

President Gene Minton called the meeting to order at 9:00 am with Board Members Dr. Parker Chesson, Carol Yates Day, Robert J. McLaughlin, Lazelle Marks, and Bill Mixon present. Also present were Executive Director Jay Campbell, Board Counsel Clint Pinyan, Director of Investigations Karen Matthew, Director of Operations Kristin Moore, Financial Administrative Services Director Gail Brantley, and Director of Licensing Deborah Stump. Present as visitors were: Tom Readling, NC Mutual; Rich DeBenedetto, Walgreens; Christine Davis, Cardinal Health; Brenda Shaffer, Quarles & Brady; David Moody, Mutual Drug; April Sorrentino, Target; David Catalano, Walgreens; James Satterfield, Walgreens; Katie Ringley, Walgreens; Bill Pickard, Campbell University; Rob Patchett; Jennifer Kuijer; Jia Kim, UNC/ESOP; Lauren Nienas, UNC/ESOP; Vishal Barnela, UNC/ESOP; Stephen Ries, Wingate/SOP; Melanie Thompson, Creighton Univ./SOP; Brent Longmire, Campbell Univ.; Bhavesh Patel, Carepoint Pharmacy; Erin Damery, UNC/ESOP; Michel Simon, UNC/ESOP; Chelsea Wilson, UNC/ESOP; Marie Waddles, UNC/ESOP; Wanda Andrews, NCBOP; Wendy Watson, NCBOP; Missy Betz, NCBOP; and Krystal Brashears, NCBOP .

#### Ethics Statement & Welcome

President Minton read the Ethics Statement regarding any conflicts of interest and/or appearances of conflicts of interest of any Board member. No conflicts were noted by any Board member.

#### Minutes of the May 2013 Board Meetings

The members received the May 14, 2013 meeting minutes prior to this meeting for review. It was moved by Mr. McLaughlin and seconded by Mr. Marks to accept the Minutes as submitted. The motion passed with no dissenting votes.

#### Consideration of Reciprocity Candidate – Martin Beasley

Martin Beasley appeared before the Board in consideration of his reciprocity application. Mr. Beasley submitted an application to reciprocate his pharmacist license from Alabama. Mr. Beasley has been out of pharmacy practice for more than 5 years. Board policy states that a pharmacist out of practice more than 5 years must obtain 1500 hours of practical experience and pass the MPJE and NAPLEX exams. Mr. Beasley requested a variance from the policy in that the Board reduce practical experience hours required to 250 hours and waive the NAPLEX exam.

After discussion, on a motion from Mr. McLaughlin, seconded by Mr. Mixon with no dissenting votes, the Board moved into closed session to discuss the matter. When open session resumed, Mr. Minton stated that on a motion from Mr. McLaughlin, seconded by Dr. Chesson with no dissenting votes, the Board waived the NAPLEX exam but would require that he receive 750 hours of practical experience before licensure. He is also required to pass the MPJE exam.

#### Consideration of Pharmacy Permit Application – Carepoint Pharmacy

Bhavesh Patel appeared before the Board in consideration of his out-of-state permit application for Carepoint Pharmacy. On the permit application RPh. Patel is listed as owner and pharmacist manager of Carepoint Pharmacy. Mr. Patel received a consent order of Reprimand from the Illinois Board of Pharmacy while working as pharmacist manager at Orsini Pharmaceutical

Services for inspection violations. Mr. Patel, duly sworn, gave testimony on the circumstances of the discipline. Mr. Patel stated that Carepoint Pharmacy is licensed in several other states and will not ship sterile compounded products into North Carolina.

After presentation of evidence and testimony, on a motion from Mr. Marks, seconded by Mr. Mixon with no dissenting votes the Board moved into closed session to deliberate the matter. Open session resumed on motion from Mr. McLaughlin, seconded by Mrs. Day with no dissenting votes. Mr. Minton stated that on a motion from Mr. McLaughlin, seconded by Dr. Chesson on a 5 to 1 split vote, the Board moved to approve the out-of-state permit application with conditions that Mr. Patel provide the Board's executive director the February 2013 inspection report conducted by NABP on behalf of the Iowa Board of Pharmacy and April 2013 certification report on Carepoint Pharmacy's clean room. If the reports disclose no concerns, then the Executive Director is authorized to approve the permit application. If permit is granted and Carepoint Pharmacy decides to ship sterile compounded products into North Carolina, it must notify the Executive Director 15 days prior to shipping any product.

#### Activation of Controlled Substance Reporting System Activation Link on Board's Website

Mr. Campbell stated that pharmacists may now register on the Controlled Substance Reporting System (CSRS) via portal on the NC Board of Pharmacy website. Almost 400 pharmacists have already registered on CSRS using the portal. Mr. Campbell thanked Kristin Moore and Debbie Stump for their work on this project.

#### Continuing Discussion of Pharmacy Compounding Regulation Issues

At the May 2013 Board Meeting, Mr. Campbell informed the Board on proposed federal legislation concerning compounding. S959 states that if a pharmacy compounds sterile products, compounds non-patient specific prescriptions, and ships compounded medications interstate it would be considered a "compounding manufacturer" and would be regulated by the FDA. Repackaging of sterile single dose vial products would also make a facility a "compounding manufacturer". A compounding manufacturer would also be prohibited by federal law from operating as a pharmacy.

Mr. Campbell stated that a compounding bill has also been introduced in the U.S. House of Representatives. The bill is similar to the Senate bill, but would not prohibit a compounding manufacturer from operating as a pharmacy. The House bill is also more restrictive than the Senate bill on what may be compounded.

Mr. Campbell updated the Board on the Compounding Working Group's recommendations that staff has implemented. The Board has retained Ken Latta as an expert consultant on compounding training for investigators and is working on a standard curriculum for compounding inspections. Investigative staff attended a compounding training session at Campbell University School of Pharmacy in May.

At the May 2013 Board Meeting, it was the consensus of the Board that Mr. Campbell draft a possible rule change to include USB 797 and 795 standards. Mr. Campbell requested that the Board approve a compounding working group subgroup to meet with him and Rob Patchett to review and make recommendations to the proposed rule change draft. Mr. Campbell recommended that Bill Mixon, Ken Latta, and Gigi Davidson make up the subgroup. It was the

consensus of the Board that the subgroup works with Mr. Campbell and Mr. Patchett on a draft of the proposed rule change.

Report on Possibly Contaminated Compound Products Distributed by Main Street Family Pharmacy, Newbern, Tennessee

Main Street Family Pharmacy, Newbern, Tennessee, permit #11044, voluntarily surrendered its NC out-state pharmacy permit May 24, 2013 for failure to comply with health and safety regulations resulting in the contamination of sterile products. Five North Carolina clinics received these products. To date, there are 2 possible cases of contaminated products reaching patients. Main Street Family Pharmacy has conducted a recall on the product and Board staff has been working closely with NCDHHS, DEA and CDC to monitor the situation.

Report on the Fourth Circuit Court of Appeals Decision, *North Carolina State Board of Dental Examiners v. Federal Trade Commission*

The North Carolina Board of Dental Examiners lost their appeal in the Fourth Circuit Court of Appeals regarding whether they are immune from anti-trust scrutiny stemming from a case brought against them by the Federal Trade Commission.

MALTAGON and Pharmacy Leaders' Forum Planning

Mr. Campbell stated that the planning for the 2013 Pharmacy Leaders' Forum and the 2013 MALTAGON meeting is coming together. He also presented the final invitation list for the forum.

NABP District III Meeting, Nashville, TN, August 3-5, 2013

Mr. Campbell reminded Board members that the 2013 NABP/AACP District III meeting will be held in Nashville, TN, August 3-5<sup>th</sup>. If any Board member would like to attend, they should contact Stacie Mason for registration.

Reports to the Board

Wendy Cox, UNC Eshelman School of Pharmacy, updated the Board on various issues at the school including graduation rates and enrollment.

Legislative Report, North Carolina General Assembly

Executive Director Jay Campbell updated the Board on potential legislation that could impact pharmacy including S.B. 33 which proposes that boards must consider certain criteria before denying licensure if candidate has criminal conviction. The bill has passed both chambers and has been signed by the Governor.

Financial Report

Gail Brantley, Financial and Administrative Services Director, presented the May 2013 financial statistics to the Board.

Report on Visit from State Auditor

The NC State Audit office conducted a financial audit and a Chapter 93B compliance audit of the Board. The final audit report has not been presented to staff as of the June 2013 Board meeting.

Investigative Statistics

Director of Investigations Karen Matthew presented the investigative report for June 2013.

Report from National Association of Board of Pharmacy Annual Meeting

Mr. Campbell stated that the report from the 2013 NABP Annual Meeting held in St. Louis, Missouri in May is now available on the NABP website.

Consent Agenda

Following a review of the consent agenda, it was moved by Mr. McLaughlin, seconded by Ms. Day to approve the consent agenda as presented. The motion carried with no dissenting votes. The following items were approved.

**Prehearing Conference**

**Consent Orders**

RPh. Joseph Black, license #07113, was subject of a prehearing conference held April 15, 2013, heard by Mr. McLaughlin, regarding allegations of a dispensing error where it was not clear which pharmacist dispensed the medication by cause of incorrect pharmacist initials on the medication and violating a rule of pharmacy while still under a 2012 Consent Order. Recommendation: **Active stayed suspension of 2012 Consent Order for 1 day**, other 19 days of suspension stayed for 2 years.

A copy of the Consent Order can be found elsewhere in the Minutes and are incorporated by reference herein.

**CPP Candidates**

RPh. Charlene R. Williams – License #15022

**Increase in Pharmacist to Technician Ratio**

1. Greer Pharmacy Lenoir, Permit # 08255, Kevin Alan Plant RPh App. 5/16/2013
2. CVS Pharmacy Charlotte, Permit # 10436, Pheshetta Fisher RPh App. 5/23/2013
3. Wal-Mart Pharmacy Wilson, Permit # 08028, Jonathan Eric Owens RPh App. 6/10/2013
4. Town & Country Drugs Taylorsville, Permit # 01435, Larry Wilson Jones RPh App. 6/10/2013
5. Biologics, Inc. Cary, Permit # 10544, Adam James Childs RPh App. 6/10/2013

Closed Session

On a motion from Dr. Chesson, seconded by Mr. McLaughlin with no dissenting votes, the Board moved in to close session to discuss a litigation matter. When open session resumed, Board authorized the filing of a brief amicus curiae supporting a Dental Board petition for rehearing en banc in FTC v. North Carolina Board of Dental Examiners.

There being no further business, the meeting adjourned at 1:45pm.

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Gene Minton, President

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E. Lazelle Marks, Vice-President

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J. Parker Chesson, Jr.

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Robert J. McLaughlin, Jr

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Carol Yates Day

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William A. Mixon