the agreement and during the entire time the registration remained active. So the first disciplinary action that's detailed in your report is encapsulated machine. We implemented the procedure where each encapsulating machine is reported to the DEA prior to shipping to the customer. The second one is the failure to report suspicious order activity. So we have a suspicious order monitoring program where we actually have a third party, third-party, a company that

actually audits our customers. They are ex-DEA inspectors themselves and that provides us with more information on our customer. We get to know our customer and understand their business, understand what they are doing with Medisca's material that we sell to them. If, of course, following the audits from the third party, we're not comfortable with this customer, then we do not ship to them. We have a do not ship list. Once a customer is on there, they stay on there forever and we report them to DEA for suspicious activity. So at that time in 2007 we had 12 and now we are in the 20s for customers that we no longer ship to, because we do not feel comfortable doing business with them.

MR. BUSHARDT: This was just a routine DEA inspection?

MS. VERNI: That's right. The third violation was a failure to include in its initial controlled substance inventory and samples and waste material in the monthly and biannual inventory counts. So we obviously updated our procedures to include all controlled substances inventory in our cycle counts.

And finally the last violation was failure of its manufacturing records to set forth actual controlled substances repackaging yields. So now on our actual packaging master it indicates the actual yield versus the

theoretical one. So this was during the 2007 inspection, but it only actually got completed in 2010. Like I said our DEA registration remained active during the whole time.

MR. BUSHARDT: All these are cleared up?

MS. VERNI: Yes. We have been inspected by the DEA since then as well as well as the FDA every year since then and we have had no 43s in our last three inspections. So we definitely cleaned up our procedures.

MR. LIVINGSTON: These violations occurred in your New York facility?

MS. VERNI: That's correct. The Texas facility is rather new and that's why we are applying for a new license.

MR. LIVINGSTON: Your New York facility where these violations occurred, do you currently hold a South Carolina permit?

MS. VERNI: Yes.

MR. LIVINGSTON: You're just asking for a permit for a new facility?

MS. VERNI: That's correct.

MR. BUSHARDT: Any questions?

MR. ROSE: I wonder why their New York permit didn't have a question answer yes when they renewed it.

MR. LIVINGSTON: Can you all look at that?

MS. BUNDRICK: We can check that.

MR. LIVINGSTON: Our question is this. You should have renewed your permit for your New York facility just recently.

MS. VERNI: Hm-hmm.

MR. LIVINGSTON: And there's questions on there that are identical to the questions that you answered for this Texas facility.

MS. VERNI: Yes.

MR. LIVINGSTON: We're wondering why there wasn't a yes answer on that application for renewal for your New York facility.

MS. VERNI: There should have been.

MR. LIVINGSTON: Also do you have a third facility somewhere?

MS. VERNI: In Las Vegas.

MR. LIVINGSTON: Do you have a South Carolina permit for that facility?

MS. VERNI: Yes, we do.

MR. LIVINGSTON: That one should have been yes as well.

MS. VERNI: They should all have the same information.

MR. ROSE: You do sell chemicals plus you also sell compounding devices too, is that correct?

MS. VERNI: Devices, yes, but not compounding products.

MR. ROSE: Just chemicals and devices?

MS. VERNI: The raw material, exactly. Lab devices really.

MR. ROSE: Encapsulating...

MS. VERNI: Encapsulating machines as well.

MR. ROSE: Tablet machines?

MS. VERNI: No.

MR. ROSE: Just mainly for capsules?

MS. VERNI: That's correct.

MR. ROSE: No suppository molds or anything like that?

MS. DINEZZA: We have molds, we have spatulas, beakers, cylinders, all compounding devices.

MR. BUSHARDT: Any other questions?

MR. LIVINGSTON: We need to find out about those other applications.

MR. ROSE: We can do that in the interim.

MR. LIVINGSTON: Yes.

MR. BUSHARDT: We will go into executive session later on today and we will check those others just to make sure and then we will notify you within the next two or three days.

MS. VERNI: Thank you.

DISPENSING SOLUTIONS, INC.

MR. BUSHARDT: Request approval of Non-Resident Wholesale/Distributor/Manufacturer Dispensing Solutions, Incorporated, Rodney Bias. Be sworn in first.

Thereupon,

RODNEY BIAS,

being first duly sworn to tell the truth, the whole truth and nothing but the truth, as hereinafter certified, testified as follows:

MR. BUSHARDT: Tell us a little bit about what you do and why you are here today.

MR. BIAS: Yes, sir. I work for PSS World Medical. We are a pharmaceutical distributor to physician industry and in January of this year we acquired a company called Dispensing Solutions, Incorporated, DSI, and at the time we had to submit applications due to change of ownership one including South Carolina. At the time we acquired that company we were aware of a pending issue they had in the State of Florida which was intended to deny their registration and so we marked yes on our application. The purpose for the intent to deny the application was due to pedigree, alleged pedigree violations in the State of Florida. We were confident that we could correct those issues and address that with the State of Florida at the time of acquisition and have done so since. I actually

brought a copy of the final order from the State of Florida if you would like a copy to be entered into the application process. It shows the issue as being resolved in the State of Florida and a license has been issued since we acquired them. We didn't have it at the time of the application is why it wasn't. The reason it wasn't submitted with the application is the matter had not been resolved at the time of the application. It was still pending.

MR. BUSHARDT: It's been resolved now?

MR. BIAS: Yes, sir. After the acquisition we implemented pedigree procedures consistent with our company, with the parent company I should say, PSS World Medical, submitted those enhancements to the State of Florida for review and they agreed and they have resolved the issue. There was an administrative fee paid. But all issues were resolved which is defined in the settlement.

MR. ROSE: You're only in one location?

MR. BIAS: PSS World Medical is a national company. We have multiple locations. The company we purchased, DSI, is in one location. It's in Santa Anna, California. They repackage products for physician offices for dispensing purposes. Yes, sir, it's in only one location.

MR. LIVINGSTON: It's repackaging for physician dispensing?

MR. BIAS: Yes, sir. That's what's Dispensing Solutions does. They take products that come in various sizes and repackage them into smaller dosage units that physicians can then dispense in office.

MR. ROSE: Is the facility VAWD approved?

MR. BIAS: It is VAWD approved as well, yes, sir.

MR. ROSE: Still VAWD approved?

MR. BIAS: Yes, sir.

MR. LIVINGSTON: Does Dispensing Solutions, I don't know what the right language is for this, but do they submit applications to FDA for a new NDC number for the products they resubmit?

MR. BIAS: Yes, sir. We have a labeling code, yes, sir.

MR. LIVINGSTON: You create a new NDC number with a new AWP?

MR. BIAS: Yes, sir. That's submitted. That's not my specialty. I can't talk about the AWP and how that works. I can tell you from the regulatory side. I'm in charge of regulatory compliance. I don't know how that works to be honest with you. But, yes, we do have a labeling code, we have a new NDC for every product that is repackaged.

MR. BUSHARDT: Any questions? Mr. Bias, we will address this when we address the others in executive

session later on today. You will be notified in the next two or three days.

MR. BIAS: Thank you, sir. Have a good day.

JOSEPH KNISLEY

MR. BUSHARDT: Requests approval of reciprocity application Joseph Knisley.

Thereupon,

JOSEPH KNISLEY,

being first duly sworn to tell the truth, the whole truth and nothing but the truth, as hereinafter certified, testified as follows:

MR. BUSHARDT: Mr. Knisley, would you like to tell us why you are here today?

MR. KNISLEY: I have applied for reciprocity to the State of South Carolina. I have been a pharmacist for 34 years. I'm part of two pharmacies in Johnson City, Tennessee, for the better part of 30 years. My wife and I love South Carolina. We love to travel down here. We love the beach area and something I've always wanted to do is to have a license in South Carolina so that possibly I could practice down in the beach area if we ever decide to semi-retire or to move down here and so I went through that process and I was informed that because we had one disciplinary action that I needed to appear before you to explain that. That disciplinary action was in '09. As the pharmacist-in-charge we had pharmacy techs. They were certified pharmacy techs, but their state board license had expired. We didn't catch it. I didn't catch it and one

had been mailed to his address. He had moved and those were not forwarded and the other had just not applied. So we corrected that. We got those both in date. I paid the disciplinary fine and as far as I know the matter was closed.

MR. BUSHARDT: That seems to be a problem that we talked about earlier today. Does anybody have any questions of Mr. Knisley?

MR. LIVINGSTON: I move that we approve his request.

MR. HUBBARD: Second.

MR. BUSHARDT: We have a motion to approve and a second. Any discussion? This is for the application process, right?

MS. BUNDRICK: Reciprocity.

MR. BUSHARDT: Reciprocity application process.

MS. BUNDRICK: He's met all the requirements.

MR. BUSHARDT: All in favor signify by raising your right hand. Opposed the same way. Approved.

MR. KNISLEY: Thank you very much.

MR. BUSHARDT: Request Approval of Pharmacy Technician Registration Application, Waletha Short.

MS. CROUCH: I'll check outside.

(Break in hearing.)

MR. BUSHARDT: Ms. Short is not present. Do we want to carry on without her or delay to the next meeting?

MR. LIVINGSTON: I make a motion that we defer it.

MR. HUBBARD: Second.

MR. BUSHARDT: Discussion? All those in favor signify by raising your right hand. Motion passes.

(This case was heard on September 15, 2011.)

MR. HANKS: Dean, we could put up an agreement to relinquish if you all could hear us out of order. The Respondent has to appear before a judge and he just wants to relinquish his license, 2010-104.

MR. BUSHARDT: That's fine.

MR. HANKS: Again in this case this individual, Mr. Chairman, he diverted some controlled substances for his use and he also sold some out on the street and the OIE conducted the investigation and in the midst of the OIE investigation he signed this document with the OIE Department and we wanted to present it in front of you to see if you would agree to allow him to exit the practice of pharmacy. He agrees he will not be licensed as a pharmacist at any point in the future in this State.

MR. ROSE: Move to accept the agreement.

MS. LONG: Second.

MR. BUSHARDT: Discussion? All in favor signify by raising your right hand. Opposed likewise. Passes.

MR. HANKS: Thank you, sir.

BURKOW DEVELOPMENT, INC. D/B/A AMERICAN PHARMACY SOLUTIONS

MR. BUSHARDT: Request approval of non-resident pharmacy permit application Burkow Development, Incorporated d/b/a American Pharmacy Solutions, Darian Chandler. You need to be sworn in.

Thereupon,

DARIAN CHANDLER,

being first duly sworn to tell the truth, the whole truth and nothing but the truth, as hereinafter certified, testified as follows:

MR. BUSHARDT: Mr. Chandler, would you like to explain why you are here today?

MR. CHANDLER: Yes, I'm back before the Board. We made an application to be licensed here as a non-resident two sessions ago, I guess in March. I'm not remembering. But we had not sent in the new requirements for the sterile compounding with the stuff to Ms. Sanders and so she's got that now. I think that's the main reason I'm back before you here today.

MR. BUSHARDT: Did you bring that with you or did you send it in earlier?

MR. CHANDLER: I sent it. We sent it in. We tried to get it in before the last one, but we didn't get it in time for her to review it so we just had to wait

until the next session.

MS. SANDERS: I want him to remind you what products he ships in.

MR. CHANDLER: Yes. We are a compounding pharmacy. We're just like the gentleman that came in here first. We use PCCA, we use their software, statistics on that. We do no controls whatsoever at all. We don't have a DEA provider. Just a specialty for veterinarians, we do some veterinarian fertilization drugs. We also do Tri-Mix injections for ED patients. Metrodin progesterone for OB/GYN. We do dental gels and such. We also do ketoprofens and creams for the podiatry division. And do some HCG for weight loss and then do injectables as well in all those categories.

MR. BUSHARDT: You don't have anything against you, you just didn't send in the proper, all the proper documentations?

MR. LIVINGSTON: The first time he answered yes.

MS. SANDERS: The first time he came.

MR. CHANDLER: Yes, the first time I addressed it. I can address those again if I need to.

MR. BUSHARDT: You need to refresh our memory.

MR. CHANDLER: The main owner Steve Burkow back when he first started his mom and pop store, he did not do a counseling on a patient and was presented before the

Board and a disciplinary action on there. Pharmacist-in-charge Wayne Waits had a, was owner of his own pharmacy in Kansas. And I apologize for not having these dates in front of me.

MR. ROSE: 1993.

MR. CHANDLER: Yes, 1993. He had his pharmacy and his wife was his technician. He had to go outside the pharmacy, across the street, to get something for his computer from his testimony and in that time his wife had filled a prescription for one of their patients that came in without him being there. He was brought before the Board on that and now I will, since being here last time, we were inspected and there's nothing on our record showing this, but we had an inspection where I put a -- we had a relief pharmacist come in and she was supposed to be there, she was not there. I had the pharmacy open, but I had a sign on the front door stating we were closed. Had called Steve Burkow who was also another pharmacies to get him to come over there which is the owner, he showed up within 30 minutes of the inspector being there. The inspector came and then 30 minutes later Steve was there. We were investigated by the State Board of Florida and we were found with no fault there, because we had nothing going on at that time. Since then we made -- entrance to our pharmacy is the pharmacy is a situation where we didn't

have a way to cut off the prescription room and everything from there. Since then we have done that. We have a door there that nobody can get into the pharmacy at all without the pharmacist being there. At least my office can come in and conduct, you know, answer phone calls or anything that comes in that way, but nobody can go in the prescription room. It has its own alarm system. Everything has been redone there as a thing we saw that potentially it could have been a bad situation for us. But we didn't get any sanctions or any violations on us on that part. It may not be on our record. All we got was a guidance letter on what we need to do to prevent that. But it may not be on our record, it may be so that's why I brought it up.

MR. LIVINGSTON: You are the owner?

MR. CHANDLER: No, I'm the operations manager.

MR. LIVINGSTON: Are you a pharmacist?

MR. CHANDLER: No. Been in it since I was 15 years old.

MR. LIVINGSTON: Your prescriptions that you ship in will be patient specific?

MR. CHANDLER: Patient specific, yes, sir.

MR. LIVINGSTON: Not going to physicians?

MR. CHANDLER: Patient specific. We instituted that a long time ago. It works a lot better.

MR. LIVINGSTON: You are marketing to patients

here in South Carolina?

MR. CHANDLER: What we do is we have gone to like the AUA show for urology. We'll go and attend those shows such as that, get business that way. We don't actually have reps that come into the State of South Carolina to do that. We just go to shows and IF A physician happens to be there, then we'll stop and show what we do. We do that. We also have a web site that patients will, for ED, that will go. That's the only thing we have on our web site at this particular time is for the ED stuff. Patients can learn about the different things that we have. We have needle-less Tri-Mix for patients that works really well. There's a patent pending on that. We're the only people in the country that's actually doing that and so they can actually see a video on there and then take that. We have some forms they can take to their physician that they can print off if they notice something they have seen and the physician can prescribe it if he wants to.

MR. LIVINGSTON: Are you shipping anything into South Carolina now?

MR. CHANDLER: No, sir.

MS. SANDERS: FYI part of the delay for this coming is invariably it happens with most everybody that they're sent our list of what we want reviewed, and then from what I review and see, I always end up having to send

back a second request of I need this, this, this and this, it's not in my packet. And so that's part of the reason for their delay is because the first information that was sent had nothing about non-sterile compounding, but some of the documents he sent me was for non-sterile. I have the same question, but because he's not a pharmacist I don't know if he can answer it. When I look at the forms and I didn't get back with the PIC on this, but again I look and I see an expiration on a sterile product for six months, but how is the sterility portion being handled. If it's made, again making 20 vials today, 5 going to Mr. Smith, so you're storing those vials so you have to have a sterility beyond use dating as long as it's in your possession, and I didn't see -- I saw where you say you assigned them, but nothing...

MR. CHANDLER: What happens, the same thing what he was telling about PK software that it has that in the system where everything is -- we send it off to either Eagle Labs or ARL which is out of Oklahoma and then we have a lot number assigned to those specific patients and that specific drug so we can go back at any time. If it comes that we have those that are in there, we don't make up a large volume, because we don't want to lose product, but if it gets to an expiration date of less than 30 days, we won't ship that out. We just destroy that drug.

MR. ROSE: I think one of the problems originally, Cle, was that his policies and procedures weren't specific to his location. He just sent the general policies from PCCA and we require specific policy and procedure.

MS. SANDERS: And also one of the other big things is their label had the wrong facility on it. Their labeling in one place said Alabama and another place said Florida.

MR. CHANDLER: I'll tell you how that happened. We moved our facility from Mobile, Alabama to Pensacola, Florida, in February of 2010. I guess it was in the software. We changed our American Pharmacy logo at the top. I think the address may change, but the city and state had stayed Mobile, Alabama, and it was just an oversight on ours, because it was on that particular label that we sent her. It's not one that goes out with the patient. It's going on our hard copy there.

MR. LIVINGSTON: You received all the documents that you requested, Cle?

MS. SANDERS: I have received all the documents, yes, that I requested. Some of the stuff they state they don't do like hazardous other than doing hormones and what they do, they have a containment hood.

MR. CHANDLER: We don't do any hormone

replacement therapy at all.

MS. SANDERS: Their copy of their last inspection, I had them to send their certification of IV hoods, et cetera. And because they told me they weren't doing certain types of products and they had a horizontal and a vertical flow, I asked for their flow of what made the decision as to what you made to which hood and they don't really have a policy for that. They said they do it by work flow.

MR. CHANDLER: We don't use those particular hoods, but we just have two different hoods and we just put them in there. It's not that we do anything different as far as like cancer drugs or anything like that. We just use -- there are two different hoods, but we use them for the same purpose at all times. One's just wide and one's, to us, one's wider and one's shorter.

MR. LIVINGSTON: This gel that you have the patent on, is it a sterile gel?

MR. CHANDLER: It would not be sterile once this patient has taken the thing out. What we do is we actually take the three drugs and put them in the lyophilizer into a syringe, lyophilize it down to a, lyophilize powder and then we take a gel and the syringes are interlocked together, you activate the drug back and forth and then there's an adapter put on the end and it just goes on top

of the urethra. It's very good for a lot of Tri-Mix which you know has to be shipped cold. This allows the patient to be able to travel with it. We'll put it in a 3 ml or 5 ml. They no longer have to use an ice pack to travel out of the country or travel across the states or anything like that. Very ease of ease for the patient.

MS. SANDERS: From the policies and procedures that I have received, I'm not at their institution, they have changed them a little bit different than PCCA, but they're still very close and they do use the PCCA products.

MR. CHANDLER: Right, we do.

MR. ROSE: The HCG tablets, are they tablet triturates or are they just compressed tablets?

MR. CHANDLER: Compressed tablets.

MR. ROSE: You have a machine?

MR. CHANDLER: I have a pill press, yes.

MR. BUSHARDT: Any other questions? We will go into executive session probably pretty shortly and you will be notified in two or three days.

MR. CHANDLER: I appreciate it.

MR. ROSE: I make a motion to go into executive session.

MR. LIVINGSTON: Second.

MR. BUSHARDT: We'll go into executive session.

(Executive Session.)

(Lunch.)

MR. ROSE: Move to come out of executive session.

MR. LIVINGSTON: Second.

MR. BUSHARDT: All in favor raise your right hand. Opposed the same. We are out of executive session. Please excuse us. We have been behind all day and it seems like we are still there, but we will try to catch up in just a few minutes. Let's go ahead and do these. Do I hear a motion for request of approval for non-resident pharmacy application University Compounding Pharmacy.

MR. HUBBARD: I move that we deny.

MR. BUSHARDT: Do I hear a second?

MS. RUSSELL: Second.

MR. BUSHARDT: Any discussion? All in favor signify by raising your right hand. Opposed likewise. Motion is denied.

Request approval for non-resident pharmacy application Hartley Medical Center Pharmacy, Incorporated.

MR. LIVINGSTON: Mr. Chairman, I make a motion we approve this request.

MR. BUSHARDT: Hear a second?

MS. LONG: Second.

MR. BUSHARDT: Any discussion? All in favor signify by raising your right hand. Opposed likewise. Approved.

Request approval of non-resident wholesale/distributor/manufacturer Medisca, Incorporated.

MR. ROSE: Mr. Chairman, I make a motion that we approve the request.

MR. BUSHARDT: Do I hear a second?

MR. HUBBARD: Second.

MR. BUSHARDT: Any discussion? All in favor signify by raising your right hand. Motion approved.

Request approval of non-resident wholesale/distributor/manufacturer Dispensing Solutions, Incorporated.

DR. RICHARDSON: Mr. Chairman, I move that we approve this request.

MR. BUSHARDT: Do I hear a second?

MS. RUSSELL: Second.

MR. BUSHARDT: Any discussion? All in favor signify by raising your right hand. Opposed likewise. Approved.

Request approval of non-resident pharmacy permit application Burkow Development, Incorporated doing business as American Pharmacy Solutions.

MS. LONG: Mr. Chairman, I move that we accept this request.

MR. BUSHARDT: Do I hear a second?

MS. RUSSELL: Second.

MR. BUSHARDT: Any discussion? All in favor signify by raising your right hand. Opposed likewise. So approved.

Starting on our after lunch agenda.

MR. BUSHARDT: Request approval of pharmacy technician registration application Troy Smith. Troy Smith present?

Thereupon,

TROY SMITH,

being first duly sworn to tell the truth, the whole truth and nothing but the truth, as hereinafter certified, testified as follows:

MR. BUSHARDT: Tell us a little bit about why you are here today and what you want us to do for you.

MR. SMITH: I'm here to get my application approved for a pharmacy tech program to finish my externship at Virginia College in Charleston.

MR. BUSHARDT: You answered yes to a question. Would you like to tell your side of the story?

MR. SMITH: Yes, sir. The reason I'm here is because I had a felony on my background. And I was going, I was finishing my program, but I couldn't do my externship because of my criminal background and felony, so I had to come here to get my application approved or whatnot so I can complete the program.

MR. BUSHARDT: Was it just one time?

MR. SMITH: Yes, sir, in 2004.

MR. ROSE: Virginia College, did they know about

this when you enrolled in Virginia College?

MR. SMITH: Yes, sir. I requested to get a pardon on the charge. She told me as long as I go through that process or whatnot and I come here and see if you guys would approve me to finish the program.

MR. ROSE: You went through PTI, pretrial intervention?

MR. SMITH: No, sir. I did probation. I served probation for and paid restitution and I'm just trying to get through this program so I can make a better living for myself.

MR. LIVINGSTON: We have a SLED report in front of us that has a few other things on it. An incident in November 2007.

MR. SMITH: 2007. What is that?

MR. LIVINGSTON: A felony as well. Looks like transaction card theft.

MR. SMITH: Yes, sir. I finished probation for that also.

MR. LIVINGSTON: But that's an additional felony besides the one in 2004.

MR. SMITH: Yes.

MR. LIVINGSTON: I have some misdemeanors on here as well. 2009 September 18 actually is the court date for this particular charge, but it says obtained goods under

false pretenses.

MR. SMITH: That, I believe that was when, with the charge, the same charge I got in 2004, but I got -- when I was -- the charge in 2004 it was under Youthful Offender Act so I guess that is not on my record I'm guessing.

MR. GRIGG: Mr. Smith, if I may. You had the felony you spoke of in 2004, correct?

MR. SMITH: Yes, sir.

MR. GRIGG: Then you're saying that these others that you went to trial on in 2007 are part of that same incident?

MR. SMITH: They're separate as far as obtaining under false pretenses.

MR. GRIGG: That felony that Mr. Livingston just asked you about from November 2007 is completely separate from the '04 incident?

MR. SMITH: Yes.

MR. GRIGG: You got two convictions?

MR. SMITH: Yes.

MR. GRIGG: This last one obtaining goods under false pretenses it looks like it's a non-conviction.

MR. SMITH: Yes, I wasn't charged with that.

MR. LIVINGSTON: May 1, 2010, you were arrested for speeding?

MR. SMITH: Speeding ticket, yes, sir.

MR. LIVINGSTON: Were you arrested?

MR. SMITH: Because at the time I didn't have insurance on my vehicle I was ticketed. I was going actually taking the vehicle to the paint and body shop which is about five minutes, I actually took the chance in taking the car there and unfortunately I didn't make it and got arrested and I paid the speeding ticket or whatnot for it.

MR. LIVINGSTON: Our purpose here at the Board of Pharmacy is to protect the safety and well being of the people of South Carolina, and you are asking us to give you a certificate so that you can actually work with medications and dispense to people in South Carolina which can cause real harm and we don't want that. So give me -- I'm looking over this sheet and I'm seeing some reckless events. Can you tell me anything about yourself to make me believe that you won't continue these reckless events whenever you start to work in our profession?

MR. SMITH: I made a few mistakes and the evidence is right there in front of you. I made mistakes, but I've also -- I recently received my TWIC card and my Merchant Mariner credential and I'm waiting on my passport to try to make a better living for myself. I understand I made those decisions. I do regret them because of the

consequence that, I mean like I got the choices and my opportunities to move further is being hindered because of my past decisions. So I'm trying my best to actually make a change and do better. Like I said those are mistakes that I made and I learned from them. I'm just trying to better myself.

MR. LIVINGSTON: When did you enroll in Virginia College?

MR. SMITH: In October of 2009.

MS. LONG: What made you go into pharmacy?

MR. SMITH: It was just something different. It was something different. My dad always told me to work smart and not harder and with my background I always had to be working in like warehouses and working in heat and I just, I think pharmacy would have been a different, a program that I can get into that I would be interested in and also helping others, but.

MR. LIVINGSTON: Just FYI I grew up working in the heat too and some days I would like to go back to it.

MR. SMITH: It's good money working in the heat, I'd rather work in the AC.

DR. RICHARDSON: How old are you?

MR. SMITH: I'm 25, sir.

MR. BUSHARDT: Mr. Smith, we will look at your request. We will go into executive session after we have

looked at all of the requests and you will be notified in two or three days what our decision is.

MR. SMITH: I appreciate your time. Thank you.

BOEHRINGER INGELHEIM VET MEDICA, INC.

MR. BUSHARDT: Request approval of non-resident wholesale/distributor/manufacturer application Boehringer Ingelheim Vet Medica, Inc., Michael Hermann.

Thereupon,

MICHAEL HERMANN,

being first duly sworn to tell the truth, the whole truth and nothing but the truth, as hereinafter certified, testified as follows:

MR. BUSHARDT: Mr. Hermann, if you would tell us a little bit about what you do and why you are appearing before us today.

MR. HERMANN: I am the general counsel for Boehringer Ingelheim Vet Medica, Inc., and I was requested to be here today.

MR. BUSHARDT: You must have answered some yes questions.

MR. HERMANN: That is correct. Our regulatory people answered some yes questions.

MR. BUSHARDT: Would you like to explain and make sure you tell us whether they have been resolved.

MR. HERMANN: Boehringer, Vet Medica for short, it's a rather long name, we received notice of not properly registering in Colorado Board of Pharmacy as an out of state wholesaler in February of 2009. We obtained a

license completed, consent order, paid the minimal penalty and resolved the case within two months. And we have renewed our license since then which expires October 31, 2012. The background of that situation that happened, we are a private warehouse for pharmaceutical manufacturer of tablets and vaccines. We ship to distributors. We shipped to a distributor in another state where we also have a license. They decided on their own accord to open a warehouse in Colorado. We did not know that. We shipped to them in the state. They shipped to Colorado, that site was inspected and then we were placed in violation without knowing, but we rectified it within two months.

MR. BUSHARDT: Be careful in Colorado. The Oregon Board also, was that something else too?

MR. HERMANN: That's correct. June 2007 we did not -- we received notice of not properly registering in Oregon Board of Pharmacy as a non-resident manufacturer, every state has a different title, we obtained the license, completed that consent order, we did not admit or deny the allegation, that was a settlement and we since submitted a renewal application with them and we're currently licensed there. The background to that is I believe we didn't have the sufficient manpower or people power frankly to support the regulatory state licensing in each state. Since then we've grown exponentially. I have 2000 employees and I

have people that are explicitly dedicated to state licensure. In 2007 when I arrived at this company we didn't have that.

MR. BUSHARDT: Any other questions from Board Members? Mr. Hermann, we will take this into executive session and we will let you know in a couple of days.

MR. HERMANN: Excellent. Thank you, Mr. Chairman.

MR. BUSHARDT: Request approval of state certified pharmacy technician application Alice Tomkins Beck.

Thereupon,

ALICE T. BECK,

being first duly sworn to tell the truth, the whole truth and nothing but the truth, as hereinafter certified, testified as follows:

MR. BUSHARDT: Would you like to state your case before us please.

MS. BECK: Yes, sir. My name is Alice Beck. I have been working in Pickens, South Carolina. Been a technician for 25 years. I'm asking you to look at my appeal for being grandfathered as a state certified technician. I have all my required information and I was registered to take the exam by the deadline, but the exam wasn't actually until 17 days later, but I was signed up for it. I had all my CE, all my work experience. So I would like you to look at that.

MR. BUSHARDT: The first exam was what date?

MS. BECK: I actually took the very first exam in '95, but then for a couple of years I worked in a doctor's office so I didn't keep my CE up and stuff. Then when they started talking about technicians being required to do this

again, I took the exam again and then at a CE in '09 we heard there was going to be another grandfathering so I sent all my stuff in, but like I said I was 17 days past the cutoff date.

MR. BUSHARDT: I'm not sure we have the right to open up a grandfather clause.

MS. BUNDRICK: The only reason it was opened up before it was in a proviso in the state budget.

MR. ROSE: For one year.

MS. BUNDRICK: For the one year. That's the only reason we could open it up.

MR. BUSHARDT: I understand your plea, but I truly don't think we can do anything for you. I know you've done all the work, but unless it's done in that particular time period, then our hands are tied. We can't do it. We can't open up a grandfather clause. If we could open it up, it would be --

MR. ROSE: The dam would break.

MR. BUSHARDT: That's exactly right. We don't have the right to do that anyway. That was a legislative thing. So legislatively that was done, but this Board, we don't have any jurisdiction over that.

MS. BECK: I don't have any other recourse?

MR. BUSHARDT: I don't know of any. Lee Ann, do you know of any only other recourse? The only other

recourse I know is to take that education course, ACPE and then if you do that, then you've already done all the other stuff to do that, but the education course is the only recourse that I see that you have. I'm sorry.

MR. ROSE: Where are you currently employed?

MS. BECK: Corner Drug Store in Pickens. I have a letter from my current employer.

MR. ROSE: My personal opinion is that the easiest way for you to get past this hurdle is to work for one of the people that have an ACPE course and the only ones that do that are the three largest chains. You can get it in about a year or less.

MS. SANDERS: Doesn't Midlands Tech have the online course?

MR. BUSHARDT: You can do online courses also.

MR. ROSE: Sounds like to me you got all the experience, you just need to get, some way to get through that hurdle.

MS. BECK: Yes, sir.

MR. BUSHARDT: Wish there was something we could do for you. We don't have that right.

MR. BUSHARDT: Request approval of non-resident pharmacy application Special Design Healthcare Kelley Pipkin.

MR. RICKERT: Good morning. Edward Rickert, I'm counsel for Special Design Healthcare and Roy Winters is the compliance officer. We came along with Ms. Pipkin to answer any questions.

MR. BUSHARDT: Okay. You need to get sworn in. Thereupon,

KELLEY PIPKIN, ROY WINTERS AND EDWARD RICKERT,

being first duly sworn to tell the truth, the whole truth and nothing but the truth, as hereinafter certified, testified as follows:

MR. BUSHARDT: If you want to state what you do and why you are here before us today.

MS. PIPKIN: My name is Kelley Pipkin. I'm the pharmacist-in-charge of Special Design Healthcare. Been there since last November, and I'm also the front end manager of it and we would like to have a non-resident pharmacy permit in your state.

MR. BUSHARDT: The reason that you came before us is that you answered yes to a couple of questions. Would you like to explain and tell us whether they have been resolved or not.

MS. PIPKIN: Can I have Ed explain a little bit better since I've not been there very long.

MR. RICKERT: The reason that I'm here is I was retained by Design Special Healthcare back in 2009 to help them get through some regulatory issues. Back in 2008 and actually prior to 2008, they had an inspection by Missouri Board of Pharmacy and they found some recordkeeping violations and some other problems in the pharmacy which led to a consent order, five years probation by the State of Missouri. Along with that they self-reported some conduct to the Office of Inspector General concerning billing issues and that resolved in 2009 with a corporate integrity agreement that they agreed to. I was retained by Special Design after that to help them with their compliance program, help them get back on track. I'm a pharmacist and an attorney and I've represented Special Design since '09 to help them with their code of conduct and corporate integrity training. They also retained Mr. Winters who actually holds the official title of compliance officer. So they've done everything they can to make sure that everything is proper, not just in the State of Missouri, but in every other state that they do business. They're a specialty pharmacy. They specialize in drugs that treat certain conditions. Kelley will discuss that a little bit more. Since the date of the

Missouri discipline they have applied for and received licenses in several other states notwithstanding the fact that they have this past compliance history. So we are here to ask that you do the same and grant a non-resident license to Special Design. Kelley can answer and Mr. Winters can answer some of the questions concerning the current compliance program.

MR. BUSHARDT: You've never been licensed in South Carolina?

MS. PIPKIN: No, I have not.

MR. HUBBARD: You circled yes on the first question Part A, any pending disciplinary action.

MS. PIPKIN: Yes. It was five years and we have two more years left. It's not really pending.

MR. RICKERT: Probably shouldn't have said yes is there any pending disciplinary action. I think she was thinking of the Missouri probation which they're in their third year now of five-year probation, but there's no other pending disciplinary action in Missouri or any other state. She just made an error.

MR. LIVINGSTON: Give us an idea of the products that you would be shipping into South Carolina.

MS. PIPKIN: Sure. We specialize in Hepatitis C medications, rheumatoid arthritis medications, psoriatic medications mainly Orencia, Remicade, Crohn's patients. We

do have a few antibody infusions, we have about locally a couple times a week, but we're very small. But we have a big Hepatitis C program right now.

MR. LIVINGSTON: You listed yourself as a sterile compounder. Do you make any high risk sterile compounds?

MS. PIPKIN: No. Just simple antibiotics, Vancomycin.

MR. LIVINGSTON: Reconstitute commercial products?

MS. PIPKIN: Yes. They would be local products.

MR. RICKERT: Those products would just be for local patients around Cape Girardeau area. It's not something they'll be shipping into South Carolina. In South Carolina specialty drugs, Hepatitis C primarily, rheumatoid arthritis, manufactured products, not anything compounded.

MS. PIPKIN: They do know us quite well locally. It's been opened for over 20 years. You asked me if I had my license in the state, but I do have my license in other states. Virginia, Kentucky, Tennessee, Missouri.

MR. BUSHARDT: Colorado?

MS. PIPKIN: No.

MR. BUSHARDT: Any other questions?

MS. SANDERS: Since I'm the one that reads the policies and procedures, there was one concern I don't

think that I mentioned that. I've spoken with Ms. Pipkin on the phone a couple of times now I think and received some e-mails. One thing in your controlled room temperature you got down it's 59 to 86 degrees on your policies and procedures. Majority of drugs can't be stored above 77 degrees except for short excursions. So you all may want to revise that. Just like some of the other policies and procedures, they have policies and procedures for things they don't do. So you have to weed through that and ask questions. They also have an online prescription on their web site. I believe that was supplied in your packets. And again I guess the question that I ask most everyone is, can you explain with your sterile products how you assign sterility beyond your dating to the Board versus stability expiration. Let's say that you are making up a batch of your medications and you got orders for history for one of the products that you make and you make 20 vials. Are they made just before shipping, are they made and held on site.

MR. WINTERS: We don't batch fill. We fill for that patient and send it out.

MS. SANDERS: Patient specific?

MR. WINTERS: Yes, and we comply with 797 rules and the expiration dates.

MS. SANDERS: And they did supply for me their

policy and procedure for shipping cold products.

MR. WINTERS: We do have testing on that too. I think that was one of your questions about we send out packages, just empty packages, with the cold dot that you send out to see if they turn red and we've done that quite often to make sure that the time frame is still okay. Even in the heat of summer, we sent it out, one came back three days it was no good, two days it was fine. So we send overnight.

MS. SANDERS: The other thing that I discussed with Ms. Pipkin on the phone is that it appeared like they had a 6 to 1 ratio. Their state does not have a ratio and by our laws if their state does not have a ratio, they have to conform to the 2 to 1. Is that going to be ...

MR. WINTERS: I have a question about that, because I wasn't sure that the ratios would apply to a non-resident pharmacy.

MS. SANDERS: It does. In our statute, I don't have my book here.

MR. ROSE: I have my book.

MR. WINTERS: We were addressing this. We were talking about this, because all of our people are technicians and a lot of them I consider just clerical, but since -- we have a specific area for just the pharmacy part and for the clerical, but we make them all pharmacy techs.

Even though they're just inputting information, they have nothing to do with the preparation. It would be easier for us if we didn't have them registered as techs and they could just be clerical help, but we do that just to make sure that, you know, everybody that's in the pharmacy, even if they were to walk back into the area, they would be okay, but they've never ever had anything to do with the preparation or anything of the prescriptions.

MS. PIPKIN: I did tell her that the number of pharmacy technicians we do have that prepare prescriptions are only at the number --

MR. WINTERS: One to one. You got three pharmacists and three techs. The rest are clerical.

MR. LIVINGSTON: You got three pharmacists and three people working in your facility.

MS. PIPKIN: Yes.

MR. LIVINGSTON: That meet the requirement.

MR. ROSE: If they're entering prescriptions --

MS. PIPKIN: We enter the prescription.

MR. WINTERS: We enter them. All they do is enter the patient information. They do enter patient information like if they get, you know, the insurance and demographics of the patient.

MS. PIPKIN: Address.

MR. WINTERS: But that's all they enter.

MS. SANDERS: I can send that regulation to you, because just flipping through our book, I can't -- it's not one I have to refer to very often, but it is in statute.

MR. BUSHARDT: What's the statute, Cle?

MS. SANDERS: I'm having to look. My computer has died. I'll have to find it in here.

MS. BUNDRICK: If they don't have a ratio, it has to be 2 to 1 if their state doesn't.

MR. WINTERS: We talked to the Board of Pharmacy inspector in Missouri and what I found out, I wasn't there the day that she was there, when we asked about registering, she wanted to know where the drugs came through, well, they came to a side door and she said because they came through a side door everybody had to be registered, if they didn't come right to the pharmacy, into the pharmacy themselves. So we talked about maybe just bringing them right back to the pharmacy bypassing the front and going right back to the back, because we would like to get rid of the expense and taking care of technician licenses in Missouri also.

MR. LIVINGSTON: It's not a problem having them registered by any means. You can have more registered, but it's just while you are working or dispensing medication, you have to work under that ratio.

MR. WINTERS: That's one to one. We can send you

the names of people in the pharmacy that work.

MR. LIVINGSTON: I'm fine. It's not an issue of how many you have registered to your facility. It's how many you have working at the time.

MR. ROSE: Are all your records handwritten or are they computer driven?

MS. PIPKIN: No, computer.

MR. WINTERS: We electronically sign them.

MR. ROSE: I'm just talking about like your compounding, like how much you weighed out. You don't do any powders?

MS. PIPKIN: Commercially they're already...

MR. ROSE: Commercially they're already...

MS. PIPKIN: Yes.

MR. ROSE: Things like immunoglobulin you would just buy and then resell, is that right?

MS. PIPKIN: In liquid. Because our primary focus is Hepatitis C and rheumatoid. It's very small. Mainly three or four patients a week at tops.

MR. BUSHARDT: Any other questions? We will be going into executive session shortly and we'll let you know. You're welcome to wait around or we'll let you know one way or the other in two or three days.

MS. PIPKIN: Thank you.

GAYCO HEALTHCARE MANAGEMENT

MR. BUSHARDT: Request approval of non-resident pharmacy permit renewal Application, Gayco Healthcare Management, Davey Brown.

MS. BUNDRICK: They have requested to withdraw their application.

NEFISE KARANFIL

MR. BUSHARDT: Request approval of pharmacy technician registration renewal application, Nefise Karanfil.

Thereupon,

NEFISE KARANFIL,

being first duly sworn to tell the truth, the whole truth and nothing but the truth, as hereinafter certified, testified as follows:

MR. BUSHARDT: Tell us about yourself.

MS. KARANFIL: My name is Nefise Karanfil. I'm a pharmacy technician. I went to TriCounty Technical College for pharmacy technician program. During my clinicals Bi-Lo Pharmacy in Clemson hired me. I've been working there since 2009. And I applied for the state certification. My application was held back because my college diploma came from out of country. So that's why I'm here. I got a phone call from you guys to be here today.

MR. BUSHARDT: I saw that one. The Board is going to have to decide on this, but it's just a matter of -- this is a case where they just didn't take her high school, they needed a high school diploma and since it was out of country, then we have to approve it as a Board, but everything else is in order. We just have to approve her out of country diploma.

MR. ROSE: She's already graduated from TriCounty, is that right?

MR. BUSHARDT: Yes.

MR. LIVINGSTON: I make a motion to approve.

MS. RUSSELL: Second.

MR. BUSHARDT: Any discussion? All in favor signify by raising your right hand. Opposed same way. Welcome.

MS. KARANFIL: Thank you.

MR. BUSHARDT: You will be getting your certificate shortly.

eVENUS PHARMACEUTICAL LABORATORIES

MR. BUSHARDT: Request approval of non-resident wholesale/distributor/manufacturer application, eVenus Pharmaceutical Laboratories, Inc., Rose Zhao.

Thereupon,

ROSE ZHAO,

being first duly sworn to tell the truth, the whole truth and nothing but the truth, as hereinafter certified, testified as follows:

MS. ZHAO: My name is Rose Zhao. I'm the director of regulatory affairs for eVenus Pharmaceutical Laboratories. We're in Cranbury, New Jersey, and our company is the US agent for a Chinese pharmaceutical company, Jiangsu Hengrui Medicine Company. We are also going to be the distributor for Jiangsu Hengrui's products in the US. In the last few years we have applied ANDAs for generic product for Jiangsu Hengrui, generic product, and I expect approval for several products. That's why last year we started the process of applying for state licensing for wholesale and distribution and I believe we started the process for South Carolina in February and we received a letter of not approval in August. The reason is in 2000, 11 and a half years ago, FDA did inspection of Jiangsu Hengrui API manufacturing site and issued a warning letter. This warning letter is on FDA's official warning letter web

site so everybody has access. I think that's maybe that's where Cle found the warning letter. We addressed all the violations cited in the warning letter and we filed a response to the warning letter in January 2001 and then since that we have successfully passed many inspections by, not only US FDA, but also China state FDA and European and other worldwide agencies. And then -- so we provided the information to the person we've been communicating with and now we're still asking to present information at this meeting. That's why I'm here. And then Monday I e-mail Ms. Sanders four documents, one is FDA's official warning letter issued in 2001. And another one is our response document, just first couple pages of our responses and others is appendixes and attachment which is about this thick, okay, and then along with that there are two other FDA official letters. They are the approval letters for inspection FDA conducted in Jiangsu Hengrui last year and so from this inspection 2010 FDA found not only our API manufacturing site, but also the sterile drug compound sites are acceptable in term of FDA compliance. I believe we have all the evidence to be granted for this application and if you have any additional questions I would like to answer them. But I want to point out that Jiangsu Hengrui is a relatively young company. It was founded in 1970s and the products were more in '70s, '80s and '90s is more to

the Chinese market and in beginning of late '90s and 2000 we start selling APIs to the US and other markets. You have to look at the fact that this deficiency has been 11 and a half years old and since that there's no, not another FDA warning letter issued to the company. So I believe I have all the evidence to ask your approval for this application.

MS. SANDERS: We just explained to her that on a staff level, because we did not have, when this was being reviewed, anything where the FDA had actually given the approval of what they sent in. So therefore we could not on a staff level approve.

MS. ZHAO: Can I explain that one thing? FDA did not have the close out -- if you check FDA's web site, FDA started a close out program in September 2009. Before that if they issue a warning letter there would be no close out. So outsider wouldn't know whether or not issues are resolved, but they started the practice since September 2009. After that there's such things as close out program. The two letters that you have are the result of that program. So the fact that after 2000, year 2000, we have passed many inspections as late as last year. So that official site, all the details, I mean the violations that happened since 2000, the company has grown significantly in term of product capability and quality

management.

MR. BUSHARDT: What you are saying is that after 2009 FDA closed out their records, is that what that is?

MS. ZHAO: FDA, if they -- if a company, if FDA issue a warning letter to a company and a company address the FDA's violation, the citations, then request a reinspection, after FDA's reinspection, if they found the inspection acceptable, satisfactory, they will issue a close-out letter and that close-out letter is on the FDA's official web site. It's accessible to, I mean it's open to the public. But before that there was no official, and Cle is saying there is no FDA close out. So we do not know whether or not the violation has been addressed.

MR. BUSHARDT: So how do we find this out?

MS. SANDERS: The documents that she just sent the end of last week, she was already on the agenda. I did not have those documents in the past. But there again because there have been problems with the parent company and nothing had been -- there was no yes answer, but we saw problems with the parent company, the staff cannot approve that. You all have to approve which way to go.

MR. BUSHARDT: We are talking about something that happened in 2001.

MS. ZHAO: 2000.

MR. BUSHARDT: 2000. And there's been nothing

since 2000?

MS. ZHAO: There's no warning letter since 2000. You can check FDA's web site.

MR. BUSHARDT: Was there any action taken in 2000 or just a warning letter?

MS. ZHAO: Yes. The company has taken a large amount, actually in terms of the FDA compliance and they have been in compliance ever since.

MR. BUSHARDT: Did you pay a fine or anything like that?

MS. ZHAO: No.

MR. BUSHARDT: There was no fine at all involved in 2000?

MS. ZHAO: No.

MR. ROSE: All the medications are made in China, is that correct?

MS. ZHAO: That -- the warning letter is for API manufacturing sites. So, yes. This application is for drug product what we intend to sell in US once FDA approve them which would be very soon. Yes. To answer your question all the drug substances and drug products are made in China coming to...

MR. ROSE: That's a separate company or part of the same company?

MS. ZHAO: We are wholly owned Jiangsu Hengrui.

We're in New Jersey, but our parent company is in Jiangsu Province in China and all the products are manufactured there.

MS. SANDERS: When we pulled up eVenus web site it stated the company that was their parent company so therefore we reviewed to see if there had been any issues. There were issues, and because they could not produce anything that they got finalization from FDA is why they had to come before you and you were provided a list of the products from their web site, et cetera.

MS. ZHAO: The products on our web site are not all approved in the US yet.

MR. LIVINGSTON: I didn't see a list of products.

MS. LONG: It's in the handout.

MR. LIVINGSTON: What kind of products are they?

MS. ZHAO: So far no finished product from Jiangsu Hengrui is on the US market yet. Okay, but some US company by API, the active pharmaceutical from Hengrui and when they get FDA's approval for their final product and sell the product in the US. We don't have official we don't have any product on the US market.

MR. LIVINGSTON: You said you don't have any official products on US market?

MS. ZHAO: Yes, on our own yet. That's the purpose of this application.

MR. LIVINGSTON: You're distributing for your parent company right now?

MS. ZHAO: Yes.

MR. LIVINGSTON: The parent company has drugs that have been approved by the FDA?

MS. ZHAO: There's no product that has been approved by FDA, but we are expecting the approval soon.

MR. ROSE: The only product that they're distributing now is in China, is that correct?

MS. ZHAO: Yes.

MR. ROSE: It's waiting FDA approval in the United States?

MS. ZHAO: Yes.

MR. ROSE: You're just getting ahead of the boat a little bit?

MS. ZHAO: Yes. It takes time to set up your distributing sell chain.

MR. LIVINGSTON: Can you tell us what that product, the first product, will be?

MS. ZHAO: Irinotecan, it's an old cancer drug.

MR. BUSHARDT: Any other questions?

MR. ROSE: I just have one question about the name, eVenus, is that like internet? What does that E mean?

MS. ZHAO: That's an interesting question. The

company was found in 2009. The name was Venus and then we found out there was another New Jersey company and their name is Venus and so we added E in front of Venus. It became eVenus. It doesn't have any meaning actually.

MR. ROSE: I thought like e-mail or internet.

MS. ZHAO: No, nothing to do with. EVenus Pharmaceutical Laboratories.

MR. ROSE: We have to watch internet pharmacies.

MR. LIVINGSTON: I noticed on your application you said you are a virtual distributor, US agent for manufacturer. Virtual distributor. Does that make you believe it was internet based?

MS. ZHAO: That meant we are a distributor. I'm not an expert on it, but my understanding is we are going to be the official distributor, but we are in the process to have this distributing company, wholesale company, to work with us with distributing our products.

MR. BUSHARDT: Any other questions?

MS. ZHAO: I just want you to focus on one thing. The reason I'm here because there was a violation, warning letter, in 2000, and that has been addressed and FDA has inspected the site many times after that and found our site successful in term of FDA compliance. I do not know what else you need to approve this application.

MR. LIVINGSTON: I will let you know it's a

little difficult for me to say yes we'll give you a permit without some total understanding of what you would be shipping into the State of South Carolina. As you've seen these people who have been before you we really question them on what products they ship, the process they're going through and you're here before us saying we're hoping to get approval on a product. We don't approve too many hopes around here.

MS. ZHAO: This is -- I have not personally handled this issue. You've had communication with Javier, right, and he's not here. This really is not my specialty to talk about that, but this is my understanding and I haven't heard anybody question whether or not we're qualified to apply for this license.

MR. LIVINGSTON: I didn't say we're questioning your qualifications.

MS. ZHAO: Can you say again what is your concern?

MR. LIVINGSTON: Yes. We want to know actually the ins and outs of what you would be shipping and you don't have a product that's approved to even ship into South Carolina from what I'm understanding. Am I incorrect about that?

MS. ZHAO: Because I'm just telling you what product I expect to approve. The first one Irinotecan.

Second will be Vinorelbine and then hopefully soon it will Ketoprofen, and then again, I'm not expert, but we were told you need to set up your distribution, get a license in all states. So far we got licenses in 30 some states, and South Carolina is the first state we've had to come to present information in person and take about a year. We have some consulting company come to us and say oh you expecting approval any time, actually any time soon, okay, but they said you haven't -- you don't have any distribution wholesale chain. Said no, we're not. So actually we're behind. So my understanding this is quite standard practice to setup, you're getting all the licenses ready. Your distribution chain to anticipate approval. As a matter of fact after FDA approval, after certain time after approval, I can't tell you the number, if you don't actually sell the product in US you've lost that approval. You'll lose that approval.

MR. BUSHARDT: Do you have any other states that you are --

MS. ZHAO: We are applying for application in all states and so far we received approval from 20-30 some states.

DR. RICHARDSON: I guess my concern would be before I could say yes is to get approval from the FDA. If FDA were to say this product is a good product, whatever

that product is, then I think that we could probably say yes, but we could not say yes to you at this point because it's not FDA approved.

MS. ZHAO: I know what you are saying. But we would not be able to sell the product until FDA's approval. So this is --

DR. RICHARDSON: Until then I'm not sure we can even approve until we see that.

MS. ZHAO: But this is contingency approval. It's contingency on FDA's final approval.

DR. RICHARDSON: What you are saying is you're looking for approval on the contingent that FDA will approve it?

MS. ZHAO: Yes.

DR. RICHARDSON: That's what you're asking for?

MS. ZHAO: Yes.

MR. BUSHARDT: Any other questions? Ms. Zhao, we will go into executive session shortly and you will be notified within the next two or three days of whether we have approved or not.

MS. ZHAO: Thank you very much. Let me know if you need any other information. We'll be glad to provide it.

MR. BUSHARDT: We certainly will.

MR. BUSHARDT: Carole, you are going to report on the NABP/AACP District 3 annual meeting.

MS. RUSSELL: Yes. We attended the meeting in Biloxi, Mississippi. The Board of Pharmacy was represented by Mr. Rose, Dr. Richardson, Ms. Bundrick and myself. South Carolina was further represented by Mike Gunthe (phonetic) from South Carolina College of Pharmacy, Gene Reeder from Presbyterian and Sarah Braga from South. We heard topics about the CMS partnership for patients, future practice of pharmacy, NABP report and AACP report. Patient safety and quality improvements and about ACPE accreditation. We had breakout sessions on intern hour requirements as they varied from state to state, technician roles and certifications as they varied from state to state. Prescriptive authority and more patient safety and clinical pharmacy service collaborative program such as the program they are doing in Mississippi Delta area.

Dr. Richardson commented that it was a very good conference. He very seldom sees in a conference be it district or national the concern for the individuals who need the services that we have to offer specifically when it comes to pharmacy. When he first joined the Board the Medical University of South Carolina had provided services to depressed community in Charleston. He talked about the

University of Mississippi has gone into a Delta community and developed relationships in this community where they are helping people who need the services and that it was done by pharmacists in Mississippi. A gentleman that he cannot remember his name started a relationship with communities to help, the less deprived communities, to help those citizens and he has not seen that before other than the Medical University of South Carolina trying to go into depressed communities and trying to assist those people. He further said there are at least three type models that the Board could really look at to go into depressed communities. The other thing is CMS is beginning to provide some services for these areas. There is some funding from CMS. It was a very good conference and for lay people like myself, he states, we like to see those kind of things as we go from state to state. So it may be something that we could look into and probably do something regarding those depressed communities.

Mr. Rose added about the conference what Leo was talking about CMS, what they're looking for is people to come up, individual pharmacists or pharmacy systems or chain pharmacies or whatever, to come up with ideas on how to get the clinical aspect of pharmacy to their patients, Medicare and Medicaid patients, and they're wanting these programs, like Leo said there's three of them, two

different ones in Mississippi and one MUSC has done in the past, they're wanting to do this and they're willing to pay for patients in their care I believe they call it and they talked about the medical home type idea and they're looking for people that are willing to work in quality improvement to enhance patient care and health care delivery in general and they were talking about clinics that would take care of people with high risk patients like asthma, metabolic conditions, diabetes, anticoagulation clinics and they're willing to pay for these MTM services if you can come up with a program that has policies and procedures and the number of patients you want to impact and things like that. First you have to be either Medicare provider or a Medicaid provider to do this and the guy that spoke, the first meeting with us, we had the CMS speaker, and we actually had a joint meeting with the executive director of Southeastern and he's the president or whatever, and actually did an internship with CMS one summer and got hired by them to work for them. His name is Timothy Mitchell. He said that he's looking for opportunities for pharmacists to get involved in extensions of patient care where they help educate the patients and make sure they're compliant with their drug regimes and things like this. He also talked about 340B pharmacy. They're buying almost 5 billion dollars a year

worth of medications. Mr. Rose believes his name is John Michael O'Brian. He's interested in schools of pharmacy sending students to Washington to CMS, student rotation and also summer internships. He hopes that people from pharmacy schools take that back to their schools and offer it to their students, because it's an excellent opportunity for students to learn about CMS and how the federal government works and also a possibility of getting jobs with those people. The more pharmacists we have involved in that, the better off we are going to be. He was part of the innovation center which has a budget over the next eight years of $10 billion. They're going to do partnerships for patients is the program they are talking about and what they want you to do is come up with programs to help patients no matter whether they're indigent or not to improve the utilization of medication and to prevent adverse drug reactions, help them with their diabetes or if they're anticoagulation patients to help them meet their goals and things like that. Mr. Rose stated it was a very good conference, he enjoyed it very much. One of the best district conferences he's ever been to.

Mr. Richardson commented that it was Michael O'Brian who Mr. Rose was talking about with CMS, partnerships for patients and CMS innovation center, pharmacists

contributing to better care, lower cost. Mr. Rose said they are willing to put $10 billion in the next eight years into the program. The other man Mr. Richardson was talking about is Jimmy Mitchell, that he did a session on pharmacy collaboration for patient safety. Ms. Sanders commented that just recently within the last month in Columbia there were multiple hospitals, some retail settings, et cetera, in conjunction with the United Way and one was held in the upstate, that the one here Ivy Coleman was involved with and they were permitted by us and services were provided at the Coliseum, free drug, free medical care, et cetera for two days and then people were referred to get them help further along the way. Ms. Sanders wanted the Board to know there are programs that are going on in the state that the pharmacies are involved with and if they are going to be dispensing medication, the Board will have to be involved. Mr. Richardson said that was the second one that was presented in South Carolina. There's supposed to be two others, one in Florence. Ms. Coleman said next year it will be held in the Charleston area. Ms. Coleman also publicly thanked the Board representatives who helped out. She really appreciates what the Board representatives did to make that happen. Ms. Coleman asked a question about the grants for outreach for medical home and that type of

thing was that through CMS. Mr. Rose answered her that this was a separate program from that. It's CMS but it's only the innovation center. It's $10 billion, but they're going to pay people to do innovative drug therapy management, for innovation. They're going to pay people to do this. They got $10 billion to use in the next eight or nine years and after that it will be refunded if they can prove that it's doing some good for people. The projects in Mississippi didn't actually get any reimbursement and that's a little problem, because they had a volunteer staff from the University of Mississippi doing it. What Mr. Rose is trying to tell people is if you will turn programs into this innovation center and they approve them, they will pay you to do it. No matter whether it's Medicare, Medicaid or both or any combination. It could be done by a hospital in conjunction with their medical practices. It could be done with an independent pharmacy in conjunction with a hospital or a medical practice. It could be done by a chain with their group. In any way that you can get involved and it would be very worthwhile. Mr. Rose continues that's what made this program so good, because we're going to have to find something for all these pharmacists coming out of pharmacy school to do in the next five years. The ACPE person was at the conference

and he said, and I quote, we cannot control the number of pharmacy schools. We have no control over it. All we can do is approve their agenda. There is no certificate of need. Mr. Rose said the only people that can do that is the Board of Pharmacy in each state. If we approve each pharmacy school every year. He says, as far as I know no one else do they have to go to other than ACPE to keep up their standards to match the standards of ACPE. So South Carolina Board of Pharmacy actually approves the pharmacy schools every year. If we don't approve them or if we only approve them for 40 students instead of 60 or whatever, I presume the Board of Pharmacy can do that. He said we have never denied anyone but again we've only had two pharmacy schools. Something is going to have to happen plus there's no control over the ones around us, we have at least six that are right on the border of South Carolina all the way around, that are either now or pending.

Ms. Bundrick commented that she thought it was one of the best conferences she has been to and MALTAGON coming up is a good one too as far as the internet working of more one on one with the districts and other boards of pharmacy.

MR. BUSHARDT: Medication temperatures during shipping.

MS. BUNDRICK: Previous Board member Davis Hook sent a letter in. You all should have it as a handout. I spoke with him. He did not want to appear, but he wanted the Board to look at this matter, discuss it and possibly look at some legislation in regards to it.

MR. BUSHARDT: I read an article the other day about that.

DR. RICHARDSON: I think what you said in our meeting and another meeting that we had regarding checking on what's being shipped and looking into, and Dock too said the same thing, with so many of these requests coming in from companies wanting to ship in South Carolina the only way we can do that find out what's being shipped and where and we may need to really look into that in terms of what we have already allowed to come in and really look into the future of things that's coming in the state. That's the only way we can find out.

MR. LIVINGSTON: There's a lot of things being shaped into South Carolina. A lot of insurance companies basically mandate that you use their mail order pharmacy. Because of that, medicines arrive in the mail instead of going to your local pharmacy to pick them up. So I think it's definitely an issue. It's a safety issue.

MR. BUSHARDT: Is it something we need to give to the Pharmacy Practice?

MR. ROSE: We've kind of already had this before. We can't check with UPS and FED-EX, the mail service, all these people. The only thing I know you can do is write each mail order pharmacy and ask them what their policy is.

MS. BUNDRICK: We did that on renewals last time, time before last. They had to send in their policies and procedures, but sometimes policies and procedures are only as good as the paper they're written on.

MR. ROSE: It's like the South Carolina wholesalers, if they dump delivery off to a service, they're not going to have any control over it either, how long something sits in a truck before it's delivered. It is an important thing. I just think it's a very hard thing to control. The only way to control it is by legislation. I don't mind taking it to the Pharmacy Practice Committee. We can come up with legislation.

MR. BUSHARDT: Yes, or should it go to the Legislative Committee?

MR. ROSE: I think it's appropriate.

DR. RICHARDSON: Come from the Practice Committee to the Legislation Committee.

MR. BUSHARDT: You're just delaying, you're putting two months behind there. Why don't we ask the

Legislative Committee to discuss that. Put that on their agenda for their next meeting and I'll get you some ammunition. I got some ammunition for that.

MR. ROSE: It is certainly a legitimate concern.

MR. BUSHARDT: We all understand that. This worried me forever, but what are you going to do about it. That's the thing.

MR. ROSE: That's the hard thing. And I don't really think, Lee Ann, that any state as far as you know or I don't know of any state that has come up with an answer for that problem.

MS. BUNDRICK: To the best of my knowledge I don't know if they have.

MR. LIVINGSTON: Some of them are much hotter and colder than South Carolina like Texas, Oklahoma and the states in the middle of the country.

MS. SANDERS: The Board of Pharmacy got a call I believe it was yesterday, we received a phone call from a patient and they had ordered their medication off of the internet from another country and were calling the Board, it was something that was supposed to be temperature-control, and they were calling the Board of Pharmacy wanting to know where they could get assay to make sure they got the right drug. True story. We just told them we didn't have anywhere we could tell them.

MR. BUSHARDT: I'm not going to get to committee reports, because I have changed all of the committees around and I did not get them out in adequate time for the committees to get together. I know Dock has one and Leo has one. We didn't change those two. Before I get going good, I've sent everybody a letter asking them to take a certain committee. I've sent them the guidelines for selecting your own committee. You have free reign to select your committee, if you want to change your committee or whether you want to leave it intact as long as it fits the guidelines. Whenever you get your committee together I need you to send it to Marilyn so she can send out, whenever you have a committee meeting, she can send out a note to let everybody know that the meeting is coming up. If you all can handle that, I would greatly appreciate it.

MS. RUSSELL: Dan, can you tell us who the committee chairs are?

MR. BUSHARDT: Addison has Legislative Committee and he has Compounding and that includes the compounding task force. Leo has RPP and Finance. Dock has Pharmacy Practice and Nuclear. Rob has Technology and Medication Integrity. That's yours, Carole. And Rebecca has pharmacy technician. And I have not got one on continuing education at the time, because we got two new ones coming up pretty

soon and we will find a committee for them. That's what it is at the present time. I didn't try to overburden the new members until you finally get your feet wet and then you'll have your opportunity later on down the road to have others. Do you want to start off with yours, Leo? S decided not to show.

COMMITTEE REPORTS:

DR. RICHARDSON: I have two people from RPP here. I'm sure they want to make some comments after. Let me get started with it first by saying this. We had one of the best RPP meetings that we've had I think since I've been a part of this process on Friday, last Friday, September 9. Let me say a couple of things regarding RPP which I think is important. As I understand this from Dr. Coleman who has been a part of RPP and a physician, been around a long time, I think he's president emeritus of RPP. From what we gather, and that includes me, we don't think that there is another program in any other state that does what our RPP program does. Now, Lee Ann, you may correct me if I'm wrong, but we do more, I say we, because I mean RPP, provide more services for the State of South Carolina than we know of any other program that's similar to what we do.

What we also want to say to you the success rate we have more volunteers, we say volunteer, people who

volunteer to come into RPP that's going through the program than any other group of people. So what we're saying is if you volunteer to go to RPP, the success rate is great.

One of the other things that I need to share with you in addition to that, ladies and gentlemen, I'm sorry, I guess I got caught up in this, but I do have, what I'm saying to you is I do have some copies that I can share with you. We don't mind you using this, because we think that out of this program there can be several articles that can be published regarding what RPP does. And we just feel so good about it. The one thing that, I guess one thing, what we like to share with you nursing admissions are down. We seem to think that's because of the cost. They are down and even though we have more nurses in the program, they just aren't able to afford it. The economy we think may have something to do with that.

These two gentlemen will come and share with you some other things. What I think we should also be concerned about that nursing admissions are down and medical and pharmacy admissions are up. So make sure that something is going on that we aren't quite sure of yet. I think that we can also say to you who is using what, who is using what medication and probably, I'm not sure why, but there's some statistics that you have in front of you to

sort of verify what we are saying. I haven't said that. I'm going to ask Mr. Sheheen and Mr. Wilson to come and share some thoughts with us regarding RPP and some other things I think that we want to share with you regarding what RPP is all about. I think I've done a good job in trying to be their representative for the Board of Pharmacy and for RPP. Mr. Sheheen and Mr. Wilson.

MR. SHEHEEN: Thank you, Dr. Richardson. I'm the director of RPP and Mr. Wilson is our legal counsel and liaison with LLR and the boards. And what Dr. Richardson said is true. Our voluntary admissions are up which we feel like is very heartening. We're glad for that, that people have decided they want to get help and are coming to us, but another thing that you will see in the report with that is the people who come into it voluntarily have a higher rate of successfully completing the program. That is skewed somewhat by what Dr. Richardson said, because with nurses we lose them more than we do any of the other professions and as he said what we have identified as the fact that there is a financial cost of it. But also with nurses, and this is something we discuss with them readily, is they have different parameters with their probation and it's harder for them to get work because they have to get supervision and they have to get quarterly reports and do certain things. So people get a nurse that's not

encumbered with RPP and the Nursing Board dictates then they'll hire the other nurse where it's not that way in the other professions. So we are having more success, more success with completions and a higher rate of volunteers with pharmacists and the Medical Board.

We are currently somewhere around 575 active clients which seems to us, and we don't know and I say this cautiously, because if I say it too loudly our numbers will spike, I don't want to jinx this, but it looks like we may have plateaued somewhat between 550 and 600. We've been that way for sometime. Couple years ago for a couple of years we were averaging about 240 admissions a year and now we're in the 180 to 190 range which is much more manageable. As far as budgetary constraints, we cannot put on another case manager and we like to cap it at 75 clients per case manager. We found through our research over the years that that's what's more manageable and give the quality of care we want to give and right now we got several people that are in the 75 to 80 range of our case managers, but most of them are the 60 to 70 range and so we have room for more enrollments as they come. So those are the big numbers that Dr. Richardson was talking about and the things that we have identified there.

As far as the drugs of abuse that we are seeing, what is getting people to us is still opiates are the main

vehicle that are getting people to us and what we see is not what is across the board as far as society. Society, you see a lot of cocaine, methamphetamines, those type of things. We are seeing more opiates, benzodiazepine, alcohol and recent, in the last couple of years, more central nervous system stimulants and what we've seen in pharmacists, pharmacists is looking at the prescription medications that they are on, we're starting to see quite a few pharmacies that are on Adderall and we have our beliefs about that, but that would be our speculation, not something that we've been able to do. We went with a different company for our data management system, what we do our electronic case management and drug testing through a system called First Lab. We've been with them over two years now and they're very proficient in the way that data is collected so we can do better studies and better research and get you better numbers so for those who haven't been here before, on the Board for a while, our quarterly report is much bigger and thicker than it used to be, because our data management person gathers a lot more information. We won't go through that, but we will be glad to answer any questions you have about that.

In saying all that, a dilemma that we have had for years has been our clients being with us and coming to us with a specific problem having been caught diverting or

fraudulent prescriptions or getting into trouble and coming to us as a voluntary client with a particular drug. And as I said 60 percent of those are opiate pain medication and then our contractors always said that it's abstinence is the only exceptions if you have a valid prescription from a physician who says that you need the medication and the dilemma that we faced for a while now not knowing how to handle it and have done several different things to handle it is those prescriptions that people are getting their drug that got them to us, I hate that term drug of choice, because I don't think anybody chooses to be a drug addict, but the drug got them to us we got so many people that are getting prescriptions for those medications. As we all know health care has changed so much over the years and our physicians for various reasons don't have as much time to spend with the patients and so the medications are more easily available and patients can get the medication easier. So in trying to deal with that, the strategies we've used for several years that we talked to you about have not helped in that. So what we have done is I did some research in some other states and found some other states, and as Dr. Richardson said also, we're unique in that we cover all the disciplines. We're one of the few states. Virginia and Washington state are the only other two states that have

as many boards under their umbrella for monitoring as South Carolina. We feel like we're on the leading edge of doing that and so we found that what seemed to work best in this dilemma has been to have an abstinence policy and if someone has to have a prescription for an opiate medication, a benzodiazepine or a central nervous system stimulant and some other medications such as Soma or others that we list, and I could talk more about why Soma is in there if you need me to. We went to training recently and that's one of the number one drugs of abuse right now is Soma. So what we are proposing we would like, and we presented this to the Medical Board and they voted unanimously to support us in this, is that our abstinence policy state that if you have a need for any of these medications we need the prescription for it, but also you cannot practice while you are on the medication. Say you have to have surgery and you have to have Vicodin for six days after your surgery or you break your leg and you need some pain medication or you got some real anxiety going on and you need to get it under control, you can take those medications but you can't work in your profession, because we don't feel they're safe taking those drugs and working. And then when they are able to stop the medication, then they have to produce a clean urine drug screen before they can return to practice. We

don't stop monitoring. We don't encumber their license. We just take them out of work until they come off the medications. As I said, we presented it to the Medical Board and they supported unanimously. The week after next we present it to the Nursing Board and shortly after that when the Dental Board meets we'll talk to them about it too. Rick has written up the policy and how we will proceed with it. I think you have it. Lee Ann has provided it.

MS. BUNDRICK: It's a handout.

MR. SHEHEEN: You have the policy. We wanted to give you a little bit of the history there. As I said if you want to see another strategy we tried that failed, I'll be glad to tell you those. Several different things, but if there's any question about that or about our quarterly report or our data or how we're operating right now, we'll be glad to answer them. I'll see if Rick has anything else he wants to add.

DR. RICHARDSON: Before you get started, there are 15 different agencies that's in our RPP.

MR. WILSON: 15 boards. We have all the health and medically related as of week before last. We had the long term health care, Lee Ann's other board, came under our umbrella and that's the last one. That's as large as we are going to grow. I know there's a lot of folks out

there with alcohol and drug problems, but they're not in health care. They don't present the same risk that folks in that field do as other people. Our mission is limited to them. And that plateau that Frankie mentioned before it probably, knock on wood, we'll see if it holds, but that could be where we are, grow to that. The 15 boards we're looking at the numbers, 98 percent of our clients come from the Medical, Pharmacy, Dental and Nursing board, 98 percent. Those other 11 boards only make up 2 percent of the clients that we have. The numbers are there. We can look at the reasoning for that, but probably accessibility and hours worked and on your feet and all those kind of things, stress, has as much to do with it as anything.

The big thing in this policy to recognize is this applies only to the SC RPP participants. So these are people with the diagnosis of some substance abuse or dependence who have a problem and we know it's not the substance, it's a brain thing that goes with all of this. So regular practitioners are not affected at all by this. It's just the people who are in the program in recovery who are trying to manage to keep their practices kept in safe fashion and that's what we are looking to do is keep them in safe practice and get them through the five years that we feel like is a good foundation for continued

recovery after that. It's important to remember the scope of what we are talking about. The proposal coming off of Virginia and also the nurses in North Carolina have used this for many years, it works as an incentive for these people to get off what they're on. They need their medication. We don't want them not to have it, but when you start to compare public safety and one's individual needs, you got to have the balance tip in favor of public safety. They can't practice until they have a documented return to abstinence and there's every incentive for them to do that as quickly as they can. It's worked well in those other states and was recommended by them and Dr. Early down at Talbert is a leading expert in the field and he concurred that this was by far the best approach to it than trying to somehow guess whether somebody on the drug was safe. Just kind of nuts to think that they could be. We've done this as Frankie said to bring to all the boards and we would ask that this Board review and hopefully approve the change in our abstinence policy so we can go forward with that.

MR. SHEHEEN: To put it in perspective too like Rick said it's only for our clients, it's not for all pharmacists. It's just pharmacists who have an addiction problem and I didn't brief myself on the number of pharmacists we currently have, but I would guess about 75

to 80 and if you look at our data, it's in there, if you look at our data, if we look at percentages what we've been able to look at with this problem is positive drug screens with a prescription for the drug that got them to us is about 30 percent of our clients. So if we have 75 pharmacists, we're only talking about 20 people total for the whole state. So it's not an enormous problem in numbers, but it's an enormous problem for us and our clients and knowing something about addiction, the relapse rate and the way that taking those medications for an addict can trigger a relapse is phenomenal.

DR. RICHARDSON: I guess there is one other thing that we forgot to mention. Dr. Kowaski stated that the Medical Board if I'm correct has a statement that's given to the medical students when they graduate regarding RPP and I think what the RPP would like to recommend to Pharmacy Board that if there is an outgoing process for pharmacy students that we do something similar. And so we just want to put that on the agenda for possible consideration in terms of trying to follow suit with what the Medical Board is doing.

MR. SHEHEEN: Along that line, we are available, myself in particular, to do education or to tell new licensees, I do, this year for the second year, have talked to the pharmacy students at MUSC and we actually had a

recovering pharmacist go in and tell his story and we told them about RPP. For the second year I talked to the students at Presbyterian College School of Pharmacy about our program and about addiction. I did a short one hour seminar about substance abuse and recovery with them and then talked about RPP too. We're available to do that throughout the State whenever it's necessary.

DR. RICHARDSON: When we go into executive session I'll ask the Board to see what they think about the policy and ask that they approve it at that time. If there is an exit interview for pharmacy students we would like to have you consider looking into informing them about...

MR. WILSON: Once upon a time I know you all used to interview every applicant, but I don't think you've done that in many years. That was such a burdensome process.

MS. BUNDRICK: We do reciprocity.

MR. WILSON: That would make sense. So my guess is we probably need to address this with the deans and the schools and see what we can do about taking the message there. If we had your support I'm sure that would probably help open the door a little bit better, because Frankie is always available and willing to go and do these things. He's pretty good at it. If he could just get on the floor, he'll do okay in giving the message.

DR. RICHARDSON: Any questions?

MR. ROSE: I had one question. Do you feel like we're getting less nurses from institutional practice than you did before?

MR. SHEHEEN: Less?

MR. ROSE: Less nurses from institutions.

MR. SHEHEEN: No, sir.

MR. ROSE: Not from physician's offices or anything.

MR. SHEHEEN: No, sir. We still get the same amount from institutions.

MR. ROSE: I thought it would be better since they have continuous, they have a continuous record of the number of drugs, of each drug.

MR. SHEHEEN: Dispensing machines such as that?

MR. ROSE: Not only that, but just their -- and also all the diversion tools they have with those machines now.

MR. SHEHEEN: Some of the ways that some of the nurses divert medications are simply amazing.

MR. ROSE: I realize that. And a lot of times it's a nurse that's always willing to help somebody out by going to get something out of the machine for them.

MR. SHEHEEN: You know all the games. I won't sit here and list them, but there's plenty. We hear new ones all the time, but, no, we're not seeing less from

institutions. In looking at our percentages from each board even though our nurses seem not to be as many and we're getting more voluntary from pharmacy and medical, nurses are still the highest percentage per profession. We're close to 2 percent of the nurses statewide are in our program with Pharmacy and Medical it's close to 1 percent.

MR. ROSE: I thought for sure we're getting less hospital pharmacists than retail pharmacists. I would think they would get caught faster with all the inventory control.

MR. WILSON: They probably would, but I'll tell you, and Frankie is being nice, but some institutions don't report.

MR. ROSE: They don't report violations?

MR. WILSON: They don't tell anybody. They don't call DHEC. They just fire the nurse or whatever and never tell anybody. Or the pharmacist. And they go on to the next place and pick up where they left off.

MR. ROSE: And there's no law against that.

MR. WILSON: That's right. It's not helping anybody, but there are some that do, not a lot, but some that do that.

MS. COLEMAN: It's against DEA regulations to fail to report. At our institution I do all the diversion cases for the pharmacy and the nurse managers are very

clear, it's one tablet or one injection, it's reported and they're serious about it. My question to you guys would be, what do you think the impact of the marketing campaign to put your third shift employees on drugs like Provisual as having a big effect on the community you're seeing coming to you or your clientele more likely to be one?

MR. SHEHEEN: I don't think we're tracking like that. We may be able to put them back in...

MS. COLEMAN: I just wonder if the number of times that someone comes to you because of a drug like Provisual is on --

MR. SHEHEEN: What is Provisual for?

MS. COLEMAN: It's a CNS stimulant to keep people up at night to try to regulate sleep cycles in people who are on a different rhythm and those who stay up all night.

MR. SHEHEEN: They have to have that for third shift?

MS. COLEMAN: They found that -- I found Diet Mountain Dew works. They say that it's better for blood pressure and less heart failure and all this stuff if your sleep cycle is adjusted. So they're coming out with studies saying this is healthy for you.

MR. ROSE: I don't think it is.

MS. COLEMAN: I don't either. But I'm wondering if these drugs are causing more people to come to you,

because that's a very serious issue.

MR. SHEHEEN: It's not a drug that has come up in our enrollments and our drug histories as a problem along that line, but Adderall has just increased tremendously hundreds of percent in the last couple of years.

MS. COLEMAN: I wonder if people are misdiagnosed, if they're depressed rather than ADD.

MR. SHEHEEN: I think misdiagnosis of ADD and ADHD with adults is rampant.

MR. BUSHARDT: Any other questions? Thank you very much. Dock, your report.

MR. ROSE: We had a Pharmacy Practice Committee meeting on Tuesday August 30, 2011 at 2:00 o'clock in the afternoon. We had a lot of people there, probably 20-25 people. We appreciate people coming to the Pharmacy Practice Committee whether they're members or not, and sometimes the best ideas come from people just attending the meetings. We certainly encourage anyone that's interested in, well, everybody should be interested in the practice of pharmacy that's a pharmacist. We appreciate all the people that do attend. One of the first things that came up was Mr. Tom Porter, he works for Harmony Care Hospice and he's interested in having a pharmacy. They have one pharmacy with a pharmacy permit delivering to all of their hospices, medications for each patient. And our

motion was to allow Harmony Care Hospice to apply for permits for all their facilities. This would be non-dispensing permits except for the pharmacy-permitted site. And have policies and procedures with all the statistics and everything included that medications are being handled correctly and delivered to patients, such things as temperature control, security and all those things. Also this came up again also under Central Site for County Disability Board facilities. They're interested in a similar idea. What we are making a motion is that these facilities that fill patient medications in one location and send them to another location rather than mailing them directly to the patients like a mail order pharmacy would do, have policies and procedures and all the facilities receiving the medications would be non-dispensing pharmacy outlets so our pharmacist inspectors could go by and see them and inspect their facilities. At the present time this is not legal to do without Board approval.

MS. BUNDRICK: Or legislation.

MR. ROSE: Or legislation. But central fill would take care of this.

MS. BUNDRICK: Not really, because it's going to another pharmacy. It would be more like the FQHC language that passed.

MR. ROSE: But it's similar to central fill.

MS. BUNDRICK: Right, similar concept, just not to pharmacy.

MR. ROSE: It's possible that, for instance, the hospital system could be filling employee prescriptions and sending them to all their pharmacies in the system plus they might be sending them to doctor's office in the system too which would be a non-permitted possibly facility or it might have a non-dispensing permit which that means pharmacy to pharmacy. That's the motion and it doesn't need a second since it comes from the Committee.

MR. BUSHARDT: Any discussion? All in favor of the motion raise your right hand. Opposed likewise. Motion passes.

MR. ROSE: The next thing we have, I'm a member of the Hospital Pharmacy Practice Managers Group, have been for six or seven years, and one of the questions that came up in there was techs providing especially for patients in the ER and patients that are just admitted to the hospital doing a medication history and listing current medications and their allergies and things like this, drugs they don't want to take, things like that as opposed to an RN doing it or a LPN or pharmacist doing this. This would be in a situation where the pharmacist would review their current list of medications, et cetera, and make recommendations to

the physician if necessary. This was not a motion. This was just for information, but I feel like and the group felt like that only the state certified technicians should do this if we're going to allow this. We didn't really make it into a motion, but it is something that I feel like state certified techs could do in a hospital or institutional setting.

MS. SANDERS: The main thing that we have to remember is reminding them that if it is a pharmacy technician they're still working under the supervision of a pharmacist and not under an ER staff person that's not pharmacy, that they're still reporting to pharmacy.

MR. ROSE: I think a lot of these places are places that now have an ER pharmacy. I don't think you would have a technician working in an ER that didn't have a pharmacy in the ER or I don't think -- this came up in this Pharmacy Practice Manager's Digest, because they had new pharmacists in the ER working and that was one of the things they felt like they could do for the ER. It also could be like you say on the floor and, for instance, St. Francis Hospital has decentralized pharmacists in Greenville and if they had a technician working with them, they could provide this service for the physician as patients are admitted. They would be working directly with a pharmacist on that floor.

MR. BUSHARDT: Is there any regulation that says they have to be nurses or technicians or something that could just, anybody or the secretary do that?

MR. ROSE: It should be done by a professional person.

MR. BUSHARDT: Is there any regulation that states one way or the other?

MS. COLEMAN: You're talking about medical histories?

MR. BUSHARDT: Yes.

MS. COLEMAN: Not that I'm aware of. I will look real quick on the Medical Practice Act and see.

MS. RUSSELL: It's also done by medical students.

MR. ROSE: In a larger hospital, but in Georgetown Hospital they wouldn't have medical students or St. Francis in Greenville they wouldn't have medical students or pharmacy students for that matter. What would your estimation be, Robert, do you think there is any laws concerning who can list the medications for patients.

MR. SPIRES: No, and I think that's one of the things I think most hospitals are struggling with who should do that medicine reconciliation, because I think most of us feel like it should be another pharmacist and maybe the pharmacy technician at least under the direction of a pharmacist certainly is more qualified to do I think a

med list than a LPN.

MR. ROSE: Or somebody from a doctor's office, a secretary.

MR. SPIRES: Again I think hospitals are trying to address that issue who is the best person to do that if it's not going to be the pharmacist. Do we let the nurse do it, do we let the resident do it or physician do it or who does it. So I think they're trying to work on that issue, but I don't think there's anything in our statute that addresses it, because med reconciliation was not thought of when we did a state certified tech and listed those specific duties that a state certified tech could do. Again it's a new field, new area to come up.

MR. ROSE: What they're trying to do is get a more accurate medication record and a more accurate -- a lot of patients come in with a whole bag full of bottles and you got to go through each one of them and say are you currently taking this, how often do you take it.

MR. SPIRES: There are multiple pharmacies, multiple physicians, end up in the ER, you have no clue of what they're really taking. That's what you're trying to accomplish, when they're admitted to the hospital, you will have a good record and, of course, when they're discharged on the back end, hopefully we'll have a good list of medications they're supposed to be taking when they leave

the hospital. Then they go to their pharmacy, you got a good list of the medications.

MR. ROSE: You actually might find out they're going somewhere else and you don't have a medication list.

MR. SPIRES: Right, that's the idea behind it. I don't how many hospitals actually use a pharmacy technician. I know it's been discussed kind of around, but I don't know.

MR. ROSE: This is a national discussion.

MR. SPIRES: It's kind of bubbling to the surface now.

MR. ROSE: It would give the physician a more accurate medication list than they're having now especially if they take the time to find out whether they're actually taking the medication or not. When the pharmacist looks over it and they duplicate medications or inappropriate medications, they could certainly.

MR. SPIRES: Right, and, of course, the technician would not be making the clinical decision. All they're doing is taking the list and compiling it for the pharmacist for them to look at, is there duplications, is there interaction, those kind of things. The technician is not doing that clinical piece of it.

MR. ROSE: This was just something that came up that we wanted to discuss. I don't think we need to make a

motion on it or anything. It's just something we need to think about.

MR. SPIRES: I guess the question is, is there anything that prevents the technician from doing that. That's the question. We kind of hear is there anything in our Practice Act that prevents the technician from doing that. As far as I know there's nothing in our Practice Act that prevents that as long as they're working under the direction of a pharmacist.

MS. SANDERS: One of the calls I received was they want to move one of my pharmacy technicians and still call them a pharmacy technician and base them out of the ER and I said just remember if they are going to be a pharmacy technician, go by the definition, they have to be under the direct supervision of a pharmacist. That was the only thing I reminded them of.

MS. COLEMAN: Does that mean that if they were to enter a medication history that it has to be verified by that pharmacist or does that mean the pharmacist has to be standing there?

MR. BUSHARDT: I think it means you don't have the ratio. The pharmacy they took them out of would still be one short, one less than what it normally would be, because that would be considered under the pharmacist.

MS. COLEMAN: That's hospital too.

MR. ROSE: They just need to be under direct supervision of a pharmacist.

MR. SPIRES: Right, but what you don't want is a pharmacy technician in the ER by themselves doing that. That to me I don't think would be appropriate either.

MS. COLEMAN: That's the question, though. Does supervision have to be face to face or can it be electronic? If nothing is approved in the computer system until the pharmacist looks over it, is that supervision?

MR. BUSHARDT: I don't think this is anything we can answer right this minute. We don't even know whether we have to have any kind of supervision for that matter. It could be a clerk.

MR. SPIRES: That's the problem. It could be anyone.

MR. BUSHARDT: That's what I say. We don't have enough knowledge to even have this conversation right now until we get it cleared up about what the law says and which direction we want to take. I think it's something to make us aware of it, but then it's something that we might look at down the road.

MR. ROSE: The reason I brought it up is it's going to happen if we don't say yes or no. It's going to happen anyway. Do you agree, Cle?

MS. SANDERS: It is happening.

MR. ROSE: Right now.

MS. SANDERS: Yes.

MR. ROSE: I know in the Greenville Hospital System they have a pharmacist on duty in the emergency room or two pharmacists actually that work.

MR. BUSHARDT: Ivy, are you going to check on that and you might want to --

MS. COLEMAN: Yes. In the Medical Practice Act Section 40-47-1260 it talks about, I know this is just a small section, but it talks about the limits of anesthesiologist assistant and it talks about medical histories and anesthesiologist assistant can do it and that's the only place that I see it mentioned in here. Makes me wonder if they're looking at that as not something that has to be done by a medical personnel.

MR. ROSE: They would only do surgery cases.

MS. COLEMAN: Yes, sir.

MR. BUSHARDT: I don't think it's anything that we can --

MR. ROSE: I think we need to be aware of it and I think that as our inspectors are in like hospitals they need to be aware of it and think about looking at things like this to find out what's going on and Cle said she has had several calls already about it. All these pharmacy managers I would assume are reading this same information

I'm reading at a national level and there's a lot of questions on there about many areas in the pharmacy practice management and what they're allowing people to do. One thing that came up if the interns don't pass the national boards by such and such a date, what do you do and there's anything from they have to have it the day they start to we give them until August 1 or September 1 and then we terminate them. Some of them give them another chance. What it is, it's a national forum to kind of get everybody on the same page as pharmacy managers on how to do things. That was the idea of it and hopefully the Pharmacy Practice Committee can keep up with it.

Moving on to the next thing. I got a few more here. Some old business. We had electronic emergency boxes. Emergency kits. Lee Ann talked to Connie Overton with the South Carolina DEA about electronic emergency boxes and DEA is not in agreement and will send a letter confirming this. We have not gotten the letter yet. It's been two weeks. And before that it was a month. Mr. Spires made a motion that electronic emergency boxes could be used in long term care facility settings provided it does not contain any controlled substances and it was seconded by Mr. Hubbard and carried unanimously. Since this comes from a committee it doesn't require a second. What this is allowing nursing facility pharmacist to do is to keep

all non-controlled medications for emergency use in an electronic emergency box, because we don't want to say anything else, because they get all upset about machines. That is the question.

MR. BUSHARDT: DEA would only be involved if it had controls, correct?

MR. ROSE: That's correct.

MR. BUSHARDT: Motion has been made. Does not need a second. Any more discussion? All in favor of the motion please raise your right hand. Motion passes unanimously.

MR. ROSE: Next is transferring of on-hold prescriptions. For instance, if CVS Pharmacy Number 1 received an e-prescribed prescription or a fax prescription, telephone prescription, but was actually meant to go to CVS Pharmacy Number 13 and CVS Pharmacy Number 13 calls CVS Pharmacy Number 1 and says Ms. Green is here to get her medication and it's not here and evidently you got the prescription instead of us. And what we're trying to do is, you can't transfer a prescription that has not been logged into the computer. So what we were saying was that if you just had a prescription, the only way you can let them have it is to physically take it to them. You can't give them a copy of it, because it hadn't been filled and doesn't have an identification number to go back to in

case the information given over the phone is incorrect. So Ms. Beasley made a motion that all on-hold non-controlled prescriptions be assigned a prescription number in each pharmacy so it can be transferred to another pharmacy. Ms. Coleman seconded the motion and it carried unanimously. That's coming from the committee, doesn't need a second.

MR. BUSHARDT: Any other discussion on this motion? All in favor signify by raising your right hand. Carries unanimously.

MR. ROSE: Just remember in all pharmacies to make sure that they go ahead and assign each prescription that comes in a number so they can be transferred if they need to be. If they're never filled, it's okay. If they need to be transferred, you have a tracking record for that.

MS. BUNDRICK: There's a lot of confusion, getting a lot of phone calls primarily because it went out in the RX alert for controlled substances. Because in the controlled substance statute they say that you cannot transfer it if it has not been filled.

MS. COLEMAN: That's why our recommendation was for non-controls.

MR. BUSHARDT: How is the best way to get this to the public?

MR. ROSE: We don't have to. It's a motion.

MR. BUSHARDT: Put it in the newsletter.

MS. BUNDRICK: Newsletter.

MR. ROSE: I guess we could put it in the newsletter coming up.

MS. COLEMAN: I think the people who got confused by this are reading newsletters. So I would say they would be reading your newsletter.

MR. ROSE: I think all these things that have come up so far would be good to put in the newsletter.

The next thing that came up was medication on time type of nursing home pharmacy dispensing to nursing homes for patients and Cle brought this up and we kind of came to an impasse with it. One time, I don't know if anybody ever looked back and saw whether medication on time was not approved to start off with. Seems like when I first came on the Board it came up and it was not approved by the Board, but anyway. What we've done -- the problem is that when you send the patient's medication out the first of the month, they get a whole bingo card or whatever full of medication and if during the month one of the medications is discontinued or another medication is added, it has to be changed. If it's added, it's not as bad, because you can just send another card with AM or PM or noon or whatever time to do it, but if you got to go back and take one out, the question came up that some

people were putting it back in stock bottles and things like that which is a violation of the Pharmacy Practice Act and also whether or not they credit the patient or not cannot be our concern, but we certainly care about whether they put it into stock bottle. It may not be the same lot number or expiration date. So we have to come up with some kind of procedure for these changes. So I took the, as chair, decided to appoint a subcommittee to do this and Ms. Long is going to be the chairman of this subcommittee and Ed Vess is going to be a member and Sanders and also Ms. Boguski is also going to be on it. Cle also discussed unused medications being transferred from prescription bottles into the doctor sample inventory which is not a good practice either. That's something we probably need to send to the Medical Board or discuss with the Medical Board.

MS. SANDERS: It was through one particular group that we had run into this that's already been addressed with them. I guess since we were asking the Practice Committee to put something about consultant pharmacist responsibilities that we could put that as a portion of that.

MR. ROSE: We kind of thought we ought to have some kind of educational program for pharmacists-in-charge sometime in the future. I don't believe, it's not my

personal opinion, that most pharmacists-in-charge actually know what they're responsible for. They're pretty much responsible for everything in the practice whether they're keeping up with it or not. If you're a PIC I would suggest you be very careful.

MS. SANDERS: And consultant pharmacists too.

MR. ROSE: And consultant pharmacists too. Diversion can certainly happen in their area too very easily. Things like using expired drugs and this kind of stuff too. We have people that are very conscientious and then we have some -- I remember a few years ago one consultant pharmacist that couldn't even tell us where the pharmacy was.

The last thing, Mr. Chairman, Mr. Hubbard brought up a discussion of multiple prescriptions on one blank and also preprinted prescriptions. Additional prescriptions added on the margin on the side which we don't want to do. Actually Ms. Bundrick said that preprinted prescriptions should only have one drug and one set of instructions on it and we have seen, I think you brought one that had three different drugs on it and check to use or not to use for an ophthalmology practice I think it was, or maybe eye surgery cases. Saw it somewhere. But anyway it had more than one. Mr. Hubbard also discussed the same thing that Mr. Hook did about the storage temperatures and delivery

temperatures. If you got a question, I will respond to questions.

MS. COLEMAN: If I could ask a point of clarification. When we were at that meeting and we talked about preprinted prescriptions, you can get them, gosh, they'll put as many on a paper as they can fit. But computer-generated is different if you have a patient whose going to get three medications and those are customized to that patient, you can generate that prescription and give it to the patient?

MS. BUNDRICK: Correct.

MS. COLEMAN: That's even cleaner than have them write it. You can actually read it.

MR. ROSE: They need to separate it, not all slammed down one side of the page. I've seen some that you couldn't tell where one prescription stopped and the next one started because they were so close together. The format is very important with that. He was mainly talking about practices where the physician has three or four drugs that they use all the time and they're just checking them off and then one might not be checked and you don't know whether to do it or not. It might have a strength change, but if you check on the right hand side...

MR. BUSHARDT: Ophthalmologists are notorious for that and they have three drugs they want before surgery,

but that's not legal?

MS. BUNDRICK: If it's preprinted, that's like --

MR. ROSE: Or stamped.

MR. BUSHARDT: It has to be one drug at a time.

MS. BUNDRICK: One drug and one set of instructions. That's not me. That's what the statute says.

MR. BUSHARDT: We will send some prescription pictures to inspectors to go see these?

MS. BUNDRICK: Rob gave us the prescriptions. What we do --

MR. BUSHARDT: Every town has this same problem, not just in his area.

MS. BUNDRICK: I have actually sent letters to Dean to review to send out to these people for corrective action and give them a certain period of time to send us their corrective action. If they don't send it to us, we don't have jurisdiction over them and we would have to refer it to the Medical Board or Dental Board or wherever, Nursing Board for them to handle the disciplinary part of it to make them do it. They may ask us to come in or ask our advice, but we can't do much of anything other than ask for the corrective action.

MR. BUSHARDT: What is the policy that we need to do to get this corrected?

MR. ROSE: I think we need it appoint Davis Hook and Rob Hubbard to a subcommittee to take care of this situation, gather all these things and go to the Medical Board or whatever board has jurisdiction.

MS. SANDERS: Inspectors are actually recognizing some of that when they go on inspections or actually going and visiting and making phone calls. We do have places that will fax them to us, but the letters will help us to expedite it quicker.

MR. ROSE: Anyway it's a problem and I appreciate Rob bringing that to my attention and Davis with his problems with temperature control and storage temperature. I would say if the Board Members or anybody else has these prescriptions we need to get them to the inspectors.

MR. BUSHARDT: Or either get this letter written and then we send it out.

MS. SANDERS: The inspectors will probably be the ones sending the letters when they receive the...

MS. BUNDRICK: Or if we receive it as a complaint or whatever, we would send it out that way.

MS. SANDERS: Or if they see them when they go in to do an inspection or if it's sent to us, but please remember when you give us stuff like that HIPAA so cross out patient names. We don't need all of that.

MR. ROSE: That's all, Mr. Chairman.

MR. BUSHARDT: Nothing on nuclear?

MR. ROSE: No.

MR. BUSHARDT: Any other topics that we need to discuss as a group today?

MR. LIVINGSTON: I will quickly tell you we are continuing to meet, the 795/797 task force. We are working quickly on that or continuing that process. We are getting close to having 797 taken care of.

MR. BUSHARDT: How about the gallery, do you have anything you need to add? Do I hear a motion for executive session?

MR. ROSE: So moved.

MR. LIVINGSTON: Second.

MR. BUSHARDT: We got a motion and a second. All in favor raise your right hand. Okay.

(Executive Session.)

MR. BUSHARDT: Do I hear a motion to come out of executive session?

MR. LIVINGSTON: So moved.

MR. ROSE: Second.

MR. BUSHARDT: All in favor raise your right hand. Opposed. We are out of executive session. Do I hear a motion on technician application request by Troy Smith.

MR. LIVINGSTON: Mr. Chairman, I make a motion

that we deny his request.

MR. ROSE: Second.

MR. BUSHARDT: Any discussion? All in favor signify by raising your right hand. Opposed likewise.

DR. RICHARDSON: I abstain.

MR. BUSHARDT: One abstain. Motion passes. Request approval for non-resident wholesale Vet Medica, do I hear a motion?

MR. ROSE: I make a motion that we approve the request from Vet Medica.

MR. BUSHARDT: Do I hear a second?

MS. RUSSELL: Second.

MR. BUSHARDT: Any discussion? All in favor signify by raising your right hand. Opposed likewise. Motion approved unanimously. The request for approval of state certified pharmacy technician application Alice Tompkins Beck.

MS. LONG: Make a motion that we deny this request.

MR. ROSE: I second that.

MR. BUSHARDT: Discussion? All in favor signify by raising your right hand. Denied unanimously. Request approval of non-resident pharmacy application Special Design Health Care, do I hear a motion?

DR. RICHARDSON: Yes, Mr. Chairman. I move that

we approve this request.

MR. BUSHARDT: Second.

MR. HUBBARD: Second.

MR. BUSHARDT: Approved and seconded. Any discussion? All in favor raise your hand. Mr. Rose votes no. So it is approved still. Request approval of non-resident wholesale/distributor/manufacturer application eVenus.

MS. RUSSELL: Mr. Chairman, I move that we deny this request.

MR. BUSHARDT: Do I hear a second?

MR. LIVINGSTON: Second.

MR. BUSHARDT: Any discussion? All in favor of the denial motion raise your hand. Opposed likewise. Ayes have it.

DR. RICHARDSON: Mr. Chairman, I would like to make a motion that we approve the request from RPP about the abstinence policy statement please.

MR. BUSHARDT: Do I hear a second?

MR. HUBBARD: Second.

MR. BUSHARDT: Any discussion? All in favor of the motion raise your hand. Unanimous. Can I have a motion for adjournment.

MR. ROSE: So moved.

MR. HUBBARD: Second.

MR. BUSHARDT: No discussion on this issue. All in favor raise your hand and we will go home.

AT THIS TIME THE HEARING IS ADJOURNED.

CERTIFICATE OF REPORTER

This is to certify that I, Kathryn J. Lindler, am a duly qualified court reporter; that I took the minutes and testimony in this meeting; that the said respondents and applicants were duly sworn by me and cautioned to speak the whole truth; that I took notes, by Stenograph Machine, of the said minutes and testimony; that the said notes were reduced to typewriting by me; and that the foregoing pages, inclusive, constitutes a full, true and correct record of such minutes and testimony and oral proceedings, to the best of my skill and ability.

I do further certify that I am neither employed by nor related to any of the parties in this matter or their counsel; nor do I have an interest, financial or otherwise in the outcome of same.

In Witness Whereof, I have hereunto set my hand and official seal this 26th day of September, 2011.

_____

Kathryn J. Lindler
Notary Public for the State of South Carolina
My Commission Expires June 4, 2018