



COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Dr., Conference Room 2 (804) 367-4456
Richmond, Virginia 23230 (804) 527-4472

Tentative Agenda of Meeting

September 12, 2007

9:00 AM

<u>TOPIC</u>	<u>PAGE(S)</u>
Call to Order: Bobby Ison, Chairman	
• Welcome of new Board Member Gerard Dabney	
• Reading of emergency evacuation script-Cathy Reiniers-Day	
• Approval of Agenda	
• Approval of previous Board meeting minutes:	1-24
• June 12, 2007	
• Sanction Reference Committee	
• Inspection Committee	
Call for public comment	n/a
DHP Director's Report: Sandra Whitley Ryals	n/a
Legislation:	
• Review of legislative proposals-Scotti Russell, Elaine Yeatts	25-27
Regulations: Elaine Yeatts	
• Update on regulation processes	
> PPG final	28-33
> Periodic review-Regulation Committee needs to draft proposed rules for Board adoption at Dec. meeting	n/a
> petition for rulemaking by Sherry Fortune related to use of Pyxis in LTCF for stat and emergency boxes bypassing the requirement for pharmacist review prior to removing doses-withdrawn	34-35
> petition for rulemaking to allow pharmacists not licensed in VA, working at a non-resident pharmacy to perform outsourcing functions for hospital and LTCF pharmacies in Virginia	36-38
> other	
• Adoption of response to public comment and final pedigree regulations	39-58
Miscellaneous:	
• Sanction Reference Committee Update and adoption of worksheet and manual as guidance document	59-70
• Inspection Committee Update	n/a

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING**

June 12, 2007
Fifth Floor
Conference Room 2

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

CALL TO ORDER:

The meeting was called to order at 9AM.

PRESIDING:

John O. Beckner, Chairman

MEMBERS PRESENT:

Gill B. Abernathy
Willie Brown
Jennifer H. Edwards
Bobby Ison
David C. Kozera
Diane Langhorst
Leo H. Ross
Michael E. Stredler
Brandon K. Yi

STAFF PRESENT:

Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
Ralph Orr, Program Manager, Prescription Monitoring Program
Elaine J. Yeatts, Senior Regulatory Analyst
Ishneila Moore, Assistant Attorney General
Tiffany N. Mallory, Administrative Assistant
Sandra W. Ryals, Director, Department of Health Professions
Emily Wingfield, Chief Deputy Director, Department of Health Professions

QUORUM:

With ten members present, a quorum was established.

APPROVAL OF AGENDA:

Additions to the agenda included consideration of whether to allow a pharmacist licensed in another state to become licensed by examination in Virginia rather than reciprocity and the presentation of a possible summary suspension were added to new business. Hearing no other changes to the agenda, the agenda was approved as amended.

APPROVAL OF MINUTES:

Hearing no changes to the minutes of March 28, 2006 and March 29, 2007, the minutes were approved as provided in the agenda package.

PUBLIC COMMENTS:

Mr. Beckner called for public comment. There was no public comment.

- Issue of whether to docket a case against a pharmacy technician identified in a dispensing error case as making the error or to just docket against the checking pharmacist n/a
- Issue of whether a pharmacy may assign two different prescription numbers to a single schedule II prescription for which the total quantity is dispensed at one time, but in order to bill a third party for part of the quantity and have the patient pay cash for the remainder n/a
- Issue of whether drop boxes for new prescriptions may be outside a prescription department in a pharmacy n/a
- Issue of whether pharmacists may use stamps for initialing documents indicating a check for accuracy 71
- Request for newsletter topics n/a

Reports:

- Report on Board of Health Professions-Jennifer H. Edwards
- Executive Director's Report-Scotti Russell n/a
 - NAPLEX suspension update
 - New offices, staff responsibilities, and phone system
 - Upcoming meetings
 - report on disciplinary program-Cathy Reiniers-Day
 - report on licensing, inspections, website-Caroline Juran
 - report on the prescription monitoring program-Ralph Orr

New Business

- Appointment of 2007-2008 standing committees
- Set dates for Regulation Committee and ad hoc inspection committee, CQI committee, and drug disposal committee

Consideration of consent orders (if any)

Adjourn

***The Board will have a working lunch at approximately 12 noon and the formal hearing panel will convene at 1PM.**

It in conformity with DEA scheduling action. Mr. Yi moved, and the Board voted unanimously, to approve the draft legislation and submit it to the Director for inclusion in the agency's legislative submissions.

- **RENEWAL DATES**

The Board reviewed draft legislation that would remove language from the Code that assigns specific expiration dates to a number of different types of licenses issued by the Board. This will allow the Board to shift some of its license expiration dates to dates other than December 31 annually. Currently the 20,000-plus licenses issued by the Board expire on December 31 of each year which makes workload during that time period too heavy. The Board had agreed that pharmacists, pharmacy technicians, and possibly pharmacies should continue to renew at that time, but that other types of facilities could be shifted to alternate dates. Mr. Ross moved, and the Board voted unanimously, to approve the draft legislation and submit it to the Director for inclusion in the agency's legislative submissions.

- **MANDATORY REPORTING**

The Board reviewed draft legislation for a new section of law that would require two different types of mandatory reporting. The first type of reporting, in paragraph A of the new section, would somewhat mirror the mandatory reporting requirements of §54.1-2400.6 and require certain persons to report knowledge of either mental or physical conditions, or knowledge of actions on the part of another pharmacist or pharmacy technician that may either make that person's practice a danger to the public or that constitutes a violation of law for which the Board could take action. After some discussion, the Board reached agreement that the requirement for reporting should be made for every pharmacy owner, pharmacist, or pharmacy technician, with language included in the legislation to not obligate reporting if one of these persons knows that someone else has already reported it.

The second type of reporting, in paragraph B of the new section, would require reporting of every dispensing error with all identifiers of both the patient and the dispenser redacted. This would allow the Board to collect information and collaborate with USP, FDA and ISMP concerning types of errors for analysis of cause, and subsequently facilitate improvements to products and systems to reduce the possibility of the same error occurring again. Ms. Russell stated that if the Board would consider approving this portion of the proposal in concept, she would research other states, and the CQI committee would meet and wordsmith this part before it is released for comment from interested parties. She stated that there would need to be a definition of "dispensing error" or similar term to ensure that the Board gets the type of information that will be helpful. After much discussion, the Board agreed to allow the CQI committee to research and wordsmith the proposal with the

understanding that the full Board would review the language in September. Ms. Yeatts explained that we had not received the 2008 legislative proposals instructions and deadline dates, but if it follows previous years, there would be an opportunity for "placeholder" legislation if the deadline for submission to the Secretary is prior to the September 12 Board meeting, so the Board will be able to review and approve the final draft. Mr. Stredler moved, and the Board voted unanimously to approve the draft legislation in paragraphs A, C, and D and approve B in concept with final approval of that exact language at the September Board meeting, and submit it to the Director for inclusion in the agency's legislative submissions.

REGULATION UPDATE:

• **COLLABORATIVE
PRACTICE-FINAL**

Ms. Yeatts gave a brief update of current regulation processes. The Board reviewed a summary of public comment on the amendments to the collaborative practice regulations, 18 VAC 110-20-40 et seq. The comments were all positive, commending the Board for easing some of barriers to being able to participate in collaborative practice agreements. Kaiser made one comment requesting clarification of what the Board meant by the phrase related to alternates being at a "location where patients receive services" because they were thinking of centralizing their clinical pharmacy services to a location where patients were not routinely seen. Representatives from Kaiser were present at the meeting, and responded to some questions from Board members as to whether clinical pharmacists could talk to patients by telephone. It was determined that this phrase in the regulations did not mean that some of the contact could not be conducted by use of the telephone. Mr. Kozera moved, and the Board voted unanimously, to adopt the summary of public comment as presented and to respond to the commenters that the Board appreciates their participation in the process and that based on the comments received, the Board will make no changes to the proposed regulations. Mr. Yi moved, and the Board voted unanimously, to adopt the proposed regulations as published as final regulations.

• **NOIRA FROM
PERIODIC REVIEW OF
REGULATION 18
VAC 110-20-ET SEQ.**

The Board reviewed a draft NOIRA of issues or problems identified with this set of regulations during the periodic review recently concluded. Mr. Yi moved, and the Board voted unanimously to approve the draft NOIRA as presented.

• **PUBLIC HEARING ON
PEDIGREE
REGULATIONS,
18 VAC 110-50 ET SEQ.**

The Board held a public hearing on the proposed regulation for establishment of a pedigree system. Anne Leigh Kerr, Esquire, Troutman Sanders, provided comment on behalf of PhRMA that there may need to be clarification of 18 VAC 110-50-180 (A) to clarify that a manufacturer or wholesale distributor would not be required to provide information for the authentication of a pedigree for any transaction other than one in which that manufacturer or

wholesale distributor participated. She stated that one member company had concerns that the current language could be construed to require a manufacturer to provide information concerning transactions that were conducted by another party. There were no other commenters during this hearing. Mr. Beckner informed the public that written comments would be received until August 10, 2007.

REPORTS:

• **NABP ANNUAL MEETING REPORT, MAY 19-23, 2007**

Ms. Russell reported on the NABP annual meeting. Ms. Russell and Mr. Beckner attended the meeting on behalf of the Board. Ms. Edwards and Mr. Ross also attended the meeting.

- Ms. Russell stated that she had been successful in her election to the Executive Committee as District II's representative for a three year term, and acknowledged and thanked the Board members who had worked very hard to get her elected. Mr. Beckner also acknowledged the efforts of former board member Mike Ayotte in the campaign. Larry Mokhiber rotated to Committee Chair after serving as President, and Rich Palombo was elected President-Elect which gives District II three members on the Executive Committee.
- Continuing education presentations included sessions on pedigree requirements of Nevada and California, pseudoephedrine sales tracking, regulating for patient safety, and a regulatory update on issues affecting boards of pharmacy.

• **REPORT ON THE DISCIPLINARY PROGRAM**

Ms. Reiniers-Day presented the Board's disciplinary caseload report and stated that as of June 8, 2007, 253 cases were at the enforcement level, 93 cases were at the probable cause level, 9 cases were at the informal conference level, 31 cases were at the APD level, 10 cases were had Confidential Consent Agreements pending, 5 cases had pre-hearing Consent Orders pending for a total of 401 cases. Further, there were 236 cases at the Compliance Tracking level.

• **REPORT ON LICENSING, INSPECTIONS, NEWSLETTERS AND THE WEBSITE**

Ms. Juran reported that 275 inspections had been performed between March 1, 2007 and June 1, 2007. The majority of the inspections consisted of 182 routine inspections, 28 remodel inspections, 36 new inspections and 20 change of location inspections. Additionally, she reported that 599 licenses had been issued between March 30, 2007 and June 11, 2007. Of significance, 348 pharmacy technician registrations were issued and 125 pharmacy intern licenses were issued. Lastly, Ms. Juran reported that there had been a few changes to the Board's website including new pictures and the Board Powerpoint presentations to the section formerly designated solely to newsletters. Ms. Juran



stated that the Board continuously monitors the website in an effort to provide current and helpful information to its licensees.

• **REPORT ON THE
PRESCRIPTION
MONITORING
PROGRAM ("PMP"):**

Mr. Orr reported some highlights of the annual National DEA conference he attended the previous week:

- DEA plans to release a Methadone training module this summer after their Methadone Mortality Conference in July. Continuing Medical Education credit will be available for completion of the module.
- A more efficient electronic DEA106 is coming soon. It enables the person to edit and provides a greater drop down selection of drugs.
- The CII multiple prescription regulation has been sent to the Department of Justice and will then be sent to OMB. It is anticipated that the final regulation printed in the fall of 2007.
- The electronic prescription regulations are not ready for publication, however, discussions between DEA and HHS are continuing.
- Sometime in June, DEA registrants will be able to update name, address, etc online.

Mr. Orr reported that PMP now holds over 13 million records with about 1 million records being added each month. The number of non-reporting dispensers continues to decrease to less than 1% on the current non-reporting list. He stated that the number of registered users of PMP and noted that to date in 2007, PMP has processed 7881 requests for information compared to 6333 in the 2006 year. Mr. Orr stated that, while the workload is increasing, response time still averages less than 30 minutes and advised that the program hired a new part-time administrative assistant, Debbie Carter. Mr. Orr informed the Board of a new project with Virginia Commonwealth University's School of Medicine to develop a web-based module training program on pain management practices, laws and regulations and the role of PMP. The project should be complete in late September 2007. Mr. Orr advised the effect the recent Purdue Pharma settlement will have on PMP in that, if by the presiding Judge, PMP will receive \$20 million that will be placed into a trust for PMP. Only a certain amount of money may be removed from this fund on an annual basis and should fund the program for the foreseeable future. This new funding will enable the program to enhance its marketing and education functions as well as provide stability to the budget. The program forecast had been that in fiscal year 2009, the program would need to use licensing fees for its operation. Mr. Orr invited the Board members to attend the next meeting of the PMP Advisory Committee that is scheduled for July 25, 2007.

6

NEW BUSINESS:

- **ELECTION OF OFFICERS, BOARD OF PHARMACY, PERIOD JULY 1, 2007-JUNE 30, 2008**
- **2008 CALENDAR FOR FULL BOARD MEETINGS**
- **LICENSURE BY EXAMINATION FOR PHARMACIST IN ANOTHER STATE**

Mr. Kozera nominated, and the Board voted unanimously to elect, Bobby Ison for the office of Chairman. Mr. Stredler nominated, and the Board voted unanimously to elect, Dave Kozera for the office of Vice-Chairman.

Dates for the 2008 full Board meetings were determined and are as follows: March 12, 2008, June 11, 2008, September 10, 2008 and December 10, 2008.

Ms. Russell explained that she recently received an inquiry from a pharmacist initially licensed by examination in Tennessee, and by reciprocity in Maryland where she is currently living and working. Ms. Russell stated that because of a steep professional tax in TN, this pharmacist no longer wanted to keep her TN license, but was afraid to give it up because TN is her base state, and not all states allow reciprocity from a reciprocal state, even though NABP allows and facilitates this now. She requested that MD allow her to re-take the NAPLEX and be licensed there by examination, but MD told her that because she is already licensed by reciprocity, she cannot do that. She then called Virginia to see if we would allow her to become licensed here by retaking the NAPLEX. Ms. Russell stated that she has received similar requests from pharmacists who have had their licenses suspended or revoked in other states and because of the difficulty in getting the license back in the other state, want to start all over again in VA. She stated that NABP states that they can perform a clearinghouse check for VA about an applicant for licensure by exam who has already passed the NAPLEX and been licensed by another state. Ms. Moore advised the Board that unless it had a specific prohibition against allowing a person to be licensed by examination if they were already licensed in another state, and provided there were not disciplinary grounds to deny a license, that the Board would have to allow this. Ms. Russell stated that there was nothing that specifically prohibited it. Based on advice of counsel, the Board took no action, and staff will inform the requestor that she can apply.

COMMITTEE MEETING DATES

- **CQI committee**
- **Sanction Reference Committee**
- **Drug Disposal Committee**
- **Inspection Committee**

Mr. Beckner accepted volunteers for the "Inspection Committee" to work on revamping the inspection process. Ms. Russell stated that she will be contacting the members of the various committees to set dates in June or July as follows:

Ms. Abernathy, Mr. Stredler, Mr. Beckner, and Ms. Edwards with Sammy Johnson and Vicki Garrison
Mr. Ison, Mr. Ross, Mr. Kozera and Mr. Yi

Mr. Beckner, Mr. Yi, Ms. Edwards, Mr. Kozera, with Becky Snead and Lynn Rubenstein as consultants if needed

Mr. Ross, Mr. Ison, Mr. Yi, and Mr. Stredler with Sammy Johnson

and Vicki Garrison

SUMMARY SUSPENSION:

Closed session:

Mr. Ison moved, and the Board voted unanimously, to convene a closed meeting pursuant to § 2.2-3711.A.28 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of a possible summary suspension. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, Tiffany Mallory, Caroline Juran, Ishneila Moore, Tiffany Mallory, James Schliessmann and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.

KEISHA M. HAZELWOOD
Pharmacy Technician
Registration Number:
0230-009019

James Schliessmann, Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a summary suspension.

Reconvene:

Mr. Ison moved, and the Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision:

Mr. Ross moved, and the Board voted unanimously in favor of the motion that, according to the evidence presented, the pharmacy technician practice by Keisha Hazelwood poses a substantial danger to the public; and therefore, the registration of Keisha Hazelwood to practice as a pharmacy technician be summarily suspended and that a Consent Order be offered to Ms. Hazelwood for the indefinite suspension of her registration in lieu of a hearing.

**CONSENT ORDER
PRESENTATION:**

Closed Meeting:

Mr. Ison moved, and the Board voted unanimously, to enter into closed session pursuant to § 2.2-3711(A)(28) of the Code of Virginia for the purpose of deliberation to reach a decision regarding a consent order. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, Tiffany Mallory, Caroline Juran and Ishneila Moore attend the closed meeting.

Reconvene:

Mr. Ison moved, and the Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed session were heard, discussed or

considered during the closed meeting.

Mr. Ross moved, and the Board voted unanimously, to accept the consent order signed by Ronald Clark.

ADJOURN:

With all business concluded, the meeting adjourned at 1:15 p.m.

Elizabeth Scott Russell
Executive Director

John O. Beckner, Chairman

Date

**DRAFT/UNAPPROVED
VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD**

Tuesday, June 12, 2007
Fifth Floor
Conference Room 2

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

Orders/Consent Orders referred to in these minutes are available upon request

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 1:22 p.m.

PRESIDING: John O. Beckner, Chairman

MEMBERS PRESENT: Gill B. Abernathy
Willie Brown
Jennifer H. Edwards
Bobby Ison
David C. Kozera
Leo H. Ross
Michael E. Stredler
Brandon K. Yi

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
Ishneila Moore, Senior Assistant Attorney General

QUORUM: With nine members of the Board present, a quorum was established.

JEFFREY R. MARTIN
0202-204815

Mr. Schliessmann presented a signed Consent Order to the Board for consideration in lieu of proceeding to the formal hearing regarding this matter.

Mr. Martin was represented by Michael L. Goodman, Esquire.

DECISION: Mr. Ross moved, and the Panel voted 9-0 to accept the Consent Order as presented. The Consent Order made certain Finding of Fact and Conclusions of Law and reinstates Mr. Martin's license on probation with terms and conditions (Attachment 1)

RONALD J. MALSAM
License #0202-005051

A formal hearing was held in the matter of Ronald J. Malsam following the summary suspension of his

pharmacist license on February 14, 2007, and to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia.

James Schliessmann, Assistant Attorney General, prosecuted the case with the assistance of Amanda E. Mitchell, DHP Adjudication Specialist.

Scott Arnott, DHP Pharmacy Inspector, and Billy Lambrinides, Rite Aid District Manager, testified on behalf of the Commonwealth.

Mr. Malsam appeared with Melinda L. VanLowe, Esquire.

Mr. Malsam testified on his own behalf. Also, Linda Kleiner, HPIP Case Manager, testified on behalf of Mr. Malsam.

CLOSED MEETING:

Mr. Ison moved, and the Panel voted 9-0, to convene a closed meeting pursuant to Section 2.2-3711(A)(28) of the Code of Virginia for the purpose to reach a decision in the matter of Ronald J. Malsam. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, Caroline Juran and Ishneila Moore attend the closed meeting.

RECONVENE:

Mr. Ison moved, and the Panel voted 9-0, that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

DECISION:

Mr. Kozera moved, and the Panel voted 9-0, to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Schliessmann and modified by the Panel and read by Ms. Moore (Attachment 2).

Mr. Kozera moved, and the Board voted 9-0 that Mr. Malsam be continued on indefinite suspension for a period of not less than three months.

ADJOURN:

With all business concluded, the meeting adjourned at 4: 20 p.m.

11

Cathy M. Reiniers-Day
Deputy Executive Director

John O. Beckner, Chairman

Date

Attachment 1
Board of Pharmacy
Formal Hearings - Panel
June 12, 2007

VIRGINIA:

BEFORE THE BOARD OF PHARMACY

IN RE: JEFFREY R. MARTIN, PHARMACIST
License No. : 0202-204815

CONSENT ORDER

Now come the Virginia Board of Pharmacy ("Board") and Jeffrey R. Martin, as evidenced by their signatures affixed below, and enter into this Consent Order affecting the license of Mr. Martin to practice pharmacy in the Commonwealth of Virginia.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Jeffrey R. Martin held license number 0202-204815 issued by the Board to practice pharmacy in the Commonwealth of Virginia, which was summarily suspended by an Order of the Board entered on October 30, 2006.
2. During the course of Mr. Martin's employment as a pharmacist at Sentara Williamsburg Community Hospital ("SWCH"), Williamsburg, Virginia, by his own admission, he violated § 18.2-250, § 54.1-3316(5) and (7), and § 54.1-3408 of the Code. More specifically, on ten occasions between on or about August 15, 2006, and on or about September 1, 2006, Mr. Martin entered falsified information in various Pyxis automated dispensing devices throughout SWCH, where he both reported and resolved discrepancies involving Percocet (oxycodone), a Schedule II controlled substance; Vicodin (hydrocodone), a Schedule III controlled substance; and Ritalin (methylphenidate), a Schedule II controlled substance. Mr. Martin gave a range of admissions when questioned about the above discrepancies by SWCH's Pharmacist-in-Charge on or about September 5, 2006, and by an inspector from the Department of Health Professions on or about September 5, 6, and 13, 2006; however, at a minimum, he did admit to diverting Percocet for his own personal and unauthorized use on or about August 27, 2006, and on or about September 1, 2006. As a result of his actions, Mr. Martin's employment with SWCH was terminated on or about September 11, 2006.

J.N. MARTIN

3. On or about November 1, 2006, Mr. Martin entered into a Participation Contract with the Health Practitioners' Intervention Program ("HPIP"). Subsequently, on or about February 28, 2007, Mr. Martin entered into a Recovery Monitoring Contract with HPIP.

4. Pursuant to a letter dated June 4, 2007, Patricia A. Pade, M.D., Associate Medical Director of HPIP, stated:

- a. Mr. Martin attended the residential treatment program at William J. Farley Center, Williamsburg, Virginia, from November 13, 2006, until February 23, 2007, when he was successfully discharged;
- b. Mr. Martin is compliant with his treatment and has a solid recovery program in place;
- c. Mr. Martin's random urine drug screens have all been negative; and
- d. Dr. Pade is advocating for the return of Mr. Martin's license to practice pharmacy in the Commonwealth of Virginia.

CONSENT

Jeffrey R. Martin, by affixing his signature hereon, agrees to the following:

1. He has been advised specifically to seek the advice of counsel prior to signing this document, and is represented by Michael L. Goodman, Esquire;
2. He is fully aware that without his consent, no legal action can be taken against him except pursuant to the Virginia Administrative Process Act, § 2.2-4000 et seq. of the Code;
3. He has the following rights, among others:
 - a. the right to a formal hearing before the Board;
 - b. the right to representation by counsel; and
 - c. the right to cross-examine witnesses against him.
4. He waives all rights to a formal hearing;
5. He neither admits nor denies the truth of the above Findings of Fact but agrees not to contest them at future administrative hearings; and

15

J.R. Martin

6. He consents to the following Order affecting his license to practice pharmacy in the Commonwealth of Virginia.

ORDER

WHEREFORE, on the basis of the foregoing Findings of Fact and Conclusions of Law, and with the consent of the licensee, it is hereby ORDERED that upon receipt of the appropriate licensure renewal fee, the license of Jeffrey R. Martin to practice pharmacy in the Commonwealth of Virginia be, and hereby is, REINSTATED ON PROBATION, subject to the following terms and conditions:

1. The period of probation shall begin on the date that this Order is entered and shall continue INDEFINITELY. Mr. Martin may petition the Board to end his probation after he has been successfully discharged from HPIP.

2. Mr. Martin shall comply with all terms and conditions for the period specified by HPIP.

3. Any violation of the terms and conditions of HPIP or any of the terms and conditions stated in this Order shall be reason for revoking the license of Mr. Martin, and an administrative proceeding shall be held to decide whether Mr. Martin's license shall be revoked. Mr. Martin shall be noticed to appear at an administrative hearing at such time as the Board is notified that he is not in compliance with the terms and conditions specified by HPIP, or has been terminated from participation in HPIP.

4. All reports required by this Order shall be submitted in writing to the Board office with the first report being received no later than thirty (30) days following the date that this Order is final. Subsequent reports must be received quarterly by the last day of the months of March, June, September and December, until the period of probation ends. Mr. Martin is fully responsible for ensuring that required reports are properly submitted and received by the Board in a timely manner.

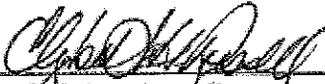
5. Mr. Martin shall submit quarterly self-reports which must include his current address and current employment, if any.

6. Mr. Martin shall maintain a course of conduct commensurate with the requirements of Chapters 33 and 34, Title 54.1 of the Code of Virginia and the Board of Pharmacy Regulations.

J.R. Martin

Pursuant to § 2.2-4023 and § 54.1-2400.2 of the Code, the signed original of this Consent Order shall remain in the custody of the Department of Health Professions as a public record and shall be made available for public release, inspection and copying upon request.

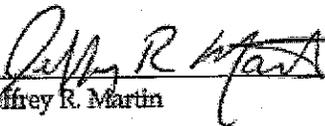
FOR THE BOARD:



Elizabeth Scott Russell
Executive Director

ENTERED: June 15, 2007

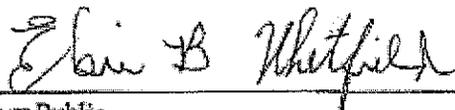
SEEN AND AGREED TO:



Jeffrey R. Martin

COMMONWEALTH OF VIRGINIA
CITY/COUNTY OF Williamsburg/James City

Subscribed and sworn to before me, a Notary Public in and for the Commonwealth of Virginia, this 11th day of June, 2007, by Jeffrey R. Martin. My commission expires the 30th day of November, 2010.



Notary Public

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing Consent Order was mailed to Jeffrey R. Martin at 225 Charter House Lane, Williamsburg, Virginia 23188, on this 15th day of June, 2007



Cathy M. Reiniers-Day
Deputy Executive Director

Attachment 2
Board of Pharmacy
Formal Hearings - Panel
June 12, 2007

Ronald J. Malsam
License # 0202-005051

Findings of Fact:

- Ronald J. Malsam previously held License No. 0202-005051 issued by the Board to practice pharmacy in the Commonwealth of Virginia, which was summarily suspended by the Board pursuant to an Order entered February 14, 2007, in accordance with § 54.1-2408.1 of the Code.
- By Mr. Malsam's own admission, during the course of his employment as the pharmacist-in-charge at Rite Aid Pharmacy #3686, Fairfax City, Virginia, from approximately January 2005 until November 29, 2006, he diverted from pharmacy stock an estimated 621 tablets total of hydrocodone (Schedule III), alprazolam (Schedule IV), acetaminophen with oxycodone (Schedule II), methylphenidate (Schedule II), Flomax (tamsulosin HCl, Schedule VI), Fioricet #90 (butalbital/APAP, Schedule VI), and Lipitor (atorvastatin, Schedule VI), for his personal and unauthorized use. As a result of his actions, Mr. Malsam's employment was terminated on or about November 29, 2006.
- Linda Kleiner, his Health Practitioners' Intervention Program ("HPIP") Case Manager, testified that Mr. Malsam signed a Participation Contract on February 23, 2007, and was evaluated by Marworth Treatment Center, Waverly, Pennsylvania ("Marworth"), from March 4, 2007, through March 9, 2007. He then received inpatient treatment at Marworth from March 19, 2007, through May 18, 2007. On June 8, 2007, Mr. Malsam signed a Recovery Monitoring Contract with HPIP. Ms. Kleiner stated that HPIP would not allow for Mr. Malsam to return to work until he has a permanent sponsor, three to six months of negative drug screens and participation in appropriate meetings and counseling.
- Mr. Malsam testified that he is currently on Naltrexone. He further testified that he gave some of the diverted hydrocodone to his wife.

Conclusions of Law:

- The Board concludes that Finding of Fact #2 constitutes a violation of § 54.1-3316(4) and (7) and § 54.1-3410(A) and (B) of the Code.

Sanction:

18

-
- The license of Ronald J. Malsam be INDEFINITE SUSPENDED for a period of not less than three months from the date of entry of this Order. Mr. Malsam may thereafter petition the Board for reinstatement, contingent upon his continued compliance with the terms of his Recovery Monitoring Contract and consistent with the recommendation of HPIP.

**VIRGINIA BOARD OF PHARMACY
MINUTES OF SANCTION REFERENCE COMMITTEE**

July 26, 2007
Fifth Floor
Conference Room 3

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

CALL TO ORDER: A meeting of an ad hoc committee of the Board of Pharmacy to consider the use of the sanction reference guidelines worksheet was called to order at 10AM.

PRESIDING: Bobby Ison, Board Chairman

MEMBERS PRESENT: Dave Kozera
Leo Ross
Mickey Stredler
Brandon Yi

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Caroline Juran, Deputy Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director

DISCUSSION: Neal Kauder, President, Visual Research, Inc gave the committee an review of the sanction reference study that had been done several years ago for the Board of Pharmacy and reviewed the worksheet that had been developed at that time. The committee made some minor modifications to the worksheet and agreed that special conference committees should begin using it. The full Board will review the recommendation at the September 12 meeting, after which the committees will begin using it.

ADJOURN: The meeting concluded at 11:30AM.

Elizabeth Scott Russell
Executive Director

Bobby Ison, Board Chairman

Date

**VIRGINIA BOARD OF PHARMACY
MINUTES OF INSPECTIONS COMMITTEE**

July 26, 2007
Fifth Floor
Conference Room 3

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

CALL TO ORDER: A meeting of an ad hoc committee of the Board of Pharmacy to review the inspections processes was called to order at 11:30AM.

PRESIDING: Bobby Ison, Board Chairman

MEMBERS PRESENT: Mickey Stredler
Dave Kozera
Leo Ross
Brandon Yi

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Caroline Juran, Deputy Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Sammy Johnson, Deputy Director, Enforcement Division

DISCUSSION: The committee began review of the current inspection forms and began work on identifying specific deficiencies which could be handled by a streamlined consent order process in which a pre-determined monetary penalty would be offered at the time of inspection. After discussion, the committee agreed that sanctions should for most deficiencies should be imposed at least initially upon the pharmacy permit rather than the pharmacist in charge. The committee will need to meet at least one additional time to continue its work. The next meeting date was not scheduled at this time due to the department's impending relocation.

ADJOURN: The meeting was recessed at 1:30PM to conduct a formal hearing, resumed at approximately 2PM, then concluded at 3:30PM.

Elizabeth Scott Russell
Executive Director

Bobby Ison, Board Chairman

Date

21

**DRAFT/UNAPPROVED
VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD**

Thursday, July 26, 2007
Fifth Floor
Conference Room 3

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

Orders/Consent Orders referred to in these minutes are available upon request

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 1:30 p.m.

PRESIDING: Bobby Ison, Chairman

MEMBERS PRESENT: David Kozera
Leo Ross
Michael E. Stredler
Brandon Yi

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Elizabeth M. Revere, Administrative Assistant
Howard M. Casway, Senior Assistant Attorney General

QUORUM: With five members of the Board present, a quorum was established.

KEISHA M. HAZELWOOD
Registration # 0230-009019

A formal hearing was held in the matter of Keisha M. Hazelwood following the summary suspension of her pharmacy technician registration on June 18, 2007, and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Ms. Hazelwood was not present at the hearing. The Panel proceeded in Ms. Hazelwood's absence as the Notice of Formal Hearing dated June 18, 2007, was mailed to Ms. Hazelwood's legal address of record, both regular and certified mail. Mr. Ison ruled that adequate notice was provided to Ms. Hazelwood and the hearing proceeded in her absence.

James Schliessmann, Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist.

22

Closed Meeting:

Mr. Kozera moved, and the Panel voted 5-0, to convene a closed meeting pursuant to Section 2.2-3711(A)(28) of the Code of Virginia for the purpose to reach a decision in the matter of Keisa M. Hazelwood. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, Howard Casway and Betty Revere attend the closed meeting.

Reconvene:

Mr. Kozera moved, and the Panel voted 5-0, that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision:

Mr. Yi moved, and the Panel voted 5-0, to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Schliessmann.

Mr. Kozera moved, and the Panel voted 5-0 that Keisha M. Hazelwood's right to renew her pharmacy technician's registration be revoked.

ADJOURN:

With all business concluded, the meeting adjourned at 1:45 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Bobby Ison, Chairman

Date

23

Attachment 1
Minutes - Board of Pharmacy
Formal Hearing - Panel
July 26, 2007

Keisha M. Hazelwood
Registration #0230-009019

Findings of Fact:

- Keisha M. Hazelwood held registration number 0230-009019 issued by the Board to practice as a pharmacy technician in the Commonwealth of Virginia. Said registration was summarily suspended on June 18, 2007.
- Based upon representations of James E. Schliessmann, Assistant Attorney General, and Commonwealth's Exhibit No. 3, the affidavit of mailing, the presiding officer ruled there was adequate notice and the panel of the Board proceeded with the hearing in Ms. Hazelwood's absence.
- Ms. Hazelwood diverted quantities of controlled substances for unauthorized use. More specifically, by her own admission, between April 2006 and April 4, 2007, during the course of her employment as a pharmacy technician at Walgreens #03683, Midlothian, Virginia, she diverted 34 pints of Tussionex suspension (hydrocodone, Schedule III) and stated she sold them to another individual.

Conclusions of Law:

- Finding of Fact #3 constitutes a violation of § 54.1-3322(2) of the Code.

Sanction:

- The registration of Keisha M. Hazelwood be, and hereby is, REVOKED.

DHP-PHA-1

1. Description/Objective: This bill will remove from statute specific dates on which licenses issued by the Board of Pharmacy will expire, and will require the Board to establish expiration dates in regulation.
2. Background: The Code of Virginia currently requires that most licenses issued by the Board of Pharmacy expire on December 31 annually, or before January 1 annually. This means that the Board of Pharmacy staff annually renews all of its 20,000 plus licenses. This creates a very unequal workload during this time of the year. The Board would like the ability to stagger some of these expiration dates to better distribute workload throughout the year. Because of recent significant increases in numbers of licensees, with addition of pharmacy technicians, and increases in non-resident facility licenses, the Board's ability to renew licenses in a timely manner is being challenged. Even though a number of persons use on-line license renewal, many facilities choose not to do so, and non-residents facilities are not able to do this because of requirement to show proof of resident licensure.
3. Impact on other constituents: None anticipated. The Board of Pharmacy has received comments of support from the Virginia Pharmacists Association, the Virginia Society of Hospital Pharmacists, and the Virginia and National Association of Chain Drug Stores

DHP-PHA 2

1. **Description/Objective:** Section 54.1-3314.1 of the Pharmacy Act of the Code of Virginia describes the continuing education requirements for pharmacists. The current code requires each pharmacist to obtain a minimum of fifteen continuing education hours through an approved program during the year immediately preceding the license renewal date. The new language in paragraph J would allow the Board of Pharmacy to require up to two hours of continuing pharmacy education in a specific subject area.

Additionally, the change in paragraph I will bring requirements for change from inactive status to active status in conformity with requirements for reinstatement of a lapsed license as set forth in Board regulations, wherein the Board puts a cap on back CE requirements of 60 hours, but requires the re-taking of the law examination for those persons who have been inactive or lapsed more than 5 years.

2. **Background:** Section 54.1-3434.02, enacted in 1992, recognizes the importance of pharmacists remaining up-to-date in advances in the many areas of pharmacy practice. The original legislation allows the pharmacist to take any continuing pharmacy education course or program that meets the requirements set forth in the code or in regulation as long as they complete a minimum of fifteen hours per year. The proposed legislation would allow the Board to specify up to two hours of continuing education in a specific subject area as part of the fifteen hour minimum requirement. This will allow the board to require training in critical areas at a given time. Examples of critical areas where training is needed now are prevention of dispensing errors, pharmacy's role in emergency preparedness, and smallpox administration. Any requirements for a particular year will be published by January 1 of that year.
3. **Impact on other constituents:** None. The Board of Pharmacy has received comments of support from the Virginia Pharmacists Association, the Virginia Society of Health-System Pharmacists and the Virginia and National Association of Chain Drug Stores.

DHP-PHA-3

1. Description/Objective: This bill will add lisdexamphetamine to Schedule II. Lisdexamphetamine is a newly approved drug by FDA for the treatment of Attention Deficit Hyperactivity Disorder and will be marketed under the name trade name Vyvanse.
2. Background: The Virginia Drug Control Act includes drugs listed in Schedules I through VI. Schedule II – V drugs are those that have some potential for abuse and physical or psychological dependency, with Schedule II being having the greater potential for abuse and dependency. Schedule I includes those drugs with potential for abuse, but no legitimate medical purpose, such as LSD, Ecstasy, heroin, etc. Schedule VI drugs are those that require a prescription but have little to no potential for abuse or dependency, and are not individually listed in the Drug Control Act, but are incorporated by definition.

Whenever the United States Drug Enforcement Administration schedules a drug, the Board of Pharmacy usually submits a legislative proposal to schedule the drug accordingly in state law. Different laws with respect to ordering, prescribing, security, and record-keeping apply depending of the schedule of the drug. Conformity of state and federal drug schedules, particularly with prescription drugs, is desirable to limit confusion on the part of those persons with prescriptive or dispensing authority in Virginia.

Additionally, drugs need to be listed in the appropriate schedule in order to prosecute under Virginia law any unlawful possession or distribution.

Lisdexamphetamine is converted in the body to d-amphetamine which is already a Schedule II drug. It has similar properties and actions of other drugs in this class

Commonwealth of Virginia



PUBLIC PARTICIPATION GUIDELINES

VIRGINIA BOARD OF PHARMACY

Title of Regulations: 18 VAC 110-10-10 et seq.

**Statutory Authority: §§ 54.1-2400 and 2.2-4007
of the *Code of Virginia***

Revised Date: August 25, 2007

9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463

(804) 367-4456 (TEL)
(804) 527-4472 (FAX)
email: pharmbd@dhp.virginia.gov

TABLE OF CONTENTS

Part I. Statement of Purpose.....	3
18 VAC 110-10-10. Purpose.....	3
18 VAC 110-10-20. Definitions.....	3
Part II. Notification Lists.....	3
18 VAC 110-10-30. Composition of notification lists.....	3
18 VAC 110-10-40. Documents to be sent to persons on the notification lists.....	4
Part III. Public Participation Procedures.....	4
18 VAC 110-10-50. Petition for rulemaking.....	4
18 VAC 110-10-60. Notice of Intended Regulatory Action.....	4
18 VAC 110-10-70. Notice of comment period.....	5
18 VAC 110-10-80. Notice of meeting.....	5
18 VAC 110-10-90. Public hearings on regulations.....	5
18 VAC 110-10-100. Periodic review of regulations.....	5
Part IV. Ad Hoc Committees.....	5
18 VAC 110-10-110. Appointment of committees.....	5
18 VAC 110-10-120. Limitation of service.....	6

Part I. Statement of Purpose.

18 VAC 110-10-10. Purpose.

The purpose of this chapter is to provide guidelines for the involvement of the public in the initial formation and development, amendment or repeal of regulations of the Board of Pharmacy. The guidelines do not apply to regulations exempted or excluded from the provisions of the Administrative Process Act. These rules seek to expand participation by providing for electronic exchange with the public and thereby increasing participation, reducing costs, and improving the speed of communication.

18 VAC 110-10-20. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Administrative Process Act" means Chapter 40 (§ 2.2-4000 et seq.) of Title 2.2 of the Code of Virginia.

"Board" means the Board of Pharmacy.

"Notification lists" means lists used by the board to notify persons pursuant to these rules. Such lists may include electronic lists maintained through the Virginia Regulatory Town Hall or lists maintained by the board.

"Person" means an individual, a corporation, a partnership, an association, a governmental body, a municipal corporation, or any other legal entity.

"Regulation" means any statement of general application, having the force of law, affecting the rights or conduct of any person, adopted by the board in accordance with the authority conferred on it by applicable laws.

Part II. Notification Lists.

18 VAC 110-10-30. Composition of notification lists.

A. The board shall maintain lists of persons who have requested to be notified of the initial formation, development, amendment or repeal of regulations.

B. Any person may request to be placed on a notification list by indicating so electronically or in writing to the board. The board may add to a list any person it believes will serve the purpose of enhancing participation in the regulatory process.

C. The board may maintain additional lists for persons who have requested to be informed of specific regulatory issues, proposals, or actions.

D. The board shall periodically request those persons on the notification lists to indicate their desire to either continue to receive documents by regular mail, be notified electronically or be deleted from the lists. Persons who elect to be included on an electronic mailing list may also request that all notices and mailings be sent in hard copy. When either regular or electronic mail is returned as undeliverable or there has been no response to the request from the board, such persons shall be deleted from the list.

18 VAC 110-10-40. Documents to be sent to persons on the notification lists.

A. Persons on the notification lists, as described in 18 VAC 110-10-30, shall be mailed or have electronically transmitted the following documents related to the promulgation of regulations:

1. A notice of intended regulatory action.
2. A notice of the comment period on a proposed regulation and instructions as to how to obtain a copy of the regulation and any supporting documents, either electronically or from the board office.
3. A notice soliciting comment on a final regulation when the regulatory process has been extended.

B. Notification of the adoption of a final regulation and copies of the regulation shall be posted on the board's website prior to the 30-day adoption period.

C. The failure of any person to receive any notice or copies of any documents shall not affect the validity of any regulation otherwise adopted in accordance with this chapter.

Part III. Public Participation Procedures.

18 VAC 110-10-50. Petition for rulemaking.

A. As provided in § 2.2-4007 of the Code of Virginia, any person may petition the board to develop a new regulation or amend an existing regulation.

B. A petition shall include but need not be limited to the following:

1. The petitioner's name, mailing address, telephone number, and, if applicable, the organization represented in the petition.
2. The number and title of the regulation to be addressed.
3. A description of the regulatory problem or need to be addressed.
4. A recommended addition, deletion, or amendment to the regulation.

C. The board shall receive, consider and respond to a petition within 180 days and shall have the sole authority to dispose of the petition.

D. Nothing herein shall prohibit the board from receiving information from the public and proceeding on its own motion for rulemaking.

18 VAC 110-10-60. Notice of Intended Regulatory Action.

A. Except as provided in § 2.2-4012.1 of the Code of Virginia, the board shall issue a notice of intended regulatory action (NOIRA) whenever it considers the adoption, amendment or repeal of a regulation. The NOIRA shall state the purpose of the action and a brief statement of the need or problem the proposed action will address.

B. The NOIRA shall indicate whether the board intends to hold a public hearing on the proposed regulation after it is published. If the board does not intend to hold a public hearing, it shall so state in the NOIRA.

C. If prior to the close of the 30-day comment period on the NOIRA, the board receives a request for a public hearing on the proposed regulation from at least 25 persons or if the Governor directs the board to hold a public hearing, such a hearing shall be scheduled.

18 VAC 110-10-70. Notice of comment period.

A. The board shall issue a notice of comment period (NOCP) whenever it proposes to initiate, amend or repeal a regulation. The NOCP shall indicate that copies of the proposed regulation are available electronically or from the board and may be requested in writing from the contact person specified in the NOCP.

B. The NOCP shall indicate that copies of the statement of substance, issues, basis, purpose, and estimated impact of the proposed regulation may also be requested in writing.

C. The NOCP shall make provision for comments pertaining to the proposed regulation by regular mail, facsimile or electronic means. With the exception of comment received at a scheduled public hearing, oral comment shall not be accepted.

18 VAC 110-10-80. Notice of meeting.

A. At any meeting of the board or advisory committee at which the formation, amendment, repeal, or adoption of a regulation is anticipated, the subject shall be described in a notice of meeting, which has been posted electronically on the Virginia Regulatory Town Hall and transmitted to the Registrar of Regulations for inclusion in the Virginia Register.

B. If the board anticipates action on a regulation for which an exemption to the Administrative Process Act is claimed, the notice of meeting shall indicate that a copy of the proposed regulation may be requested from the board at least two days prior to the meeting. A copy of the regulation shall be made available to the public attending such meeting.

18 VAC 110-10-90. Public hearings on regulations.

The board shall conduct a public hearing during the 60-day comment period following the publication of a proposed regulation or amendment to an existing regulation, unless, at a noticed meeting, the board determines that a hearing is not required.

18 VAC 110-10-100. Periodic review of regulations.

A. The board shall conduct a periodic review of its regulations consistent with an executive order issued by the Governor and with § 2.2-4007.1 of the Code of Virginia to receive comment on all existing regulations as to their effectiveness, efficiency, necessity, clarity, and cost of compliance.

B. Such review may be conducted separately or in conjunction with other meetings or hearings.

C. Notice of the proceeding shall be transmitted to the Registrar of Regulations for inclusion in the Virginia Register and shall be sent to the notification lists identified in 18 VAC 110-10-30.

Part IV. Ad Hoc Committees.

18 VAC 110-10-110. Appointment of committees.

A. The board may appoint an ad hoc committee whose responsibility shall be to assist in the review and development of regulations for the board.

B. The board may appoint an ad hoc committee to provide professional specialization or technical assistance when the board determines that such expertise is necessary to address a specific regulatory issue or need or when groups of individuals register an interest in working with the agency.

18 VAC 110-10-120. Limitation of service.

A. An ad hoc committee that has been appointed by the board may be dissolved by the board when:

1. There is no response to the Notice of Intended Regulatory Action; or
2. The board determines that the promulgation of the regulation is either exempt or excluded from the requirements of the Administrative Process Act.

B. An ad hoc committee shall remain in existence no longer than 18 months from its initial appointment unless the board determines that the specific regulatory need continues to exist beyond that time. The board may authorize the ad hoc committee to continue for an additional specified period of time to complete the task for which it was appointed.