NEVADA STATE BOARD OF PHARMACY



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MINUTES

September 5 & 6, 2018

BOARD MEETING

Hyatt Place 1790 E. Plumb Ln. Reno, Nevada

Board Members Present:

Leo Basch Kevin Desmond Wayne Mitchell Jason Penrod

Melissa Shake Robert Sullivan Kirk Wentworth

Board Staff Present:

Larry Pinson Dave Wuest S. Paul Edwards Shirley Hunting

Brett Kandt Yenh Long Joe Depczynski Kristopher Mangosing

President Basch read the mission statement of the Nevada State Board of Pharmacy to reiterate the Board's duty to carry out and enforce the provisions of Nevada law to protect the health, safety, and welfare of the public.

1. Public Comment September 5, 2018 9:05 AM

Don Mello addressed the Board with concerns about access to his pharmacy records while receiving care. Mr. Mello asked Board Staff to acknowledge receipt of his complaint and requested statistics about total complaints to the Board. President Basch thanked Mr. Mello for his comments.

2. Approval of July 18-19, 2018 Minutes

President Basch requested a correction to p.10 to clarify that Dr. Craig Weingrow's Controlled Substance Registration and Practitioner Dispensing Registration were revoked for not less than one year, effective immediately.

Melissa Shake requested clarification on p.11 regarding whether there was public comment.

Board Action:

Motion: Wayne Mitchell moved to approve the July 2018 Board Meeting Minutes with

the suggested corrections.

Second: Jason Penrod

Action: Passed unanimously

- 3. Applications for Out-of-State Pharmacy Non-Appearance
 - A. American Service and Product, Inc. Orland Park, IL
 - B. Avera eCare Pharmacy San Antonio, TX
 - C. Caremart Pharmacy LLC South Richmond Hill, NY
 - D. Crestview Pharmacy Services LLC Tempe, AZ
 - E. CTCA/Rx Newnan, GA
 - F. CVS/pharmacy #10762 Ashland, VA
 - G. Dolphin Health Pharmacy Oakland, CA
 - H. Gaston Pharmacy #1 Dallas, TX
 - I. Hudgins Pharmacy, Inc. Mathews, VA
 - J. Metro Drugs Pharmacy Department Hoboken, NJ
 - K. Midtown Express Pharmacy Nashville, TN
 - L. Omnicare Clinical Intervention Center Spartanburg, SC
 - M. Rainwood Rx LLC Elkhorn, NE
 - N. RARx, LLC Nashville, TN
 - O. Route 300 Pharmacy Newburgh, NY
 - P. SRX Pharmacy Tampa, FL
 - Q. Tarrytown Expocare, LLC Austin, TX
 - R. Uptown Drugs Pharmacy Allen Park, MI
 - S. Valencia Pharmacy, Inc. Houston, TX
 - T. Walnut Creek Rx LLC Omaha, NE

Applications for Out-of-State Compounding Pharmacy - Non-Appearance

- U. Lakeview Pharmacy of Racine Inc. Racine, WI
- V. Phar-More Rx, LLC Bala Cynwyd, PA
- W. Premier Pharmacy Services Cliffside, NJ

Applications for Out-of-State Wholesaler – Non-Appearance

- X. Alcon Laboratories, Inc. Ft Worth, TX
- Y. Aguestive Therapeutics, Inc. Warren, NJ
- Z. AveXis, Inc. Libertyville, IL
- AA. Circassia Pharmaceuticals Inc. Morrisville, NC
- BB. Crosstex International, Inc. Hauppauge, NY
- CC. Direct Success Pharmacy Department Farmingdale, NJ
- DD. Exelixis U.S., LLC Alameda, CA

- EE. Horizon Medicines LLC Lake Forest, IL
- FF. Innogenix, LLC. Amityville, NY
- GG. Interchem Corporation Allendale, NJ
- HH. JM Logistical Services LLC Laredo, TX
- II. Medunik USA, Inc. Rosemont, PA
- JJ. Melinta Therapeutics, Inc. Lincolnshire, IL
- KK. Oak Drugs Inc. Chestnut Ridge, NY
- LL. Pharma-C, Inc. Paramus, NJ
- MM. Primus Pharmaceuticals, Inc. Scottsdale, AZ
- NN. Quagen Pharmaceuticals LLC West Caldwell, NJ
- OO. Salus Medical, LLC Phoenix, AZ
- PP. Schnucks Pharmacy Distribution Center Earth City, MO
- QQ. ScieGen Pharmaceuticals Inc. Hauppauge, NY
- RR. Scripts Wholesale Inc. Brooklyn, NY
- SS. Spectrum Chemical Mfg. Corp. New Brunswick, NJ
- TT. Western Wellness Solutions, LLC San Francisco, CA
- UU. World Gen, LLC Paramus, NJ
- VV. WG Critical Care, LLC Paramus, NJ
- WW. Xellia Pharmaceuticals USA, LLC Bedford, OH
- XX. XPO Logistics Supply Chain, Inc. Ft. Worth, TX

Applications for Out-of-State Medical, Devices, Equipment and Gases – Non Appearance

- YY. Aeroflow Urology, Inc. Arden, NC
- ZZ. Avondale HME 3, Inc. Temecula, CA
- AAA. Back Braces Plus, Inc. Pinellas Park, FL
- BBB. B Braun Interventional Systems, Inc. Breingsville, PA
- CCC. Butterfly Network Guilford, CT
- DDD. C&E Medical, INC. San Diego, CA
- EEE. Cardinal Health 200 LLC Atlanta, GA
- FFF. Cardinal Health 200 LLC Chicopee, MA
- GGG. Cardinal Health 200 LLC Crystal Lake, FL
- HHH. Cardinal Health 200 LLC Deland, FL
- III. Cardinal Health 200 LLC Norfolk, NE
- JJJ. Cardinal Health 200 LLC Wabasha, MN
- KKK. Clarify Medical, Inc. San Diego, CA
- LLL. Discovery Medical Supply Largo, FL MMM. Essential HME 2, Inc. El Cajon, CA
- NNN. Gemstar Inc. Monsey, NY
- OOO. SD Orthotics, Inc. National City, CA
- PPP. XPO Logistics Supply Chain, Inc. New Jersey, NJ

Applications for Nevada Pharmacy - Non-Appearance

QQQ. ER at Aliante, a Department of Mountain View Hospital – North Las Vegas, NV RRR. Sav-on Pharmacy #3489 – Las Vegas, NV

Application for Nevada Medical, Devices, Equipment and Gases – Non Appearance

SSS. Lincare Inc. – Fallon, NV

President Basch disclosed that he works for HCA, the same company as ER at Aliante (QQQ) but he can participate without bias.

President Basch asked the Board about concerns with Lincare Inc. (SSS). David Wuest explained that those concerns have been addressed during recent inspections.

Melissa Shake expressed concern that B Braun Interventional System's (BBB) application did not specify what products the company sold. Kirk Wentworth expressed concern that Dolphin Health Pharmacy's (G) website contains pre-printed prescriptions that are not in compliance with Nevada law.

Board Action:

Motion: Jason Penrod moved to approve the Consent Agenda with the requirement that

B Braun Interventional Systems (BBB) provide a summarized list of the products it dispenses and Dolphin Health Pharmacy (G) remove/edit the preprinted prescriptions from its website in accordance to Nevada law.

Second: Melissa Shake

Action: Passed unanimously

4. Discipline

A. Anteekah McClelland, PT (18-027-PT-S)

S. Paul Edwards, Esq. appeared before the Board to prosecute the case on behalf of the State.

Respondent Anteekah McClelland was not present, nor did counsel appear on her behalf.

Melissa Shake disclosed that respondent used to be employed by Walgreens, where Ms. Shake is presently employed. Ms. Shake felt she could participate in the matter fairly and without bias.

Paul Edwards moved to have Exhibits 1 through 4 admitted to the record.

President Basch admitted Exhibits 1through 4 into the record.

Mr. Edwards described the facts of the case and offered proof that Board Staff served the Accusation as required by Nevada law. He indicated that he would ask the Board to enter default in light of Ms. McClelland's failure to respond to the Accusation and failure to appear.

Mr. Edwards also presented and described Exhibits 1 through 4 to prove the factual allegations stated in the Accusation.

Board Action:

Motion: Jason Penrod moved to find that Board Staff properly served Ms. McClelland.

Second: Wayne Mitchell

Action: Passed unanimously

Board Action:

Motion: Melissa Shake moved to find that the Board has jurisdiction over the matter.

Second: Jason Penrod

Action: Passed unanimously

Mr. Edwards asked that the Board find Ms. McClelland in default for being properly served but not responding to the allegations, and further for findings that the evidence proves each of the factual allegations.

Board Action:

Motion: Jason Penrod moved that the evidence provided by the Board Staff proves

each of the factual allegations.

Second: Melissa Shake

Action: Passed unanimously

Mr. Edwards states that based on the Board's findings of fact, Ms. McClelland is guilty of violations set forth in Causes of Actions 1 through 4.

Board Action:

Motion: Jason Penrod moved for a conclusion that the findings of fact prove that Ms.

McClelland is guilty of violations set for in Causes of Action 1 through 4.

Second: Melissa Shake

Action: Passed Unanimously

Mr. Edwards recommended that the Board revoke Ms. McClelland's Pharmaceutical Technician Registration, Certificate of Registration No. PT18976 and include in the Board's Order that Ms. McClelland may not reapply for not less than one year after the effective date of the Order, and in order to re-apply, she must pay an administrative fee of \$500.

Board Action:

Motion: Jason Penrod moved to revoke Ms. McClelland's Pharmaceutical Technician

Registration, Certificate of Registration No. PT18976, for not less than one year, and that in order for her to re-apply for registration she must appear

before the Board and pay an administrative fee of \$500.

Second: Melissa Shake

Action: Passed unanimously

B. Noah D. Silva, PT (18-059-PT-N)

Paul Edwards appeared before the Board to prosecute the case on behalf of the State.

Respondent Noah D. Silva was not present, nor did counsel appear on his behalf.

Paul Edwards moved to have Exhibits 1 through 5 admitted to the record.

President Basch admitted Exhibits 1through 5 into the record.

Mr. Edwards described the facts of the case and offered proof that Board Staff served the Accusation as required by Nevada law. He indicated that he would ask the Board to enter default in light of Ms. McClelland's failure to respond to the Accusation and failure to appear.

Mr. Edwards also presented and described Exhibits 1 through 4 to prove the factual allegations stated in the Accusation.

Board Action:

Motion: Jason Penrod moved for a finding that the Board served Mr. Silva in

accordance to Nevada law.

Second: Melissa Shake

Action: Passed unanimously

Board Action:

<u>Motion:</u> Jason Penrod moved that Board has jurisdiction over this matter.

Second: Melissa Shake

Action: Passed unanimously

Mr. Edwards recited the factual allegations of the case. Based on those factual allegations, the Executive Secretary brought four Causes of Actions related to diversion.

Board Action:

Motion: Melissa Shake moved to make findings of fact for factual allegations 2 through

5 based on the evidence presented and based on Mr. Silva's failure to appear

and to respond to the Accusation.

Second: Jason Penrod

Action: Passed unanimously

Mr. Edwards stated that based on the findings of fact and the evidence presented, Mr. Silva was guilty of the violations stated in Causes of Actions 1 through 4.

Board Action:

Motion: Jason Penrod moved that the findings of fact and the evidence provided

through Exhibit 1 through 5 demonstrated that Mr. Silva was guilty of the

violations alleged in Causes of Actions 1 through 4.

Second: Melissa Shake

Action: Passed unanimously

Based on the Board's conclusion that Mr. Silva is guilty of the violations set forth in Causes of Action 1 through 4, Mr. Edwards recommended that the Board revoke Mr. Silva's Pharmaceutical Technician Registration, Certificate of Registration No. PT19453, for not less than one year. If Mr. Silva reapplies after one year, he must first pay an administrative fee of \$500 to partially offset the Board's costs of prosecuting the case and appear before the Board.

Board Action:

Motion: Jason Penrod moved to revoke Mr. Silva's Pharmaceutical Technician

Registration, Certificate of Registration No. PT19453, for not less than one year, and to require Ms. Silva to pay an administrative fee of \$500 and to

appear before the Board if he applies for reinstatement.

Second: Kevin Desmond

Action: Passed unanimously

C. Ivan Goldsmith, MD (17-101-CS-S)

Brett Kandt, Esq. appeared before the Board to prosecute the case on behalf of the State.

E. Brent Bryson, Esq. and John Clarke, Esq. appeared as counsel for Dr. Ivan Goldsmith.

Dr. Goldsmith appeared and was sworn by President Basch.

Mr. Bryson moved to have the case dismissed on the basis that media coverage may have biased the Board Members.

Mr. Kandt addressed Mr. Bryson's motion and recommended that the Board proceed with the hearing.

President Basch and each Board Member affirmed that he or she had not been influenced by any media coverage of the case and that each could participate in the hearing fairly and without bias.

Board Action:

Motion: Jason Penrod moved to deny Mr. Bryson's motion to dismiss.

Second: Kevin Desmond

Action: Passed Unanimously

Mr. Bryson asked the Board to deny the prosecution's previously-filed motion to quash the subpoena for investigator Matthew Wehn.

President Basch asked Mr. Bryson questions to probe the relevance of Mr. Wehn's anticipated testimony.

Mr. Kandt stipulated to stay the motion until the after the defense presented its case and cross-examined other witnesses, reserving the resolution of the State's motion to quash until that time.

Mr. Kandt declined to invoke the role of exclusion.

Mr. Bryson invoked the role of exclusion and witnesses were asked to retire to the hallway until called.

Mr. Kandt presented the State's opening statement.

Mr. Bryson stated that the respondent Dr. Goldsmith would assert his 5th Amendment right against self-incrimination, then presented Dr. Goldsmith's opening statement.

Mr. Kandt called Yenh Long, Pharm.D., Administrator of the Nevada Prescription Monitoring Program as the State's first witness.

Dr. Long appeared and was sworn by President Basch. She then answered questions and offered testimony during direct and cross examination by counsel.

During Dr. Long's examination, Mr. Kandt offered exhibits marked as 1 through 8 and B through D, to which Mr. Bryson made certain objections. President Basch probed each objection and ruled to admit Exhibits 1 through and B through D into the record.

During Dr. Long's cross-examination, Mr. Bryson offered Exhibits A and E, to which Mr. Kandt offered no objection. President Basch admitted Exhibits A and E into the record.

Board Members questioned Dr. Long about the PMP, to which she provided testimony to the Board Members' satisfaction.

Mr. Bryson called Detective Matthew Wehn to testify before the Board.

Detective Matthew Wehn appeared and was sworn by President Basch prior to answering questions and offering testimony during direct and cross examination by counsel.

Mr. Bryson called Inspector Luis Curras to testify before the Board.

Inspector Luis Curras appeared and was sworn by President Basch prior to answering questions and offering testimony during direct and cross examination by counsel.

Mr. Kandt and Mr. Bryson each provided closing arguments.

Mr. Kandt asked the Board to make findings of fact based upon the facts alleged in paragraphs 1-11 of the accusation and the evidence presented, with the additional finding that Dr. Goldsmith's PMP account is the only possible source of the PMP information published by the Las Vegas Review Journal.

The Board Members deliberated.

Board Action:

Motion: Jason Penrod moved the Board to conclude that it has jurisdiction over Dr.

Goldsmith and this matter.

Second: Melissa Shake

Action: Passed unanimously

President Basch and Mr. Penrod read and discussed articles 2-11a of the Accusation, which contained the factual allegations against Dr. Goldsmith.

Board Action:

Motion: Kirk Wentworth moved to find the factual allegations in paragraphs 2-11a are

true and correct.

Second: Jason Penrod

Action: Passed unanimously

The Board Members deliberated about the applicable law listed in the Notice of Intended Action and Accusation and whether Dr. Goldsmith had violated those provisions.

Board Action:

Motion: Jason Penrod moved to find Ivan Goldsmith guilty of the First Cause of Action.

Second: Kirk Wentworth

Action: Passed unanimously

Board Action:

Motion: Jason Penrod moved to find Ivan Goldsmith guilty of the Second Cause of

Action.

Second: Kevin Desmond

Action: Passed unanimously

Board Action:

Motion: Wayne Michell moved to find Ivan Goldsmith guilty of the Third Cause of

Action.

Second: Jason Penrod

Action: Passed unanimously

Board Action:

Motion: Jason Penrod moved to find Ivan Goldsmith guilty of the Fourth Cause of

Action.

Second: Kevin Desmond

Action: Passed unanimously

Board Action:

Motion: Kevin Desmond moved to find Ivan Goldsmith guilty of the Fifth Cause of

Action.

Second: Jason Penrod

Action: Passed unanimously

Mr. Kandt offered documents that were previously marked as Exhibits 9 and 10 to support the State's request for reimbursement of its attorneys' fees and costs for prosecuting the case.

President Basch admitted Exhibits 9 and 10 into the record.

Mr. Kandt recommended that the Board require Dr. Goldsmith to implement policies and procedures to ensure that neither he nor anyone in his office may further misuse Dr. Goldsmith's access to the PMP and to provide a copy of those policies and procedures to Board Staff.

Mr. Kandt further recommended that the Board order Dr. Goldsmith to pay a \$10,000 fine, \$2,000 per cause of action, as well as \$16,130.68 in attorneys' fees and costs.

Mr. Bryson addressed Mr. Kandt's recommendations and deliberated.

Board Action:

Motion:

Jason Penrod moved for an order requiring Dr. Goldsmith to implement policies and procedures to ensure there is no further misuse of his access to the PMP, to provide a copy of those policies and procedures to Board Staff within 30 days of the effective date of the Board's order, to pay a fine of \$10,000 and the reasonable sum of \$16,000 in attorney fees and costs within 30 days of the effective date of the Board's Order. He further moved that Dr. Goldsmith's Controlled Substance Registration, Certificate of Registration No. CS20816 and Dispensing Registration, Certificate of Registration No. PD00413, be revoked. The revocation would be stayed and Dr. Goldsmith's registrations would be placed on probation for not less than one year.

Second: Melissa Shake

Action: Passed Unanimously

5. Request for Renewal of Pharmacist License:

Esther Kim

Esther Kim appeared and was sworn by President Basch prior to answering questions and providing testimony.

Paul Edwards provided some background as to Ms. Kim's request to renew her license.

Ms. Kim provided reasons for why she is asking for renewal. She explained her prior California discipline discussed the status of her California pharmacist license. Ms. Kim also

explained to the Board that she has been doing many things to change and educate herself in order to become more qualified for a renewal.

Mr. Edwards stated the facts of the accusations against Ms. Kim in California. The Board discussed the accusation.

The Board tabled Ms. Kim's renewal of her pharmacist license at her request pending resolution of the matter in California.

6. Request for Pharmacist License by Reciprocation:

Salem Mihalick

Salem Mihalick appeared and was sworn by President Basch prior to answering questions or providing testimony.

Ms. Mihalick described her Colorado discipline, the resolution of the requirements imposed by the Colorado Board, and her current work situation in Colorado.

President Basch questioned Ms. Mihalick about drug abuse and discussed with the Board Ms. Mihalick's request for reciprocation.

Board Action:

Motion:

Jason Penrod moved to approve Ms. Mihalick's application for reciprocation pending a successful PRN-PRN evaluation. If PRN-PRN recommends a treatment plan she must enroll and comply with all terms. If she falls out of compliance her registration would be suspended immediately. Staff to confirm license in good standing in Colorado.

Second: Melissa Shake

Action: Passed unanimously

7. Application for Out-of-State Pharmacy – Appearance

Marian Pharmaceuticals – Daphne, AL

Tabled to future meeting.

8. Application for Out-of-State Wholesaler – Appearance

Glasshouse Pharmaceuticals LLC – Mississauga, Ontario, Canada

Jan Sahai appeared and was sworn by President Basch prior to answering questions or providing testimony.

David Wuest provided background about the company and discussed the Board's history of approving licenses for entities outside of the United States.

Mr. Sahai described the details of his business to the Board's satisfaction.

The Board discussed the application for Out-of-State Wholesaler requested by Mr. Sahai.

Board Action:

Motion: Jason Penrod moved to approve the Out-of-State Wholesaler license with

conditions that Glasshouse Pharmaceuticals LLC will only provide FDA

approved products and will verify that all downstream distributors are properly

licensed and compliant with Nevada Pharmacy laws.

Second: Melissa Shake

Action: Passed unanimously

9. Request to Engage in the Practice of Pharmacy at a Site Other Than a Licensed Pharmacy – Appearance

Rosemary Gonzalez, R.Ph

Rosemary Gonzalez appeared and was sworn by President Basch prior to answering questions or providing testimony.

Paul Edwards provided background regarding the applicant's request. The applicant is asking to perform MTM outside of a pharmacy with a collaborative practice agreement.

Ms. Gonzalez elaborated on her current practice and the collaborative practice agreement. Ms. Gonzalez answered questions about her background to the Board's satisfaction.

Board Action:

Motion: Jason Penrod moved to approve Rosemary Gonzalez to Engage in the Practice

of Pharmacy at a Site Other Than a Licensed Pharmacy.

Second: Kevin Desmond

Action: Passed unanimously

10. Applications for Out-of-State Compounding Pharmacy – Appearance

A. Metro Drugs 3rd Ave Corp – New York, NY

Evon Zampitella appeared and was sworn by President Basch prior to answering questions or providing testimony.

President Basch explained to Ms. Zampitella why the Board asked Metro Drugs to appear before the Board.

Ms. Zampitella explained to the Board the process and procedures of how Metro Drugs operates. Ms. Zampitella explained that the company is up to USP 800 standards and has been inspected routinely.

The Board discussed Metro Drugs and the conditions to which they will allow the Out-of-State Compounding license.

Board Action:

Motion: Jason Penrod moved to approve the Out-of-State Compounding Pharmacy

License for Metro Drugs 3rd Ave Corp pending positive inspection by Board Staff at the expense of the applicant and completion of corrected application.

Second: Kevin Desmond

<u>Action:</u> Passed unanimously

B. Talon Compounding Pharmacy – San Antonio, TX

Ronda Wenzel appeared and was sworn by President Basch prior to answering questions or providing testimony.

Ms. Wenzel explained that this is an application for a change in ownership. Talon Compounding is working toward compliance with USP 800. Talon Compounding will be replacing the former pharmacist manager with Ms. Wenzel.

Ms. Wenzel answered questions about her past work experience and training to the satisfaction of the Board.

Board members discussed the request for change in ownership.

Board Action:

Motion: Jason Penrod moved to approve Talon Compounding Pharmacy's change of

ownership with conditions. Talon Compounding will work with Board Staff to

come into compliance with Nevada law.

Second: Melissa Shake

Action: Passed unanimously

C. TwelveStone Medical, Inc. - Murfreesboro, TN

Lee Golden appeared and was sworn by President Basch prior to answering questions or providing testimony.

President Basch explained that TwelveStone Medical is applying for an Out-of-State Pharmacy Compounding License.

Mr. Golden explained that TwelveStone Medical will not be providing sterile compounding products to Nevada and asked the Board if modifications are necessary to the application. Mr. Golden also explained the company's operations and listed the states into which the company provides sterile products.

The Board asked Mr. Golden about details of the non-sterile products TwelveStone Medical will provide to Nevada.

Mr. Golden answered questions to the satisfaction of the Board.

Board Action:

Motion: Jason Penrod moved to approve TwelveStone Medical, Inc for an Out-of-State

Pharmacy Compounding License. The applicant must modify their application

to remove sterile compounding.

Second: Kevin Desmond

Action: Passed unanimously

11. Applications for Out-of-State Outsourcing Facility – Appearance

A. Cantrell Drug Company – Little Rock, AR

James McCarley appeared and was sworn by President Basch prior to answering questions or providing testimony.

Dave Wuest provided background about Cantrell Drug Company and its recent interactions with the FDA, which led to the recent suspension of its license.

Mr. McCarley read a prepared statement giving background about himself and his company. Mr. McCarley explained the outcome of the company's most recent inspections and discussed the precautions his company has taken to ensure it is in compliance with Nevada law. Mr. McCarley requested that the Board approve Cantrell Drug Company's request for Out-of-State Outsourcing Facility pending a passed inspection by the FDA.

Yenh Long read a timeline that the Board Staff put together as a background to Mr. McCarley's testimony.

The Board deliberated and questioned Mr. McCarley to clarify certain facts. At Mr. McCarley's request, the Board tabled the application to allow Board Staff more time to obtain information and review additional documentation.

- B. PharMEDium Services, LLC Cleveland, MS
- C. PharMEDium Services, LLC Dayton, NJ
- D. PharMEDium Services, LLC Memphis, TN
- E. PharMEDium Services, LLC Sugar Land, TX

Melissa Shake recused from 11B-F because of her employment.

President Basch disclosed that he sees PharMedium packaging in his hospital where he works but can continue without bias.

Andrew Harrison and Ty Duginske appeared and were sworn by President Basch prior to answering questions or providing testimony.

Dave Wuest provided background about PharMedium and the recent actions taken by multiple Boards in other states. Mr. Wuest explained that Board Staff has reviewed the items PharMedium sent to the Board Office to ensure changes have been made.

Yenh Long provided a timeline created by the Board Staff of PharMedium's recent actions and disciplines.

Mr. Harrison and Mr. Duginske answered questions from the Board regarding their companies process and current standing with other Boards.

At the applicant's request, the Board tabled PharMedium's application for Out-of-State Outsourcing Facility pending Board Staff's review of additional information, including PharMedium's unredacted FDA 483, its most recent California Audit and additional documentation required by Board Staff. PharmMedium will be required to reappear in order to be approved.

F. SCA Pharmaceuticals LLC - Winsor, CT

Kevin Desmond disclosed that his company receives product from SCA but can participate without bias.

Wayne Mitchell disclosed that his company receives product from SCA but can participate without bias.

Cindy Mittman appeared and was sworn by President Basch prior to answering questions or providing testimony.

Ms. Mittman provided a letter of authorization to the Board.

President Basch and Dave Wuest questioned Ms. Mittman about company details pertaining to SCA.

Ms. Mittman provided information to the Board about SCA, inspections, and policy and procedures initiated to ensure compliance.

Yenh Long and Mr. Weust questioned Ms. Mittman about the company's redacted FDA 483, the 2018 inspection done by the FDA and went through each individual observation. Ms. Mittman answered all questions to the Board's satisfaction.

Ms. Long stated that she felt comfortable with SCA that it appears they addressed all the observations documented in the redacted 483.

Board Action:

Motion: Jason Penrod moved to approve SCA Pharmaceuticals pending the receipt of

unredacted 483's and responses to the Board Staff for review.

Second: Kirk Wentworth

Action: Passed Unanimously

12. Request to Add Compounding and Shipping of Sterile Compounded Drugs to an Existing Out-of-State Pharmacy License – Appearance

Schraft's 2.0 - Cedar Knolls, NJ

Adam Hait appeared and was sworn by President Basch prior to answering questions and providing testimony.

Mr. Hait provided background about the products Schraft's will be supplying to Nevada and the standards at which they operate.

The Board questioned Mr. Hait about policy and procedures.

David Wuest and Yenh Long questioned Mr. Hait about the products they will be compounding and providing to the State of Nevada.

Board Action:

Motion: Jason Penrod moved to approve Schraft's 2.0 to perform sterile compounding

pending receipt of VPP inspection. Board Staff is authorized to review and

evaluate the VPP inspection document.

Second: Wayne Mitchell

Action: Passed unanimously

13. Application for Nevada Wholesaler – Appearance

Forte Bio-Pharma, LLC – Las Vegas, NV

Jim Ferris appeared and was sworn by President Basch prior to answering questions or providing testimony.

Mr. Ferris provided background about his facility and what drug it will be supplying to Nevada.

President Basch questioned Mr. Ferris about his pharmaceutical background.

The Board continued to question Mr. Ferris about the medication his company will be providing to Nevada and the policy and procedures related to Forte Bio-Pharma.

The Board expressed concerns about relationships between Forte Bio-Pharma and physicians, application completeness and past history of employees.

Mr. Ferris answered questions from the Board to the satisfaction of the Board.

Board Action:

Motion: Jason Penrod moved to approve Forte Bio-Pharma, LCC pending receipt of

written clarification on Whittenbrock's criminal history question and Ansarinia's

criminal history. Board Staff is authorized to review and evaluate.

Second: Melissa Shake

Action: Passed unanimously

14. Applications for Nevada Pharmacy – Appearance

A. Sisu Healthcare Solutions, Inc. - Las Vegas, NV

Tom Dodge and Marcus Ulm appeared and were sworn by President Basch prior to answering questions or providing testimony.

Mr. Dodge and Mr. Ulm answered questions from the Board about the policies and procedures regarding their company. They explained the details surrounding their company and what kind of medications they will be providing to the public.

Jason Penrod questioned Mr. Dodge about his past criminal history and what he is currently doing to minimize chances of poor decisions.

Mr. Dodge answered all the questions about his past criminal and work history. Mr. Dodge explained what happened during his past inspections from the Board of Pharmacy.

Board Action:

Motion: Jason Penrod moved to approve Sisu Healthcare Solutions, Inc.'s application

for a Nevada Pharmacy pending positive initial inspection. Additional

inspections by Board Staff at 3 and 6 months at Sisu's expense. Pharmacy

Staff to receive formal training by a Board Staff-approved third party company. Board Staff to inspect to ensure pharmacy staff's sterile compounding competence. Board Staff authorized to approve third party sterile compounding training company.

Second: Kevin Desmond

Action: Passed unanimously

B. SNNAC, LLC - Reno, NV

Sunil Skaria appeared and was sworn by President Basch prior to answering questions or providing testimony.

President Basch disclosed that he received questions regarding SNNAC but can participate without bias.

Mr. Skaria explained to the Board what SNNAC does in the State of Nevada and the current situation surrounding employment.

Board questioned the policy and procedures regarding SNNAC and what practices will take place at their practice

Mr. Skaria answered the questions about SNNAC to the Board's satisfaction.

Board Action:

Motion: Wayne Mitchell moved to approve SNNAC, LLC application for a Nevada

Pharmacy pending a positive inspection from Board Staff. SNNAC shall hire

Pharmacist in Charge within 60 days.

Second: Melissa Shake

Action: Passed unanimously

15. Request to Retake the Nevada MPJE Examination – Appearance

Nazanin Kazeminy

Nazanin Kazeminy was not present at the Board Meeting.

Melissa Shake recused because Ms. Kazeminy was previously her intern.

Ms. Shake stated that Ms. Kazeminy was told that she did not have to appear before the Board.

Brett Kandt provided the Board with a background about Ms. Kazeminy's test history and the options they have to move forward.

Board Action:

Motion: Robert Sullivan moved to approve Nazanin Kazeminy to retake the MPJE.

Second: Kevin Desmond

<u>Action:</u> Passed unanimously

16. General Counsel Report

Brett Kandt reported that currently there is no pending litigation. Mr. Kandt reported that he responded to the Executive Branch Audit on behalf of the Board.

17. Approval of 2019 Board Meeting Dates

Tabled until future meeting.

18. Executive Secretary Report:

- A. Financial Report:
 - 1. Treasurer's Report
- B. Temporary Licenses
- C. Staff Activities:
 - 1. Meetings with other health care boards
 - 2. Treasurer training
 - 3. Governor's Opioid Accountability Meeting
 - 4. Critical Point Training, Yenh completed sterile compounding training
 - 5. Yenh participated in the National Board of Pharmacy Steering Committee
 - 6. Annual Report, update
 - 7. Paul presented at the Rotary Club Reno
 - 8. Participation in the Nevada Healthcare Option Meetings
 - 9. Roseman student rotation started August 20th
 - 10. Organized Crime Drug Enforcement Task Force National Award
 - 11. NASCSA
- D. Report to Board:
 - 1. Licensing software update
- E. Board Related News
 - 1. District Meeting October 14-17 Kansas City
 - NABP Member Forum November 28-29 2018
 - 3. NABP Executive Forum October 2-3 2018
- F. Licensing Activities Report

19. Notice of Proposed Regulation Workshop Pursuant to NRS 233B.061(2)

The purpose of the workshop is to solicit comments from interested persons on the following general topic that may be addressed in the proposed regulation:

Amendment of Nevada Administrative Code (NAC) 639.250: Restrictions on supervision. The proposed amendment to NAC 639.250 will allow for an increase in pharmaceutical technician to pharmacist ratio in certain pharmacy settings.

Tabled to future meeting.

20. Notice of Proposed Regulation Public Hearing Pursuant to NRS 233B.061(2):

Amendment of Nevada Administrative Code Chapter 639 to add a new section thereto providing for the prescribing or dispensing of controlled substances for the treatment of pain in conformance with Assembly Bill 474 from the 2017 Nevada Legislative Session. (LCB File No. R144-18)

The proposed amendments relate to controlled substances. They clarify the requirements a practitioner must follow when obtaining informed written consent to prescribe a controlled substance, entering into prescription medication agreements concerning a class of certain controlled substances and establishing a manner for obtaining an assessment of a patient's risk for abuse, dependency and addiction; and providing other matters properly relating thereto.

Tabled to future meeting.

21. Date and Location of Next Scheduled Board Meeting:

October 10-11, 2018 - Las Vegas, NV

22. Public Comment

There was no public comment.