

**TEXAS STATE BOARD OF PHARMACY
Health Professions Council Board Room
333 Guadalupe Street, Tower II, Suite 225
Austin, Texas**

May 6-7, 2008

MINUTES¹

Tuesday, May 6, 2008

President W. Benjamin Fry, R.Ph., called the meeting to order at 9:02 a.m. Other Board Members present were Vice President Kim A. Caldwell, R.Ph.; Treasurer Jeanne Waggener, R.Ph.; Juluette Bartlett-Pack, Ph.D.; W. Michael Brimberry, R.Ph., M.B.A.; Rosemary Forester Combs; Marcelo Laijas, Jr.; and Alice Mendoza, R.Ph.

Board Member Doyle High, R.Ph., was not present.

Staff present were Gay Dodson, R.Ph., Executive Director/Secretary; Carol Fisher, R.Ph., M.P.A., Director of Enforcement; Paul Holder, R.Ph., Pharm.D., Assistant Director of Enforcement; Cathy Stella, Director of Licensing and Administrative Services; Kerstin Arnold, General Counsel; Julie Hildebrand, Litigation Counsel; Mitra Woody, Staff Attorney; Caroline Hotchkiss, Staff Attorney; Allison Benz, R.Ph., M.S., Director of Professional Services; and Kay Wilson, Executive Assistant.

Public Hearing

A public hearing was held to receive testimony concerning amendments to §§291.31-291.34 regarding amendments to implement the recommendations of the Task Force on Security in Class A Pharmacies.

President Fry made an opening statement.

¹See agenda and corresponding attachments for supporting materials.

The following persons presented oral testimony to the Board regarding the above-referenced amendments:

<u>Name</u>	<u>Representing</u>
Richard Beck	American Pharmacies
Karen Reagan	Texas Federation of Drug Stores

(See Public Hearing tab.)

President Fry closed the Public Hearing at 9:20 a.m.

Board Business Meeting

President Fry convened the Board Business Meeting at 9:20 a.m.

A. Announcements

- President Fry made general announcements.
- Announcements were made concerning Board Members and staff.
- Ms. Dodson announced that use of electronic notebooks would be implemented at the August 2008 Board Meeting.
- Ms. Benz made an announcement concerning continuing education credit for attending the Board Meeting.

B. Discussion and Approval of Minutes of Previous Meetings (Tab 1)

Following discussion, the motion was made by Mr. Caldwell to approve the minutes of the Executive Committee Meeting, held April 2, 2008, and Public Hearing and Board Business Meeting, held February 5-6, 2008. The motion was seconded by Ms. Waggener and passed unanimously.

C. Discussion of and Possible Action Regarding Rules

Final Adoption of Rules

- Amendments Concerning Consideration for Criminal Offenses (§281.63) and Sanctions for Applicants with Criminal Offenses (§281.64) (Tab 2)

Ms. Benz explained that the proposed amendments to §281.63 and §281.64 would clarify that the crime of driving while intoxicated is

considered to be directly related to the duties and responsibilities of licensees and registrants, and that considerations for sanctions are applicable to all licensees and registrants, including applicants. She advised that the Board reviewed and voted to propose the amendments during its February 5, 2008, meeting. The proposed amendments were published in the March 21, 2008, issue of the *Texas Register*.

The Board reviewed comments received from Jim Martin, R.Ph., of the Texas Pharmacy Association. The Board took no action on the comments.

Following discussion, the Board delayed action on the proposed amendments to §281.63 and §281.64 until May 7, 2008.

- Rules Concerning Internship Requirements (Chapter 283) (Tab 3)

Ms. Benz explained that the proposed amendments to Chapter 283 would implement recommendations of the Task Force on Internship Requirements by:

- updating definitions;
- adding a new definition for an intern-trainee;
- updating the goals and objectives to be consistent with new guidelines set forth by the Accreditation Council for Pharmacy Education;
- outlining the requirements for individuals applying to the Board as intern-trainees;
- authorizing the Executive Director to extend the terms of an extended internship if the administration of the NAPLEX and/or Texas Jurisprudence Examination is delayed;
- clarifying the duties that may be performed by an intern-trainee working under a pharmacist preceptor serving as an instructor for a Texas college/school-based internship program;
- defining the ratios of preceptors to pharmacist-interns; and
- renaming §283.6 to *Preceptor Requirements and Ratio of Preceptors to Pharmacist-Interns*.

Ms. Benz advised that the Board reviewed and voted to propose the amendments during its February 5, 2008, meeting. The proposed amendments were published in the March 21, 2008, issue of the *Texas Register*.

The Board reviewed comments received from Karen Kenney Reagan, of the Texas Federation of Drug Stores; Dennis Wiesner, R.Ph., of HEB; and Mary Staples and Michelle Cope, of the National Association of Chain Drug Stores. Following review of the comments and discussion, the Board directed staff to make changes to the rule language to further clarify the definition of an intern-trainee and the ratio of preceptors to pharmacist-interns.

The Board delayed action on the proposed amendments to Chapter 283 until May 7, 2008.

- Rules Concerning Security in Class A Pharmacies (§§291.31-291.34) (Tab 4)

Ms. Benz explained that the proposed amendments to §§291.31-291.34 would implement the recommendations of the Task Force on Security in Class A Pharmacies by:

- clarifying the definition of the prescription department;
- clarifying the responsibilities of the owner to include establishing policies and procedures for the security of the prescription department;
- outlining the security requirements for Class A pharmacies;
- clarifying the temporary absence requirements for pharmacists;
- requiring the pharmacy to document the identity of each pharmacist involved in a specific portion of the dispensing process if the pharmacy's data processing system is capable of recording such information; and
- requiring the pharmacy to document the identity of the pharmacist responsible for providing verbal counseling on a new prescription.

Ms. Benz advised that the Board reviewed and voted to propose the amendments during its February 5, 2008, meeting. The proposed amendments were published in the March 21, 2008, issue of the *Texas Register*.

Ms. Benz pointed out that the Board had heard verbal comments concerning the proposed amendments during the public hearing earlier in the meeting, and she directed the Board's attention to written comments received from Karen Kenney Reagan, of the Texas Federation of Drug Stores; Dennis Wiesner, R.Ph., of HEB; and Mary Staples and Michelle Cope, of the National Association of Chain Drug Stores. She directed the Board's attention to rule language containing some suggested changes, based on the above-referenced comments and comments received at previous board meetings.

Following review of comments and a lengthy discussion, the Board delayed action on the proposed amendments to §§291.31-291.34 until May 7, 2008.

- Rules Concerning Prescription Labeling by Class E Pharmacies (§291.104) (Tab 5)

Ms. Benz directed the Board's attention to proposed amendments to §291.104. She explained that the proposed amendments would clarify the labeling requirements for Class E pharmacies shipping prescriptions to Texas residents.

She advised that the Board reviewed and voted to propose the amendments during its February 5, 2008, meeting. The proposed amendments were published in the March 21, 2008, issue of the *Texas Register*. Comments were received from Mary Staples and Michelle Cope, of the National Association of Chain Drug Stores.

Following review of the comments and discussion, the Board directed staff to modify the proposed language concerning non-resident pharmacies. The Board delayed action on the proposed amendments to §291.104 until May 7, 2008.

- Rules Concerning Pharmacy Technician Exemption from Certification Examination Requirements (§297.7) (Tab 6)

Ms. Benz directed the Board's attention to proposed amendments to §297.7 concerning pharmacy technician exemption from certification requirements. She explained that the proposed amendments would clarify that an individual exempted from the pharmacy technician certification requirements is required to register with the Board in order to act as a pharmacy technician in a pharmacy.

Ms. Benz reported that the Board reviewed and voted to propose the amendments during its February 5, 2008, meeting. The proposed amendments were published in the March 21, 2008, issue of the *Texas Register*, and no comments were received.

Following discussion, the Board delayed action on the proposed amendments to §297.7 until May 7, 2008.

- Rules Concerning Generic Substitution (§309.3) (Tab 7)

Ms. Benz directed the Board's attention to proposed amendments to §309.3 concerning generic substitution. She explained that the proposed amendments would implement S.B. 625, which was passed by the 80th Texas Legislature, and required a joint committee comprised of equal number of members from TSBP and the Texas Medical Board to make a recommendation to TSBP on whether to include a drug on the list of narrow therapeutic index (NTI) drugs as required by §562.0142 of the Texas Pharmacy Act. She reported that the joint committee met on November 19, 2007, to consider adding certain immunosuppressant drugs to the NTI list, and the committee met again on January 14, 2008, to consider adding certain anti-epileptic drugs to the NTI list. She advised the Board that the joint committee recommendation at both meetings was that no drugs be added to the NTI list. She also pointed out that the proposed amendments would rename Chapter 309 to *Substitution of Drug Products*.

Ms. Benz reported that the Board reviewed and voted to propose the amendments during its February 5, 2008, meeting. The proposed amendments were published in the March 21, 2008, issue of the *Texas Register*, and comments were received from the Texas Federation of Drug Stores, the National Association of Chain Drug Stores, and Gardere, Wynne, Sewell, LLP.

Following review of the comments and discussion, the Board delayed action on the proposed amendments to §309.3 until May 7, 2008.

Proposal of Rules

- Rules Concerning Disciplinary Guidelines (Chapter 281) (Tab 8)

Ms. Benz directed the Board's attention to suggested amendments to §§281.62-281.65 and explained that staff was presenting these amendments for the Board's consideration to clarify disciplinary

guidelines for use in informal conferences and proceedings before the State Office of Administrative Hearings. Ms. Arnold briefly reviewed the clarifications for the Board.

Following discussion, the motion was made by Mr. Caldwell to approve for proposal, as presented, amendments to §§281.62-281.65. The motion was seconded by Ms. Waggener and passed unanimously.

- Rules concerning Storage of Drugs (§291.15, §291.33, and §291.133) (Tab 9)

Ms. Benz directed the Board's attention to suggested language for new rule §291.15 and amendments to §291.33 and §291.133. She explained that the new rule and amendments were being presented by staff to achieve consistency by placing the requirements for storage of drugs in one section of the rules.

Following discussion, the motion was made by Ms. Mendoza to approve for proposal, as presented, new rule §291.15 and amendments to §291.33 and §291.133. The motion was seconded by Ms. Waggener and passed unanimously.

- Rules Concerning Personnel (§§291.72-291.73) (Tab 10)

Ms. Benz directed the Board's attention to suggested language for amendments to §§291.72-291.73. She explained that the suggested amendments would allow pharmacists in facilities licensed for 100 beds or less to supervise pharmacy technicians electronically. She reported that these amendments were being presented at the Board's direction, following completion of a pilot project by Envision Pharmacy and at the recommendation of the Board's task force that rules be adopted to continue the process established in the pilot project. Ms. Benz reviewed the suggested amendments for the Board.

Following discussion, the motion was made by Mr. Brimberry to approve amendments to §§291.72-291.73, as presented. The motion was seconded by Ms. Mendoza and passed unanimously.

President Fry recessed the meeting at 11:48 a.m.

President Fry reconvened the meeting at 1:05 p.m.

A. Announcements (Cont.)

Ms. Fisher introduced Lawrence Divine, a pharmacy intern from the University of Texas at Austin.

C. Discussion of and Possible Action Regarding Rules (Cont.)

- Rules Concerning Operational Standards in Class C Pharmacies (Formularies) (§291.74) (Tab 11)

Ms. Benz explained that at the Board's February 2008 meeting, it adopted amendments regarding the use of formularies in hospitals. At that time, the Board received comments recommending that the term *interchange* be used in place of *substitute*. She directed the Board's attention to suggested amendments to §291.74, which replace the term *substitute* with *interchange*. She also pointed out that §291.74(f)(1)(D) was being amended to reference §291.15 relating to storage of drugs.

Following discussion, the motion was made by Mr. Caldwell to approve for proposal, as presented, amendments to §291.74. The motion was seconded by Ms. Mendoza and passed unanimously.

- Rules Concerning Pharmacy Technician Training Programs (§305.2) (Tab 12)

Ms. Benz directed the Board's attention to suggested amendments to §305.2 and explained that staff was recommending the amendments to clarify that individuals enrolled in pharmacy technician training programs must be registered with the Board prior to working in a pharmacy as part of the experiential component of the training program.

Following discussion, the motion was made by Mr. Brimberry to approve for proposal, as presented, amendments to §305.2. The motion was seconded by Ms. Waggener and passed unanimously.

- Rules Concerning Generic Substitution (Chapter 309) (Tab 13)

Ms. Benz directed the Board's attention to suggested amendments to §309.1 and §309.3 that would establish procedures for practitioners to prohibit substitution based on the manufacturer of the brand or generic product. She explained that at the Board's February 2008 meeting, these amendments were presented, along with amendments regarding the addition of immunosuppressant and anti-epileptic drugs to the NTI list. The Board directed staff to propose the amendments regarding

the NTI list and to present the amendments regarding procedures for practitioners to prohibit substitution at the May 2008 meeting. The Board reviewed suggested language for two different amendments. Alternative proposed amendment #1 would allow a pharmacist to substitute a generically equivalent product for a product that previously had no generic equivalent unless the practitioner specifies on the initial prescription that the brand name product is medically necessary. This option would simply clarify rules that are already in place. Alternative proposed amendment #2 would not allow substitution of a generically equivalent product for a product that previously had no generic equivalent unless the pharmacist obtained authorization from the prescribing practitioner and would not allow a pharmacist to refill a prescription for a generic drug where the practitioner specified a particular manufacturer or indicated that the same manufacturer always be dispensed, with another manufacturer's product unless authorization is obtained from the prescribing practitioner.

Following discussion, a motion was made by Ms. Combs to approve for proposal the amendments referenced in discussion of alternative proposed amendment #1, as presented. There was no second. Ms. Combs withdrew the motion.

Following additional discussion, the motion was made by Mr. Brimberry to approve for proposal, with changes, the amendments referenced in discussion of alternative proposed amendment #2, concerning immunosuppressant and anti-epileptic drugs only. The motion died due to lack of a second.

Following additional discussion, the motion was made by Ms. Waggener, to approve for proposal the amendments referenced in discussion of alternative proposed amendment #1, with the addition of the word *available* in §309.3(c)(1)(A). The motion was seconded by Ms. Mendoza and passed 4-2-1. Dr. Bartlett-Pack, Ms. Combs, Ms. Mendoza, and Ms. Waggener approved. Mr. Brimberry and Mr. Laijas opposed. Mr. Caldwell abstained.

G. Disciplinary Orders

- Consideration of Proposals for Decision
 - In the Matter of Francisco Gabriel Ordonez, Applicant for Pharmacy Technician Registration (Tab 41)

Ms. Arnold advised the Board that a hearing was held before State Office of Administrative Hearings (SOAH) Administrative Law Judge Ami L. Larson on January 22, 2008, in the matter of

Francisco G. Ordonez, in which TSBP staff sought denial of Mr. Ordonez's application for pharmacy technician registration based on Mr. Ordonez's prior criminal conduct. Ms. Arnold introduced Judge Larson, who reviewed the *Proposal for Decision* for the Board. She advised the Board that she concurred with staff's assessment that Mr. Ordonez was currently not fit to be registered as a pharmacy technician and recommended that the application for registration be denied.

Ms. Hildebrand directed the Board's attention to Agreed Board Order #T-07-008 (ABO), which she reviewed for the Board.

Mr. Ordonez was present and made a statement to the Board. Mr. Ordonez answered questions posed by Mr. Laijas.

The motion was made by Ms. Waggener to accept the *Findings of Fact* and *Conclusions of Law* in the *Proposal for Decision* and approve Board Order #T-07-008, as presented, in the matter of Francisco Gabriel Ordonez to deny Mr. Ordonez's application for registration as a pharmacy technician. The motion was seconded by Mr. Laijas and passed 6-0-1. Mr. Brimberry abstained.

- In the Matter of Antonio Martinez, Pharmacist License #38929 (Tab 42) and A.M. Pharmacy, Pharmacy License #22603 (Tab 43)

Ms. Arnold directed the Board's attention to correspondence dated April 15, 2008, from Daniel Robledo, the attorney representing Antonio Martinez and A.M. Pharmacy. She pointed out that Mr. Robledo was requesting a continuance on consideration of the Proposal for Decision on Antonio Martinez and A.M. Pharmacy. Ms. Arnold presented a brief overview of the process leading up to the Board's consideration of the Proposal for Decision. She advised the Board that there was no provision for this type of motion in the TSBP rules or the Administrative Procedures Act.

Following discussion, the motion was made by Mr. Caldwell to deny the motion for continuance requested by Mr. Robledo on behalf of Antonio Martinez and A.M. Pharmacy. The motion was seconded by Ms. Combs and passed unanimously.

Ms. Arnold advised the Board that a hearing was held before State Office of Administrative Hearings (SOAH) Administrative Law Judge Ami L. Larson on September 18, 2007, in the

matters of Antonio Martinez and A.M. Pharmacy, in which TSBP staff sought to discipline Antonio Martinez and A.M. Pharmacy, based on Mr. Martinez's 2002 conviction of Driving While Intoxicated (DWI) and his 2005 deferred adjudication for felony DWI with Child Passenger. Ms. Arnold introduced Judge Larson, who reviewed the *Proposal for Decision* for the Board. She advised the Board that her conclusion was that the evidence did not support sanctions and the Board should not impose sanctions against Mr. Martinez or A.M. Pharmacy.

Ms. Woody reviewed the background in the case for the Board. She directed the Board's attention to two versions of Agreed Board Orders #G-06-022-A and #G-05-022-B and reviewed the options available to the Board.

Following discussion, the motion was made by Ms. Waggener to accept the *Findings of Fact* and *Conclusions of Law* in the *Proposal for Decision*, with the addition of *Conclusion of Law No. 15A*, and approve Board Orders #G-06-022-A and #G-06-022-B, as presented, to suspend the pharmacist license of Antonio Martinez and the pharmacy license of A.M. Pharmacy for a period of five years, with the suspensions being probated with conditions. The motion was seconded by Ms. Combs and passed unanimously.

D. Updates and Reports of Committees/Task Forces

- Task Force on Class D Pharmacies (Tab 17)

Ms. Benz directed the Board's attention to a list of the members of the Class D Task Force and reviewed the charge of the task force. She introduced Heidi Bragg, R.Ph., who chaired the task force. Ms. Bragg reviewed the recommendations of the task force. Ms. Benz directed the Board's attention to suggested amendments to §§291.91-291.94 (Tab 18) to implement the recommendations of the task force. She also directed the Board's attention to additional recommendations for amendments to §§291.91-291.94 (Tab 18), which were recommended by staff.

Following discussion, the motion was made by Ms. Waggener to merge the amendments recommended by staff with the amendments to implement the recommendations of the task force and approve the merged amendments for proposal, with the addition of language to prohibit Class D pharmacies from having Carisoprodol or drugs used to treat erectile dysfunction. The motion was seconded by Dr. Bartlett-Pack and passed 6-0-0. Mr. Brimberry was not present for the vote.

President Fry recessed the meeting at 2:53 p.m.

President Fry reconvened the meeting at 3:11 p.m.

C. Discussion of and Possible Action Regarding Rules (Cont.)

- Rule Reviews

Ms. Benz directed the Board's attention to the TSBP Rule Review Plan for FY2006-2009. (Tab 14)

Ms. Benz directed the Board's attention to the suggested review of Chapter 291 (§§291.71-291.76) concerning Class C (Institutional) pharmacies (Tab 15) and Chapter 303 (§§303.1-303.3) concerning destruction of dangerous drugs and controlled substances (Tab 16).

Following discussion, in accordance with Government Code §2001.039, the motion was made by Mr. Caldwell to approve for proposal the review of Chapter 291 (§§291.71-291.76) and Chapter 303 (§§303.1-303.3), as presented. The motion was seconded by Ms. Mendoza and passed unanimously.

D. Updates and Reports of Committees/Task Forces (Cont.)

- Task Force on Class C Pharmacies (Tab 19)

Dr. Holder advised the Board that the first meeting of the Task Force on Class C Pharmacies was held on April 10, 2008. He advised the Board that the direction of the task force was defined at the meeting, and the next meeting would focus on review of rules.

- Request from Pharmacy Unlimited for Delay in Implementation of Pilot Project (Tab 20)

Ms. Benz explained that at its February 2008 meeting, the Board approved a pilot project proposal from Pharmacy Unlimited to expand pharmaceutical services to small rural hospitals by using automated medication supply systems under the control of centrally-located pharmacists. She directed the Board's attention to an email from Danny Skaggs of Pharmacy Unlimited requesting a delay of 90 days in implementation of the pilot project.

Following discussion, the motion was made by Mr. Brimberry to approve a 90-day delay in the implementation of the pilot project by Pharmacy Unlimited, under the terms and conditions set forth in the

pilot project report, with the reporting requirements established at the Board's February 2008 meeting. The motion was seconded by Ms. Waggener and passed unanimously.

E. Discussion of and Possible Action Concerning the Following Reports and Discussions (Cont.)

- Financial Update

- Review of FY2008 Operating Budget (Tab 21)

- Ms. Stella reviewed the expenditures for the first two quarters of FY2008 (September 1, 2007, through February 29, 2008) for the Board.

- Review of Board Member Travel Budget (Tab 22)

- Ms. Stella briefly reviewed the Board Member FY2008 Travel Budget.

- Review and Approval of FY2009-2013 Strategic Plan (Tab 23)

Ms. Dodson directed the Board's attention to a draft of the *TSBP FY2009-2013 Strategic Plan*. Ms. Stella advised the Board that the strategic plan was due in the Governor's Office by June 27, 2008.

Following a brief review of the plan, the motion was made by Mr. Caldwell to approve the *TSBP FY2009-2013 Strategic Plan*, with two corrections on the cover: Mr. Brimberry's hometown should be changed to Cedar Park, and Mr. Caldwell's hometown should be changed to McKinney. The motion was seconded by Ms. Combs and passed unanimously.

- Professional Recovery Network (PRN) Update

- Dr. Holder directed the Board's attention to charts showing participation in the peer assistance program. (Tab 24)

- Jennifer Graydon, Director of PRN, reviewed expenditures and current PRN activities for the Board. (Tab 25) The Board asked Ms. Graydon to present future financial reports in a format that would correspond to TSBP's fiscal year.

- Ms. Dodson directed the Board's attention to the PRN audit for the program year ended August 31, 2007. (Tab 26) She pointed out that there were no exceptions and no problems with PRN's recordkeeping or reports to TSBP.

Following review of the audit by the Board, the motion was made by Ms. Waggener to approve the PRN audit for the program year ended August 31, 2007, as presented. The motion was seconded by Dr. Bartlett-Pack and passed unanimously.

- Ms. Dodson directed the Board attention to the PRN proposed budget for FY2010-2011. (Tab 27) Ms. Stella reviewed the budget for the Board and pointed out that while PRN was not asking for an increase in funding, it would be necessary to increase the TSBP Legislative Appropriations Request by \$14,906 in FY2010 to maintain funding for the PRN program at the level previously approved by the Board.
- TSBP Revenue Projections and Proposed Budgets for FY2010-2011 (Tab 28)

Ms. Stella directed the Board's attention to information concerning TSBP's revenue projections and proposed budgets for FY2010-2011, which included the following:

- FY2010-2011 Proposed Legislative Appropriations Request (LAR) – Summary of Exceptional Items;
- Position Justifications for New Personnel;
- Comparison Detail of FY2008-2009 Budget & FY2010-2011 Proposed LAR;
- Explanation of Expenditures FY2010-2011;
- Revenue Projections and Fee Scenario; and
- History of Fee Increases.

Ms. Stella and Ms. Dodson reviewed the financial documents for the Board and answered questions posed by the Board.

Following review and discussion of the budget documents, the motion was made by Ms. Combs to approve the proposed budget, with an increase of \$14,906 to maintain funding of the PRN budget, to add equity increases for attorneys to the exceptional item request, to give the Executive Committee authority to approve any necessary changes to the LAR, and to correct *Investigator VI* to *Investigator IV* on the exceptional item request. The motion was seconded by Ms. Mendoza and passed unanimously.

Following review and discussion of the revenue projections and the fee scenarios, the motion was made by Mr. Brimberry to approve the LAR as amended, with the stipulation that the budget request for FY2010-2011 was approved with the understanding that a fee increase would be necessary in the FY2010-2011 biennium in order to produce a Biennial Revenue Estimate that will support the LAR. The increase to the Peer Assistance Strategy of \$14,906 in FY2010 is contingent upon the Legislature increasing the cap to accommodate this request. The motion was seconded by Ms. Mendoza and passed unanimously.

- Internal Risk Assessment (Tab 29)

Ms. Stella explained that TSBP is required to submit a risk assessment report annually to the State Auditor's office. She directed the Board's attention to the report and reviewed the report for the Board. Following discussion, it was the consensus of the Board that the report was an adequate risk assessment for TSBP.

- *TSBP 2009 Calendar of Events* (Tab 30)

Ms. Dodson directed the Board's attention to a draft of the *TSBP Calendar of Events* for FY2009. Following review, the motion was made by Ms. Combs to approve the *FY2009 Calendar of Events*, as presented. The motion was seconded by Mr. Caldwell and passed unanimously.

- Customer Service Survey (Tab 31)

Ms. Dodson directed the Board's attention to the results of the TSBP customer service survey for January 1, 2007 – December 31, 2007. Ms. Dodson reviewed the report for the Board.

- Audit Conducted by State Auditor's Office (Tab 32)

Ms. Dodson advised the Board that the audit of TSBP Complaint Processing and Enforcement by the State Auditor's Office was still in progress, and the final audit report should be available by the August 2008 Board Meeting.

- Health Professions Council (HPC) (Tab 33)

Ms. Dodson reported that the Business Process Plan developed by the Governor's Office concerning the possible consolidation of some of the administrative functions of HPC agencies was complete and was being reviewed by the HPC.

Ms. Dodson advised the Board that the Health Professions Council had assumed responsibility for posting job vacancies and receiving and copying applications for TSBP.

- House and Senate Interim Committees (Tab 34)

There was no report under this topic.

- Update on TSBP Action on Legislation Passed by the 80th Texas Legislature that has an Impact on TSBP and/or the Practice of Pharmacy (Tab 35)

Ms. Dodson directed the Board's attention to an action chart concerning legislation that was passed during the 80th Legislative Session that had an impact on TSBP and/or the practice of pharmacy. The chart contained the bill number, action required of TSBP, effective date of the bill, TSBP's internal deadline, and the current status of TSBP's implementation of the bill.

- Possible Statutory Changes (Tab 36)

Ms. Dodson directed the Board's attention to a list of *Recommendations for Legislative Action Approved by the Board* for consideration during the next legislative session. She directed the Board's attention to Section 562.012 of the *Texas Pharmacy Act*, titled *Substitution of Dosage Form Permitted*. (Tab 37) Ms. Waggener explained that often prescriptions are written for capsules when a drug only comes in tablet form, or visa versa. She stated that in these situations, when the pharmacist contacts the doctor, the doctor is always agreeable to the pharmacist changing the prescription. Following discussion, it was the consensus of the Board to add substitution of dosage form to the list of possible statutory changes

during the next legislative session and seek legislative approval to allow pharmacists to change the dosage form on a prescription that indicates an unavailable dosage form without contacting the doctor.

F. Consideration of and Possible Action Concerning Enforcement Reports

- Petition(s) to Serve as a Preceptor (Tab 38)

There was no business under this item.

- Report on Dismissed Complaints (Tab 39)

The Board received a report on complaints dismissed and closed during the first two quarters of FY2008 (September 1, 2007 – February 29, 2008). The report also included quarterly averages of FY2007 as compared to FY2008, as well as percentage of change from FY2007 to 2008. Ms. Fisher reviewed the report for the Board.

H. Miscellaneous

- Items to be Placed on Agenda for August 2008 Board Meeting (Tab 44)
 - The Board reviewed a letter received from Dennis Wiesner, R.Ph., of HEB, concerning the minimum information that must be present on the dispensing container at the time of delivery of the drug for a Class A pharmacy. Mr. Wiesner asked that the Board consider the possibility of modifying this labeling requirement. Following discussion, the Board directed staff to research the issue and FDA requirements and present a report to the Board at its August 2008 meeting.

- Discussion of and Possible Action on Recent Conferences and Events

The Board reviewed Board Member and Executive Director attendance at recent conferences and events.

- Discussion of and Possible Action on Upcoming Conferences and Events (Tab 45)

The Board discussed Board Member and Executive Director attendance at upcoming conferences and events. The Board reviewed proposed amendments to the constitution and bylaws of the National Association of Boards of Pharmacy (NABP), which will be considered at the NABP annual meeting on May 17-20, 2008.

President Fry recessed the meeting at 4:55 p.m.

Wednesday, May 7, 2008

President W. Benjamin Fry, R.Ph., called the meeting to order at 9:01 a.m. Other Board Members present were Vice President Kim A. Caldwell, R.Ph.; Treasurer Jeanne Waggener, R.Ph.; W. Michael Brimberry, R.Ph., M.B.A.; Rosemary Forester Combs; Marcelo Laijas, Jr.; and Alice Mendoza, R.Ph.

Board Members Juluette Bartlett-Pack, Ph.D., and Doyle High, R.Ph., were not present.

Staff present were Gay Dodson, R.Ph., Executive Director/Secretary; Carol Fisher, R.Ph., M.P.A., Director of Enforcement; Paul Holder, R.Ph., Pharm.D., Assistant Director of Enforcement; Cathy Stella, Director of Licensing and Administrative Services; Kerstin Arnold, General Counsel; Julie Hildebrand, Litigation Attorney; Mitra Woody, Staff Attorney; Caroline Hotchkiss, Staff Attorney; Allison Benz, R.Ph., M.S., Director of Professional Services; and Kay Wilson, Executive Assistant.

Also present was Lawrence Divine, Pharmacist Intern.

C. Discussion of and Possible Action Regarding Rules (Cont.)

Final Adoption of Rules

Ms. Benz explained that earlier in the meeting, the Board had reviewed and discussed rules that were being considered for final adoption. She provided the Board Preambles and Orders Adopting Rules for each of the previously-presented rules. Following additional discussion and review of the Preambles and Orders Adopting Rules, the following actions were taken by the Board:

- Rules Concerning Disciplinary Guidelines (§§281.63-281.64) (Tab 2)

The motion was made by Mr. Caldwell to approve for final adoption, as proposed, by Board Order, amendments to §§281.63-281.64. The motion was seconded by Ms. Combs and passed unanimously.

- Rules to Implement the Recommendations of the Task Force on Internship Requirements (Chapter 283) (Tab 3)

The motion was made by Ms. Waggener to approve for final adoption, with changes to further clarify the definition of an intern-trainee and the ratio of preceptors to pharmacist-interns, by Board Order, amendments to §§283.1-283.2 and §§283.4-283.6. The motion was seconded by Ms. Mendoza and passed unanimously.

- Rules Concerning Prescription Labeling by Class E Pharmacies (§291.104) (Tab 5)

The motion was made by Mr. Caldwell to approve for final adoption, with modifications to the rules for non-resident pharmacies, by Board Order, amendments to §291.104. The motion was seconded by Ms. Mendoza and passed unanimously.

- Rules Concerning Pharmacy Technician Exemption from Certification Examination Requirements (§297.7) (Tab 6)

The motion was made by Ms. Waggner to approve for final adoption, as proposed, by Board Order, amendments to §297.7. The motion was seconded by Ms. Mendoza and passed unanimously.

- Rules to Implement Recommendations of the Joint Committee on Narrow Therapeutic Index Drugs (§309.3) (Tab 7)

The motion was made by Ms. Waggner to approve for final adoption, with changes to correct Pharmacy Act references, by Board Order, amendments to §309.3. The motion was seconded by Ms. Combs and passed unanimously.

F. Consideration of and Possible Action Concerning Enforcement Reports

- Report on Status of Active/Pending Complaints (Tab 40)

The Board received a *Report on Status of Active/Pending Complaints*. Ms. Fisher reviewed the report for the Board.

G. Disciplinary Orders

- Discussion of and Action on Proposed Agreed Board Orders and Default Orders

The Board received and reviewed a list of 18 Agreed Board Orders for pharmacy technicians and pharmacy technician trainees following informal conferences, which were held on:

- January 24, 2008 (one Order);
- February 21, 2008 (nine Orders); and
- April 20, 2008 (eight Orders).

The Board also received a list of ten Default Orders for pharmacy technicians and pharmacy technician trainees who did not appear for informal conferences.

The motion was made by Mr. Caldwell to approve the 18 Agreed Board Orders for pharmacy technicians and pharmacy technician trainees following informal conferences and the ten Default Board Orders for pharmacy technicians and pharmacy technician trainees. The motion was seconded by Ms. Combs and passed 6-0-0.

- Report on Agreed Board Orders Entered by Executive Director
 - The Board received and reviewed a list of 34 Technician Agreed Board Orders (Alternative Resolution and Falsification) that had been signed by the Executive Director on behalf of the Board in accordance with their directives during the period February 11, 2008, through April 30, 2008.

- Discussion of and Action on Proposed Agreed Board Orders and Default Orders

- The Board received four Agreed Board Orders for pharmacists, pharmacies, and pharmacy technicians that were received after the board meeting began. Ms. Arnold reviewed the alleged violations, as well as the recommended sanctions for the four Agreed Board Orders.

1. Juan Raul Ramirez ABO #T-07-775-N

The motion was made by Mr. Caldwell to approve the Order as presented. The motion was seconded by Ms. Waggener and passed 6-0-0.

2. John Carlton Grantham ABO #H-07-016-A

The motion was made by Mr. Laijas to approve the Order as presented. The motion was seconded by Ms. Waggener and passed 6-0-0.

3. Walgreen Co. #5389 ABO #H-07-006-B

The motion was made by Mr. Caldwell to approve the Order as presented. The motion was seconded by Ms. Combs and passed unanimously.

4. Walgreen Co. #6759 ABO #H-07-008-B

The motion was made by Mr. Brimberry to approve the Order as presented. The motion was seconded by Ms. Waggener and passed 6-0-0.

- The Board received notebooks containing 47 Agreed Board Orders for pharmacists, pharmacies, student pharmacist-interns, and pharmacy technicians, 19 of which were Confidential Agreed Board Orders.

Ms. Hildebrand reviewed the alleged violations, as well as the recommended sanctions for each of the following Board Orders (Alternative Resolution) concerning pharmacists, pharmacies, student pharmacist-interns, and pharmacy technicians.

1. Deepal Anantrai Dave ABO #L-08-003

The motion was made by Ms. Waggener to approve the Order as presented. The motion was seconded by Ms. Mendoza and passed 6-0-0.

2. Veterinary Pharmaceuticals, Inc. ABO #L-07-017

The motion was made by Mr. Brimberry to approve the Order as presented. The motion was seconded by Ms. Mendoza and passed 6-0-0.

3. Dionne Rechelle Smith ABO #H-07-008-A

The motion was made by Mr. Laijas to approve the Order as presented. The motion was seconded by Ms. Combs and passed 6-0-0.

4. Daniel Craig Waters ABO #J-07-007-A
5. Save Mart Pharmacy ABO #J-07-007-B

The motion was made by Ms. Waggener to approve the Orders as presented. The motion was seconded by Mr. Caldwell and passed 6-0-0.

6. Arlington Pharmacy – North ABO #J-08-012-B

The motion was made by Ms. Combs to approve the Order as presented. The motion was seconded by Mr. Caldwell and passed 6-0-0.

Ms. Hildebrand and Ms. Woody reviewed the alleged violations, as well as the recommended sanctions for each of the following Agreed Board Borders (following an Informal Conference) concerning pharmacists, pharmacies, students, pharmacist-interns, and pharmacy technicians.

7. Brandon D. Zee ABO #H-07-006-A

The motion was made by Ms. Combs to approve the Order as presented. The motion was seconded by Ms. Waggener and passed 5-0-1. Mr. Fry abstained.

8. Jissi Ngam Balon ABO #S-08-002

The motion was made by Ms. Waggener to approve the Order as presented. The motion was seconded by Ms. Combs and passed 5-0-1. Mr. Fry abstained.

9. Sorithea Chan ABO #K-08-009

The motion was made by Mr. Caldwell to approve the Order as presented. The motion was seconded by Ms. Waggener and passed 5-0-1. Mr. Fry abstained.

10. Titilayo Omodele Lawal ABO #S-08-001

The motion was made by Mr. Caldwell to approve the Order as presented. The motion was seconded by Ms. Combs and passed 5-0-1. Mr. Fry abstained.

11. Lawndale Pharmacy ABO #B-05-055

The motion was made by Ms. Combs to approve the Order as presented. The motion was seconded by Ms. Waggener and passed 5-0-1. Mr. Fry abstained.

12. The Medicine Shoppe ABO #B-05-039

The motion was made by Ms. Combs to approve the Order as presented. The motion was seconded by Ms. Mendoza and passed 5-0-1. Mr. Fry abstained.

13. CVS/pharmacy #2979 ABO #H-07-005

The motion was made by Ms. Combs to approve the Order as presented. The motion was seconded by Ms. Mendoza and passed 5-0-1. Ms. Waggener abstained.

14. Rhome Pharmacy ABO #B-07-011

The motion was made by Ms. Waggener to approve the Order as presented. The motion was seconded by Ms. Combs and passed 5-0-1. Ms. Mendoza abstained.

15. Larry Phillip Oliver ABO #K-07-008-A
16. Triad Compounding Pharmacy ABO #K-07-008-B
17. Triad Pharmacy #2 ABO #L-08-002
18. Trinity Rx ABO #L-08-005

The motion was made by Ms. Mendoza to approve the Orders as presented. The motion was seconded by Ms. Combs and passed 5-0-1. Mr. Fry abstained.

19. Soochan Na ABO #S-07-011
20. Soochan Na ABO #L-08-012

The motion was made by Mr. Caldwell to approve the Orders as presented. The motion was seconded by Mr. Brimberry and passed 5-0-1. Mr. Fry abstained.

21. David Allen Nall ABO #E-07-032

The motion was made by Ms. Mendoza to approve the Order as presented. The motion was seconded by Mr. Brimberry and passed 5-0-1. Mr. Fry abstained.

22. William H. Powell, Jr. ABO #C-05-005-A

The motion was made by Mr. Brimberry to approve the Order as presented. The motion was seconded by Ms. Waggener and passed 5-0-1. Ms. Combs abstained.

23. Dennis Martin George ABO #J-06-005

The motion was made by Ms. Waggener to approve the Order as presented. The motion was seconded by Mr. Brimberry and passed 5-0-1. Ms. Combs abstained.

24. Joyce Ann Gilmore-James ABO #J-06-010

The motion was made by Mr. Brimberry to approve the Order as presented. The motion was seconded by Ms. Waggener and passed 5-0-1. Ms. Combs abstained.

25. Douglas E. Garrie ABO #A-05-006

The motion was made by Ms. Waggener to approve the Order as presented. The motion was seconded by Ms. Combs and passed 5-0-1. Mr. Fry abstained.

26. Nermin Awad El Hadik ABO #B-07-001-A
27. Doctor's Pharmacy Rx ABO #B-07-001-B

The motion was made by Ms. Waggener to approve the Orders as presented. The motion was seconded by Mr. Laijas and passed 5-0-1. Ms. Mendoza abstained.

28. Margaret Beaulieu Novosad ABO #G-06-033

The motion was made by Ms. Waggener to approve the Order as presented. The motion was seconded by Ms. Mendoza and passed 5-0-1. Mr. Fry abstained.

- Report on Agreed Board Orders Entered by Executive Director
 - Ms. Arnold directed the Board's attention to lists of Agreed Board Orders (Alternative Resolution) concerning pharmacies, pharmacists, and pharmacy technicians that had been entered by the Executive Director on behalf of the Board in accordance with their directives during the period February 29, 2008, through April 25, 2008. The Board reviewed the lists.

C. Discussion of and Possible Action Regarding Rules (Cont.)

Final Adoption of Rules

- Ms. Benz explained that earlier in the meeting, the Board had reviewed and discussed rules that were being considered for final adoption.

She provided the Board a Preamble and Order Adopting Rule for the previously-presented rules concerning Chapter 291, Subchapter B (Tab 4), which included the following rules:

- To Implement the Recommendations of the Task Force on Security in Class A Pharmacies (§§291.31-291.34);
- Concerning Responsibility for Errors (§291.32);
- Concerning Counseling (§§291.323-291.34); and
- Concerning Emergency Dispensing of a 30-Day Supply of Drugs in the Event of a Disaster (§291.34).

She pointed out that based on comments received, the proposed amendments had been changed as follows:

- Changes to §§291.33-291.34 would allow pharmacies additional time to comply with the rules regarding documentation of patient counseling; and
- Changes to §291.33 would amend the rule to include other types of locking systems with regard to security of the pharmacy and to allow pharmacists to take short breaks from the pharmacy while on-site but not define a specific amount of time that the pharmacist may take a break.

Following discussion and review of the Preamble and Order Adopting Rule, the motion was made by Ms. Mendoza to approve the amendments to §§291.31-291.34, with changes, by Board Order. The motion was seconded by Ms. Waggener and passed 5-1-0. Mr. Brimberry opposed.

A. Announcements (Cont.)

The Board directed staff to schedule the second day of future board meetings to begin at 8:00 a.m.

President Fry recessed the meeting at 10:02 a.m.

President Fry reconvened the meeting at 10:18 a.m.

C. Discussion of and Possible Action Regarding Rules (Cont.)

Final Adoption of Rules

At Mr. Brimberry's request, the Board reopened discussion concerning amendments to the following rules, which were adopted earlier in the meeting:

- §§291.31-291.34 to Implement the Recommendations of the Task Force on Security in Class A Pharmacies;
- §291.32 Concerning Responsibility for Errors;
- §§291.323-291.34 Concerning Counseling; and
- §291.34 Concerning Emergency Dispensing of a 30-Day Supply of Drugs in the Event of a Disaster.

Following discussion, the motion was made by Mr. Brimberry to rescind the previous motion approving adoption of amendments to §§291.31-291.34. The motion was seconded by Ms. Waggener and passed unanimously.

G. Disciplinary Orders (Cont.)

- Discussion of and Action on Proposed Agreed Board Orders and Default Orders

Ms. Arnold advised the Board that an additional Agreed Board Order concerning a pharmacy technician had been received. She presented the Order for the Board's consideration.

Myesha Louise Davis

ABO #T-06-396

The motion was made by Ms. Waggener to approve the Order as presented. The motion was seconded by Ms. Combs and passed 5-0-1. Mr. Brimberry abstained.

E. Discussion of and Possible Action Concerning the Following Report and Discussions (Cont.)

- Possible Statutory Changes (Tab 36)

The Board directed staff to add confidentiality of proprietary formulas to the list of possible changes to the Pharmacy Act during the next legislative session.

G. Disciplinary Orders (Cont.)

- Executive Session to Consider Confidential Agreed Board Orders

Mr. Caldwell made a motion that the Board go into Executive Session to consider Agreed Board Orders involving impaired pharmacists and pharmacist applicants under the authority of the Texas Pharmacy Act, Section 564.002. The motion was seconded by Ms. Waggener and passed 6-0-0.

President Fry declared the Board in Executive Session at 10:35 a.m.

At 10:48 a.m., President Fry announced that the Board would resume the meeting in Open Session. President Fry announced that no action was taken and no decisions were made during Executive Session.

Mr. Caldwell made motions to approve the following confidential Orders:

1. ABO #G-08-003
2. ABO #N-08-001
3. ABO #M-08-007
4. ABO #M-08-008
5. ABO #N-08-003
6. ABO #N-07-020
7. ABO #N-08-006
8. ABO #G-08-008
9. ABO #S-07-018-A
10. ABO #G-07-022
11. ABO #M-08-004
12. ABO #G-08-010
13. ABO #L-07-025
14. ABO #L-08-004
15. ABO #M-08-005
16. ABO #E-08-001
17. ABO #N-08-002
18. ABO #N-08-005
19. ABO #G-08-013

The motions were seconded by Ms. Combs and passed as follows:

1. 6-0-0.
2. 6-0-0.
3. 6-0-0.
4. 6-0-0.
5. 5-0-1. Mr. Brimberry abstained.
6. 6-0-0.
7. 6-0-0.
8. 5-0-1. Ms. Combs abstained.
9. 6-0-0.
10. 6-0-0.
11. 6-0-0.
12. 6-0-0.
13. 6-0-0.
14. 6-0-0.
15. 6-0-0.
16. 5-0-1. Ms. Waggener abstained.
17. 6-0-0.
18. 6-0-0.
19. 6-0-0.

H. Miscellaneous (Cont.)

- Items to be Placed on Agenda for August 2008 Board Meeting (Tab 44)

Board Members and/or Ms. Dodson requested the following items be placed on the agenda for the August 2008 or future Board Meetings:

- Update and/or final report of Task Force on Class C Pharmacies;
- Report on audit conducted by State Auditor's office;
- Public hearing concerning rules on generic substitution;
- Reconsideration of Class A security rules for final adoption;
- Discussion concerning the initials of the dispensing pharmacist on the container label at the time of delivery of the drug in a Class A Pharmacy; and
- Begin Board meetings at 8:00 a.m. on second day.

President Fry adjourned the meeting at 10:50 a.m.

APPROVED:

W. Benjamin Fry, R.Ph.
President

Gay Dodson, R.Ph.
Executive Director/Secretary

August 5, 2008