

**TENNESSEE BOARD OF PHARMACY
MARCH 29 - 30, 2007
ROOM 160 - DAVY CROCKETT TOWER
NASHVILLE, TN**

BOARD MEMBERS PRESENT:

Sheila Mitchell, President
Robert Mitchell, Vice President
Monica Franklin, Consumer Member
Todd Bess, Member
Larry Hill, Member
Julie Frazier, Member

STAFF PRESENT:

Terry Grinder, Interim Executive Director
Alison Z. Cleaves, Chief Legal Counsel
Martha Agee, Board Administrator

The Tennessee Board of Pharmacy convened on Thursday, March 29, 2007, in Room 160 of the Davy Crockett Tower, 500 James Robertson Parkway, Nashville, Tennessee. A quorum of the members being present, the meeting was called to order at 9:00 a.m. CDT, by Dr. Sheila Mitchell, President. President Sheila Mitchell noted for the record Dr. Bettie Wilson will not be attending the meeting.

APPROVAL OF THE MINUTES

The minutes of the November 7 - 8, 2006 board meeting were presented and reviewed by the Board. Dr. Larry Hill motioned to **accept** the minutes; seconded by Dr. Todd Bess. All were in favor and the motion carried.

RULEMAKING HEARING - CHARITABLE CLINIC PHARMACY RULES

President Sheila Mitchell referred the Charitable Clinic Pharmacy Rulemaking Hearing to Chief Legal Counsel, Mrs. Alison Cleaves. Mrs. Cleaves, chief legal counsel, called the rulemaking hearing to order at 9:07 a.m. CDT and noted Dr. Terry Grinder is serving as the acting Interim Executive Director of the Tennessee Board of Pharmacy. Chief legal counsel, Mrs. Cleaves, stated the hearing will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, T.C.A. §4-5-204, in Room 160 of the Davy Crockett Tower, 500 James Robertson Parkway, Nashville, Tennessee on March 29, 2007. The Board is to implement rules for Public Chapter 919, "Nina Norman Prescription Drug Donation Act of 2006", which

authorizes charitable clinic pharmacies to redispense medicines to indigent patients that would otherwise be destroyed. This Act requires the Board of Pharmacy, in conjunction with the Department of Health, Health Related Boards, to promulgate as public necessity rules and requires two (2) progress reports to be submitted along with any recommendations or findings to the Health Committees of the General Assembly on March 1, 2007 and January 1, 2008. Mrs. Cleaves, chief legal counsel, stated any individuals with disabilities who wish to participate in these proceedings or to review these filings should contact the Department of Commerce and Insurance for accommodations. The proposed rules were properly filed in the Secretary of State's Office on January 31, 2007, and will become effective seventy-five days from the date of filing. The Notice of Rulemaking Hearing was published in the Tennessee Administrative Register (TAR) on February 15, 2007. Mrs. Alison Cleaves, chief legal counsel, advised Dr. Terry Grinder notified the Tennessee Pharmacists Association (TPA), Tennessee Medical Association (TMA), and all pharmacy corporate and district managers within the State.

The Substance of the Rules:

1140-12-.01 Purpose

The rules in this chapter implement the Nina Norman Prescription Drug Donation Act of 2006, T.C.A. §63-10-501, et seq., which has been enacted into law to develop a prescription drug redispensing program that authorizes charitable clinic pharmacies to redispense medicines to indigent patients that would otherwise be destroyed.

1140-12-.02 Definitions

1140-12-.03 Application and Renewal Requirements

1140-12-.04 Fees

1140-12-.05 Pharmacist Responsibilities

1140-12-.06 Pharmacist In Charge Responsibilities

1140-12-.07 Donor Patient Form

1140-12-.08 Waiver Form

1140-12-.09 Civil Penalties

The Board received comments from Dr. Bruce L. Wolf with the Dispensary of Hope.

#1 One concern expressed with that current (prior) legislation requires destruction of unused medicines on site at a given nursing facility. Does the Norman Act get around this requirement?

#2 Can the unused medicines legally be directed to a Dispensary Distribution entity or a specific clinic? If the patient or the family signs a waiver allowing the medicines to be reused, does that permission circumvent the present requirement that they be destroyed? Does the Department of Health need to render an opinion concerning this question?

#3 Under Pharmacist Responsibilities 1140-12-.05 (3), can the pharmacist *or their designee* remove or de-identify information on the contributed medications?

#4 Under Pharmacist Responsibilities 1140-12-.05 (8), the definition does not seemingly allow for the Dispensary of Hope to redistribute the donated medications to qualified indigent clinics, i.e., clinics that strictly adhere to the Charitable Clinic guidelines. The Dispensary Distribution model is a unique institution to Tennessee. It could serve as a reverse distributor of such medications. As such, it would insure medications were handled, stored, inventoried and distributed, in strict accordance with Tennessee Pharmacy Laws.

BOARD'S RESPONSE

#1 Rule 1140-4-.10 Unused Drugs, Devices, and Related Materials - The Board noted any medications, or drugs must be destroyed at the facility in a nursing home setting. The Charitable Clinic Pharmacy rule would not apply as it is the law, "Nina Norman". As long as the family has provided a waiver for the medications to be released to the Charitable Clinic, it would override the nursing home administrator's rule.

#2 Chief legal counsel, Mrs. Alison Cleaves, advised it will be up to the Department of Health to update their rules and any questions may be addressed to Ms. Robbie Bell, Director.

#3 Mrs. Alison Cleaves, chief legal counsel, stated a “technician” described as “*or their designee*”, would have to abide by the Board of Pharmacy Rules and would be acceptable.

#4 Because of their volume, everything is shipped to the one location and only sees things that are needed at their clinics. The transfer of drugs can not be shipped to another location. The Dispensary of Hope can not be a distributor.

Mrs. Alison Cleaves informed the Board there are no other individual questions to make any comments on these rules.

Comments made from Mrs. Alison Cleaves, chief legal counsel.

1140-12-.05 (3) (a) Recordkeeping. Any pharmacist working at a charitable clinic pharmacy shall create and maintain a manifest of the prescription drugs transferred from the institutional facility to the pharmacy that were not dispensed because the drugs were expired, adulterated, misbranded, recalled, deteriorated, not kept under proper conditions, or did not have the identifying drug information on them as provided in Rule 1140-12-.05 (4). Pharmacist shall maintain this manifest at the pharmacy for two (2) years from the date of destruction.

Mrs. Cleaves referenced Rule 1140-9-.01 (i), states “The sale, purchase, or trade of a prescription drug, or as offer to sell, purchase or trade of a prescription drug by a pharmacy practice site to another pharmacy practice site or to authorized prescribing practitioners, except that the total gross dollar volume of such transfer shall not exceed five percent (5%) of the total medical and prescription orders sales revenue of either the transferor or transferee pharmacy during any twelve (12) consecutive month period.

Delete language in Rule 1140-12-.05 (1) (a) (8) - the transferred drugs are not re-distributed to another location; and

Change to: the donated drugs will be transported to one licensed pharmacy to another by an individual designated by the PIC or by any other means....

1140-12-.05 (8) (3)

Addition for Subsection (c) - The pharmacist shall maintain a manifest of all prescription drugs from one pharmacy to another for a period of two (2) years.

Dr. Julie Frazier motioned to **accept** the changes, seconded by Dr. Todd Bess. All were in favor and the motion carried.

Dr. Todd Bess motioned to keep the rulemaking hearing open until 11 a.m.; seconded by Mrs. Monica Franklin. All were in favor and the motion carried.

Mrs. Alison Cleaves, chief legal counsel, stated during the recess, the Board received comments from the Tennessee Pharmacist Association (“TPA”). Mrs. Cleaves stated after the motion was made, TPA submitted the following comments.

#1 1140-12-.02 Definitions:

(11) “Single Unit Dose”

Delete the words “Postal Service” between “United States and “Class B” in the definition and instead inserting the word “Pharmacopeia”.

#2 1140-12-.05 Pharmacist Responsibilities

(1) Medication Transfers

(a)

2.

Delete the word “clinic” from between “...from the” and “to the pharmacy...” and instead inserting “institutional facility”.

Insert the words “copy of the” between “...does not receive” and “donor form...”

#3 1140-12-.05 Pharmacist Responsibilities

(1) Medication Transfers

3.

Insert the words “or redacted” between “have been removed” and “from the package...” and the words “or redact” between “...shall remove” and “this information.”

#4 1140-12-.05 Pharmacist Responsibilities

(1) Medication Transfers

(a)

6.

Adding the words “after creating the documentation required in 1140-12-.05 (3) (a)” after “...destroy them” and before the punctuation”;

#5 1140-12-.05 Pharmacist Responsibilities

(1) Medication Transfers

(a)

9.

Adding the words “of the charitable clinic pharmacy” between the words “...in charge” and “or through...”

#6 1140-12-.05 Pharmacist Responsibilities

(2) Prohibited Activities

(a)

Delete this entire section or rewriting it completely.

Suggestion: There is nothing in any law or rule prohibiting a charitable clinic pharmacy from registering with DEA to be able to purchase, possess, or dispense any controlled substances. The “Nina Norman Prescription Drug Donation Act of 2006” simply limits the prescription drugs that can be donated so that controlled substances can not be donated. This does not mean a charitable clinic could not register with DEA and then purchase and dispense controlled substances if the pharmacy chose to do so.

#7 1140-12-.05 Pharmacist Responsibilities

(3) Recordkeeping

(a)

Redefine "Manifest" as defined in 1140-12-.02 (4) or clarify use of the term "manifest" in this section.

Suggestion: The definition of "Manifest" in 1140-12-.02 (4) states "the list shall include the drug name, strength, quantity, and expiration date". If the information required in Rule 1140-12-.02 (4) is not present on the packaging when the charitable clinic pharmacy receives the donated drugs, it will be impossible for the pharmacy to create a "manifest" because the information required for a "manifest" as defined will not be available.

Mrs. Monica Franklin motioned to **accept the proposed changes for #1, #2, #3, #4, and #5. For #6 and #7, the changes were not accepted.** Dr. Julie Frazier seconded the motion. All were in favor and the motion carried.

CONSENT ORDERS

CHARLES CUTHBERT, DPH
226 Halberton Drive
Franklin, TN 37069

Interim Executive Director, Dr. Terry Grinder, presented a Consent Order which Dr. Charles Cuthbert signed on March 19, 2007 for the voluntary surrender of his license due to chemical addiction. Dr. Julie Frazier motioned to **accept** the Consent Order; seconded by Mrs. Monica Franklin. All were in favor and the motion carried.

GRADY L. SAXTON, DPH
1544 W. Churchill Downs
Germantown, TN 38138

Dr. Terry Grinder, interim executive director, presented a Consent Order for Dr. Grady Saxton, which he signed on January 26, 2007 for the indefinite suspension of his license due to chemical addiction. Dr. Julie Frazier motioned to **accept** the Consent Order; seconded by Mrs. Monica Franklin. All were in favor and the motion carried.

CRYSTAL F. HILL, RT
282 Landmark Drive
Oneida, TN 37841

Interim Executive Director, Dr. Terry Grinder, presented a Consent Order for the Revocation of Ms. Crystal Hill's pharmacy technician registration due to the admission of forging prescriptions. Dr. Julie Frazier motioned to **accept** the Consent Order; seconded by Dr. Todd Bess. All were in favor and the motion carried.

CHARLOTTE A. SMITH, RT
2151 Batavia Street
Clarksville, TN 37040

Dr. Terry Grinder, interim executive director, presented a Consent Order for the Revocation of Ms. Charlotte Smith's pharmacy technician registration due to the theft of controlled substances from the pharmacy. Dr. Julie Frazier motioned to **accept** the Consent Order; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

JOHN C. BOYETT, DPH
3326 Claybrook Drive
Cookeville, TN 38506

Interim executive director, Dr. Terry Grinder, presented a Consent Order whereas Dr. John Boyett was in violation of Rule 1140-2-.02 (6) in regards to the pharmacy technician ratio. Dr. Boyett was assessed a civil penalty of \$250. Dr. Julie Frazier motioned to **accept** the Consent Order; seconded by Mrs. Monica Franklin. All were in favor and the motion carried.

SUZI M. SHELL, RT
805 Oakwood Road
Midway, TN 37809

Dr. Terry Grinder, interim executive director, presented a Consent Order whereas Ms. Suzi Shell, a registered pharmacy technician, was in violation of T.C.A. §63-10-305 (6) for taking valid prescriptions from the pharmacy without paying for the prescription co-pays of

approximately two hundred and fifty dollars (\$250) to three hundred dollars (\$300). Ms. Shell has agreed to a one (1) year term of probation with the Board beginning on the date the Consent Order is executed by Ms. Shell (March 28, 2007); shall not fill or process any prescriptions written for herself or her family members; and shall inform the pharmacist in charge where she is employed at any time during the probationary period that she is on probation with the Board. Dr. Julie Frazier motioned to **accept** the Consent Order; seconded by Mrs. Monica Franklin. All were in favor and the motion carried.

ED SULKOSKY, DPH
1633 Lake Marina Drive
Hixson, TN 37343

Interim executive director, Dr. Terry Grinder, presented a Consent Order whereas Dr. Ed Sulkosky was in violation of Rule 1140-3-.01 (1) (a) and (f) for failure to provide patient counseling. Dr. Sulkosky was assessed a civil penalty of \$100. Dr. Julie Frazier motioned to **accept** the Consent Order; seconded by Dr. Todd Bess. All were in favor and the motion carried.

WALGREENS #3353
2514 Magnolia Avenue
Knoxville, TN 37914

Dr. Terry Grinder, interim executive director, presented a Consent Order whereas Walgreens #3353 was in violation of Rule 1140-3-.01 (1) (a) and (f) for failure to provide patient counseling and was assessed a civil penalty of \$500. Mrs. Monica Franklin motioned to **accept** the Consent Order; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

SHEILA CALDWELL, DPH
4190 Indian Brook Cove
Memphis, TN 38125

Dr. Terry Grinder, interim executive director, noted receipt of the \$500 civil penalty Dr. Sheila Caldwell rendered for violating T.C.A. §53-10-109 (a) & §43-10-106 (a) (1). The Board approved the Consent Order at the January 30 - 31, 2007 meeting.

**INFORMAL CONFERENCE
GLEN BROOKS, DPH
BROOKS PHARMACY**

Mrs. Alison Cleaves, chief legal counsel, advised on March 22, 2007, the Board conducted a teleconference meeting to consider the summary suspension of Dr. Glen Brooks and Brooks Pharmacy licenses. Mr. Jack Butler, attorney for Dr. Glen Brooks, is appearing today on his behalf. Mr. Butler stated Dr. Brooks will not contest the license for himself or the pharmacy. The Board appreciated Mr. Butler's appearance today.

WAIVERS

**ROBERT Y. SENTELL, DPH
10106 Shortwood Lane
Orlando, FL 32836**

Dr. Robert Sentell is requesting a waiver of Rule 1140-1-.07 (3) (b) (3) and (5) relevant to the successful completion of the Jurisprudence examination and a period of pharmacy internship of one hundred and sixty hours (160) for the reinstatement of his pharmacist license. Dr. Julie Frazier motioned to **grant the waiver for the internship hours** as Dr. Sentell is actively practicing in Florida but **deny the request for the MPJE**. Dr. Larry Hill seconded the motion. All were in favor and the motion carried.

**ARTHUR E. JONES, DPH
4615 N. 20th Street
Tampa, FL 33610**

Dr. Arthur Jones is requesting a waiver of Rule 1140-1-.07 (3) (b) (5) relevant to completing a period of pharmacy internship of one hundred and sixty (160) hours for the reinstatement of his pharmacist license. Dr. Jones has twenty-nine (29) years of experience in the practice of pharmacy. Dr. Todd Bess motioned to **grant** the waiver request; seconded by Mrs. Monica Franklin. All were in favor and the motion carried.

**JANE PAYSINGER, DPH
4298 Greenmount Avenue
Memphis, TN 38122**

Dr. Jane Paysinger is requesting a waiver of Rule 1140-1-.07 (3) (b) (5) (ii) relevant to completing a period of three hundred and twenty (320) hours of pharmacy internship for the reinstatement of her pharmacist license. Dr. Paysinger is the Director of Pharmacy at Baptist Medical Centre in Ghana, West Africa and has been practicing pharmacy in that capacity for the past thirteen years. Mrs. Monica Franklin motioned to **approve** the waiver; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

BRADLEY L. CROSS, DPH
CARDINAL HEALTH NUCLEAR PHARMACY SERVICES
147 West Main Street
Algood, TN 38506

Dr. Bradley Cross is requesting a waiver of Rule 1140-3-.14 (12) relevant to being the designated pharmacist-in-charge of more than one (1) pharmacy practice site at Cardinal Health Nuclear Pharmacy and Larco Pharmacy, a respiratory pharmacy. Interim executive director, Dr. Terry Grinder, noted Cardinal Health's hours of operation are Monday thru Friday from 4:00A to 12:00 noon and Larco would be open no more than ten (10) hours per week. Dr. Julie Frazier motioned to **accept** the request; seconded by Dr. Todd Bess. All were in favor and the motion carried.

KEN TURNER, DPH
OMNI HEALTH CARE PHARMACY
3218-A Morris Avenue
Knoxville, TN 37909

Dr. Ken Turner is requesting a waiver of Rule 1140-3-.14 (12) relevant to being the designated pharmacist-in-charge of more than one (1) pharmacy practice site at Omni Healthcare Pharmacy and Blue Ridge Compounding. Mrs. Monica Franklin motioned to **obtain additional information** relevant to the number of hours/days the pharmacies will be open. Dr. Todd Bess seconded the motion. All were in favor and the motion carried.

Interim executive director, Dr. Terry Grinder, stated **Dr. Mickie Ratliff has accepted the PIC position** at Omni Healthcare.

MR. JOHN AVERY
Administrator
PERRY COMMUNITY HOSPITAL
805 Squirrel Hollow Drive
Linden, TN 37096

Mr. John Avery, administrator for Perry Community Hospital is requesting a waiver of Rule 1140-3-.14 (13) on behalf of Dr. Thomas Fesmire relevant to a pharmacist being on duty a minimum of fifty percent (50%) of the hours the pharmacy is in operation. Dr. Robert Mitchell motioned to deny the request; seconded by Mrs. Monica Franklin. After discussion, Dr. Robert Mitchell withdrew his motion. Mrs. Monica Franklin motioned to contact Dr. Fesmire to have him put in writing to the Board that he is willing to accept the PIC responsibilities for the ten (10) hours per week and after receiving the information, **grant** the waiver request; seconded by Dr. Todd Bess. All were in favor and the motion carried.

RULE MAKING HEARING

Mrs. Alison Cleaves, chief legal counsel, noted the rulemaking hearing was held open until 11:00 a.m. CDT. Mrs. Cleaves stated there are no comments from the audience and it is approximately 11:20 in the morning. Mrs. Cleaves is requesting approval of the amendments made to the rules to permit the transfer of drugs for Charitable Clinic Pharmacies and the Manifest with TPA's recommendations and to approve the changes noted by TPA with the exception of #6 and #7. Dr. Julie Frazier motioned to **approve** the rules; seconded by Mrs. Monica Franklin. A roll call vote was taken:

Sheila Mitchell	Yes
Robert Mitchell	Yes
Monica Franklin	Yes
Todd Bess	Yes
Julie Frazier	Yes
Larry Hill	Yes

All were in favor and the motion carried.

Executive Order Number 38

Mrs. Alison Cleaves, chief legal counsel, advised the members on May 22, 2006, the Governor signed Executive Order Number 38, which requires state agencies to assess the impact of new regulations on small businesses prior to initiating a rulemaking process. Based upon the review of all the rules and laws from chief legal counsel, Mrs. Alison Cleaves, that assessment has been made. Dr. Julie Frazier motioned to accept; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

**TIMOTHY KOCH, DPH
WAL-MART PHARMACY
702 S. W. 8TH Street
Bentonville, AR 72717-0230**

Interim Executive Director, Dr. Terry Grinder introduced Dr. Timothy Koch with Wal-Mart Pharmacy, Mr. William Holmes, President of Distributed Delivery Networks, and Dr. Robert Hansen, Vice President of Pharmacy Services with Asteres, Inc., to discuss the secured will-call bin technology called "APM", which allows for after hour pickup of prescriptions. At the November 7 - 8, 2006 meeting, the Board noted the technology does not fit within the current rules for face to face counseling and the dispensing process. Since that time, Wal-Mart is inquiring if the "APM" can be used during the times the pharmacy is open and a pharmacist is present. Dr. Koch advised counseling would still be conducted. The Board referenced Rule 1140-3-.01 which states a pharmacist shall personally counsel the patient or caregiver "face to face" and if the patient or caregiver is not present, shall make a reasonable effort to counsel through alternative means and during normal business hours.

**JOHN HOLLIS, DPH - REQUEST FOR REINSTATEMENT OF LICENSE
NASHVILLE, TN**

Dr. John Hollis, who was accompanied with his wife, appeared before the Board to request the reinstatement of his pharmacist license. Advocating on his behalf were Dr. Tommy Malone with the Tennessee Medical Foundation and Dr. Cliff Weiss with the Tennessee Pharmacists Recovery Network. Interim Executive Director, Dr. Terry Grinder, advised the Board in October,

2006, Dr. Hollis self-reported himself to the Board and sought treatment in Atlanta at the Center for Professional Excellence. Dr. Hollis stated he began experiencing hip pain and sought relief with alcohol and controlled substances. Dr. Hollis noted he owns a compounding pharmacy and is the PIC. During Dr. Hollis' absence, two (2) other pharmacists have been maintaining the pharmacy for approximately six (6) months. Advocate, Dr. Tommy Malone stated Dr. Hollis has an A/A sponsor and if he continues to work the steps in his life, he will do fine. Dr. Cliff Weiss advised the Board, Dr. Hollis is compliant with the TPRN recommendations and has met the 90/90 meetings. After Board discussion, Mrs. Monica Franklin motioned:

1. Respondent does hereby agree to the reinstatement of license number **#4669** with the following probationary conditions. Said probation shall remain in effect for a period of five (5) years, from March 29, 2007 to March 29, 2012.

- a) The Respondent shall completely abstain from the consumption of alcohol or any other drugs, except as specified in (b).
- b) Respondent shall be able to consume legend drugs or controlled substances prescribed by the Respondent's primary physician, Judson Rogers, MD, except in the case of an emergency or upon a proper referral from the Respondent's primary physician. The Respondent shall immediately notify the Board office in writing of the name of the Respondent's primary physician each time the Respondent changes primary physicians;
- c) The Respondent shall not obtain or attempt to obtain any prescriptions in the respondent's name for any legend drugs, controlled substances or devices containing same from a physician other than the Respondent's primary physician or from any other health care provider, such as a nurse practitioner, physician's assistant or psychiatrist;

- d) The Respondent shall destroy any unused controlled substances prescribed under the provisions of subsection (b) no later than thirty (30) days following the completion of the prescribed course of treatment;
- e) The Respondent shall report to the Board, in writing, the ingestion of any and all legend drugs or controlled substances (a copy of the prescription will satisfy the requirement);
- f) The Respondent shall submit to random sampling of urine, blood or bodily tissues for the presence of drugs and alcohol, at the Respondent's own expense, by agents of the Board, such as the Tennessee Pharmacists Recovery Network for as long as the Respondent has an active license. In the event that the sampling indicates the presence of drugs for which the Respondent does not have a valid prescription or the sampling indicates the presence of alcohol, then formal disciplinary charges may be brought against the Respondent which could result in the revocation of the Respondent's remaining term of probation or the suspension or revocation of the Respondent's license to engage in the practice of pharmacy. Prior to such disciplinary charges being heard by the Board, the Respondent's license may be summarily suspended;
- g) The Respondent shall comply with all of the terms and conditions of the extended aftercare contract he or she entered into with Tennessee Pharmacists Recovery Network. Respondent shall return a copy of said contract with this Consent Order to the Board office;
- h) THE BOARD WAIVED SECTION (h) RELEVANT TO THE PHARMACIST-IN-CHARGE; and,
- i) If the license has been inactive, delinquent, suspended or revoked:

- (i) **Less than one (1) year, the pharmacist shall:**
- I. Provide written notice requesting an active license;
 - II. Satisfy all past due continuing pharmaceutical education; and
 - III. Pay all cumulative license renewal fees and any applicable penalties.

Dr. Julie Frazier seconded the motion. All were in favor and the motion carried.

During discussion with the TPRN advocates, Dr. Todd Bess requested the Board be informed if compliance with the TPRN contract is not being fulfilled.

**THOMAS SULLIVAN, DPH
DIRECTOR OF PHARMACY
VANDERBILT MEDICAL CENTER PHARMACY
1121 21st Avenue South
Nashville, TN 37220**

Dr. Thomas Sullivan, Director of Pharmacy at Vanderbilt Medical Center, appeared before the Board on behalf of Mr. Michael Andrews, a pharmacy technician applicant, who indicated on his pharmacy technician registration that he had been convicted of a misdemeanor offense. Dr. Sullivan advised the Board that at the age of eighteen (18), Mr. Andrews was caught with two (2) marijuana cigarettes and charged with possession. Dr. Sullivan noted the requirements of the court have been fulfilled and all court costs have been paid. Mr. Andrews was given an opportunity to have the charges dismissed by attending classes and 12-step meetings. A copy of the Certificate of Completion was furnished and Mr. Andrews is in the process of having his record erased. Dr. Sullivan noted Vanderbilt does not perform random drug screens. Dr. Julie Frazier motioned to **grant** approval of Mr. Andrews' pharmacy technician registration; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

LEGAL REPORT/COMPLAINTS

1. Case No.: L06-PHR-RBS-200604332

Complainant, a physician, alleges that the pharmacist at the Respondent pharmacy misfilled a patient's prescription for Cytotec 100mg.

PIC and dispensing pharmacist responded to the complaint. DPh states that she could not read the doctor's handwriting on the prescription. Although the prescription was dropped off after hours, the pharmacist called the doctor and told him that she could not read his handwriting. The doctor told the pharmacist the directions which she wrote down. The pharmacist did not have that medication in stock, so she called and found another pharmacy that had the medication in stock and communicated the prescription to them over the phone. PIC corroborated the dispensing pharmacist's response.

Prior Complaints:

Recommendation: Dismiss

Mrs. Monica Franklin motioned to **accept** counsel's recommendation; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

2. Case No.: L05-PHR-RBS-200501366

Complaint involves the Respondent who has already had his individual and pharmacy licenses summarily suspended. This instant case does not contain enough evidence.

Recommendation: Close

Dr. Robert Mitchell motioned to **accept** counsel's recommendation; seconded by Dr. Todd Bess. All were in favor and the motion carried.

3. Case No.: L06-PHR-RBS-200604174

Complainant alleges that the Respondent, pharmacist, dispensed controlled substances without a prescription. Respondent currently has criminal charges pending against him.

Recommendation: Authorize Formal Hearing

Dr. Todd Bess motioned to **accept** counsel's recommendation; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

4. Case No.: L07-PHR-RBS-200603061

Complainant alleges that his mother's prescription for Zylflo was mistakenly filled with Zyvox, 600mg. Complainant alleges that the patient consumed the incorrect medication; however, there is no indication as how long the patient consumed the incorrect medication. Complainant also indicates that his sister experienced two misfiled prescriptions with the same pharmacy in which she was given another patient's medication with the same first name.

Dispensing pharmacist responded to the complaint and admitted that the misfill occurred. When asked about patient counseling, the DPh indicated that it was a new prescription and that patient counseling was not performed.

Prior complaints:

Pharmacy: 1999 – Closed; 2003- Dismissed

Recommendation: Letter of Warning to dispensing pharmacist about misfill. LOI to PIC about the lack of patient counseling; \$100.00 civil penalty to dispensing pharmacist and \$500.00 civil penalty to pharmacy.

Dr. Julie Frazier motioned to **accept** counsel's recommendation; seconded by Mrs. Monica Franklin. All were in favor and the motion carried.

5. Case No.: L07-PHR-RBS-200705419

Respondent, pharmacy, self-reported a medication error even though it did not result in serious harm to the patient. Patient's prescription was written for Oxycontin 40mg #60; however, patient's prescription was filled with 10mg tablets. When the patient discovered the error, he had already consumed 18 out of the original 60 tablets and returned the remaining 42. Respondent gave the patient 60 of the 40mg tablets.

Prior complaints:

Pharmacy: None

Recommendation: Letter of Instruction

Dr. Todd Bess motioned to **accept** counsel's recommendation; seconded by Dr. Larry Hill. All were in favor and the motion carried.

6. Case No.: L07-PHR-RBS-200705417

Respondent, pharmacy technician, admitted to taking Alprazolam, Hydrocodone and Xanax from the pharmacy without a prescription. The Respondent was terminated, the police were called and the Respondent was arrested.

Recommendation: Authorize Formal Hearing (CO for Revocation)

Dr. Julie Frazier motioned to **accept** counsel's recommendation; seconded by Dr. Todd Bess. All were in favor and the motion carried.

7. Case No.: L07-PHR-RBS-200705535

During a routine compliance inspection, investigator observed that the pharmacist on duty was supervising five (5) pharmacy technicians. Investigator also observed that one of the technicians (who was not working that day), had her registration expire on 1/31/07.

PIC responded and stated that they were short one technician the day before, which caused more that the ratio to be present on the date of the inspection. PIC also stated that the unregistered technician would have her registration renewed.

Prior complaints:

Pharmacy: 2000- medication error; 2002 – medication error; 2006 –dismissed.

Recommendation: Authorize Formal Hearing (civil penalty of \$350.00 to PIC (\$250.00 for ratio violation and \$100.00 for expired technician registration)

Dr. Julie Frazier motioned to **accept** counsel's recommendation; seconded by Dr. Larry Hill. All were in favor and the motion carried.

8. Case No.: L07-PHR-RBS-200705533

During a routine compliance inspection, investigator observed that the pharmacist on duty was supervising five (5) pharmacy technicians. Two (2) of the technicians did not wear appropriate identification. One of the technicians did not have his registration displayed.

PIC responded to the complaint and states that three (3) of the technician should have been designated as techs while the others should have been designated as cashiers; however, some confusion resulted because two (2) more experienced techs has not been working because of military service and travel. PIC admits that lack of identification and also the failure to have a registration posted.

Prior complaints:

Pharmacy: None

Recommendation: Authorize Formal Hearing; \$250.00 civil penalty to PIC and LOI to PIC about lack of tech identification and failure to have registration posted.

Dr. Julie Frazier motioned to **accept** counsel's recommendation; seconded by Mrs. Monica Franklin. All were in favor and the motion carried.

9. Case No.: L07-PHR-RBS-200705531

During a recent periodic inspection, investigator noted that the pharmacy's license expired on 1/31/06. Investigator also noted that this pharmacy is a "closed" pharmacy meaning that it is not open to the public and open only as needed and to fill orders for respiratory medications.

Prior complaints:

Pharmacy: None

Recommendation: Authorize Formal Hearing (\$1,400.00 civil penalty)

Mrs. Monica Franklin motioned to **accept** counsel's recommendation; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

10. Case No.: L07-PHR-RBS-200705527

Complainant alleges that the Respondent, pharmacist, was found on CCTV tape consuming Hydrocodone liquids from the pharmacy shelves. Respondent admitted to a substance abuse problem by consuming Hydrocodone liquids. Shortly thereafter, Respondent was arrested and admitted himself into a substance abuse program.

Prior complaints: None

Recommendation: Authorize Formal Hearing (Indefinite Suspension)

Dr. Julie Frazier motioned to **accept** counsel's recommendation; seconded by Dr. Todd Bess. All were in favor and the motion carried.

11. Case No.: L07-PHR-RBS-200705526

Respondent, pharmacy technician, admitted to taking his son's cough syrup and cough syrup from work without a prescription, taking an Ambien from work and taking an Oxycontin from his father. Respondent was terminated for his conduct.

Recommendation: Authorize Formal Hearing (CO for Revocation)

Mrs. Monica Franklin motioned to **accept** counsel's recommendation; seconded by Dr. Todd Bess. All were in favor and the motion carried.

12. Case No.: L07-PHR-RBS-200705414

Respondent, a long term care pharmacy, self-reported a medication error. The medication error occurred at an assisted living facility in which the patient was dispensed Amitriptyline 100mg instead of Amitriptyline 10mg. Patient was administered two (2) doses of the incorrect medication and experienced lethargy and nausea. The patient was hospitalized, but has since been released and is back at the facility. PIC states that the incident was reviewed for cause analysis and procedures have been put into place, including bar code scanning, to prevent this error from happening in the future.

*Prior complaints:
Pharmacy: None*

Recommendation: Letter of Warning about the misfill.

Mrs. Monica Franklin motioned to accept counsel's recommendation; seconded by Dr. Todd Bess. Dr. Julie Frazier recused from voting. After discussion, Dr. Todd Bess withdrew his second. Motion died for lack of a second. Dr. Todd Bess motioned to issue a **Letter of Instruction**, seconded by Mrs. Monica Franklin. All were in favor and the motion carried.

13. Case No.: L05-PHR-RBS-200419851

Complainant alleges that the Respondent filled forged prescriptions and attempted to treat a patient's addiction by stepping her down on her Opiates. The evidence in the file does not support how the Respondent would have known that the patient was using aliases and was not just picking up prescriptions as the caregiver for family members. The evidence does support the following: the Respondent did admit that he told patient to step down her Opiates and the Respondent denied knowing the patient to his superiors when a CCTV tape shows that he dispensed to her.

Recommendation: Letter of Warning about prescribing treatment.

Dr. Julie Frazier motioned to **dismiss** the complaint; seconded by Dr. Todd Bess. There was one (1) nay vote. The motion carried.

14. Case No.: L05-PHR-RBS-200500603

Respondent, pharmacist, was disciplined in another state for filling and selling prescriptions (wholesaling) compounding products without obtaining patient-specific prescriptions. Respondent admitted to compounding and shipping products without authorization; the compounded drugs were similar to branded products that were unavailable from normal suppliers. Respondent had to pay a \$500.00 civil penalty and had to take six (6) hours of CE.

Prior complaints: None

Recommendation: Letter of Warning

Dr. Julie Frazier motioned to **accept** counsel's recommendation; seconded by Mrs. Monica Franklin. All were in favor and the motion carried.

15. Case No.: L06-PHR-RBS-200604333

Complainant alleges that when there was a problem with insurance approval on Complainant's son's prescription, complainant alleges that the pharmacist on duty would not assist her in obtaining approval and would not give her the prescription back because it was a prescription for a narcotic. Pharmacist's supervisor told the DPh to return the prescription. Complainant states that because of the delays that the DPh caused, her son was without his medication for two (2) days.

The DPh states that she has no specific recollection of the incident and without seeing the prescription, patient's name and prescriber; she does not remember any details.

Prior complaints:
Pharmacy: 1993- Medication Misfill;
PIC: None

Recommendation: Letter of Warning

Dr. Todd Bess motioned to issue a **Letter of Warning and to remind the pharmacist of obtaining insurance approval**; seconded by Mrs. Monica Franklin. All were in favor and the motion carried.

16. Case No.: L07-PHR-RBS-200604398

Complaint originally came to the Board alleging that the pharmacist (not licensed in Tennessee) needed to be licensed to operate a drug storage area clinical research facility for investigational studies to test the toxicity and safety level of new compounds. At the last Board meeting, you decided that the Respondent did not need an individual pharmacist license; however, you requested that an investigator go out to the facility to determine if the facility needed to be licensed as a pharmacy. Investigator determined

that the facility does not need to be licensed as a pharmacy because all of the medications are administered within the physician's office.

Recommendation: Dismiss

Dr. Todd Bess motioned to **dismiss** the complaint; seconded by Mrs. Monica Franklin. All were in favor and the motion carried.

17. Case No.: L07-PHR-RBS-200604037

Complainant alleges that her brother received someone else's prescription and charged the complainant's medication to his brother's insurance.

PIC responds that a mistake was made in that the pharmacist filled medication for the Complainant's brother instead of her. PIC attributes the error to volume of prescriptions filled that day. The dispensing DPh and technician state that although both the Complainant and the Complainant's brother get the same medication, the brother's name was put on the Complainant's prescription.

Prior complaints:
Pharmacy: None
DPh: None

Recommendation: Letter of Instruction to dispensing DPh.

Dr. Todd Bess motioned to **accept** counsel's recommendation and to **use two (2) different identifiers to distinguish between patients with similar names or similar sounding names.** Dr. Julie Frazier seconded the motion. All were in favor and the motion carried.

18. Case No.: L07-PHR-RBS-200705407

Complainant, another state's Board of Pharmacy, alleges that the FDA issued a warning letter to the Respondent stating that it does not meet the standards to be an approved manufacturer. Respondent is a licensed manufacturer, wholesaler, distributor in Tennessee. Other BOP found several instances of false patient names used by the pharmacy to appear to be making compounds which were patient specific and therefore bypassing FDA requirements. According to our rules, the Respondent would have to be a licensed pharmacy with a PIC in order to ship patient-specific products into Tennessee. The issue before the Board is whether the Respondent is compounding and therefore needs a pharmacy license in order to ship to Tennessee or whether they are manufacturing for which they do not have approval by the FDA.

Prior complaints:
Pharmacy: None

Recommendation: Discuss

Dr. Todd Bess motioned to **issue a Cease and Desist if engaging in manufacturing after being issued a warning letter from the FDA stating the facility does not meet the standards of an approved manufacturer; and, to Cease and Desist if compounding**

patient-specific medications that are being dispensed to Tennessee patients as this constitutes the practice of pharmacy. Dr. Robert Mitchell seconded the motion. All were in favor and the motion carried.

19. Case No.: L07-PHR-RBS-200705408

Respondent, pharmacist self-reported an incident to the Board in which the Respondent refilled a patient's prescription before he obtained authorization; patient's prescription was for Alprazolam. Respondent states the following reasons for his actions: the unavailability of the physician by phone, fax or email; the 30 + year relationship with the patient; the patient's consistent refill record; after the fact knowledge that the physician had already renewed the patient's prescription; that the physician did renew the patient's prescription.

Prior complaints:
Pharmacy: None
PIC: None

Recommendation: Letter of Instruction to DPh

Dr. Julie Frazier motioned to **accept** counsel's recommendation; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

20. Case No.: L06-PHR-RBS-200314003

Complainant alleges that pharmacists at the Respondent pharmacy were dispensing medications without a prescription, which was based on an allegation that a box of Tussionex and Hydrocodone were found outside of the pharmacy. Controlled substance losses were found at the pharmacy in 2000; however, the cause of the losses could not be found.

Recommendation: Close

Mrs. Monica Franklin motioned to accept counsel's recommendation; seconded by Dr. Julie Frazier. The motion did not carry. Dr. Julie Frazier motioned to issue a **Letter of Instruction to the PIC relevant to the security of drug losses**; seconded by Dr. Larry Hill. All were in favor and the motion carried.

21. Case No.: L06-PHR-RBS-200604159

Complainant alleges that the Respondent is chemically dependent; however, there is no evidence to support this allegation. We do not have a positive drug screen; there are no admissions by the Respondent; there are no observations by the pharmacists and pharmacy staff that he works with indicating addiction.

Recommendation: Dismiss

Dr. Julie Frazier motioned to **accept** counsel's recommendation; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

22. Case No.: L07-PHR-RBS-200704719

Complainant alleges that the Respondent, pharmacist, has been filling prescriptions for two (2) websites in which there may not be a legitimate doctor/patient relationship. Respondent admits to filling these scripts, but states she did not know that she was doing anything wrong.

Recommendation: Letter of Warning about filling prescriptions in which there may not be a valid doctor/patient relationship.

Dr. Julie Frazier motioned to **accept** counsel's recommendation; seconded by Dr. Larry Hill. There was one (1) nay vote, and the motion carried.

23. Case No.: L06-PHR-RBS-200604346

Complainant alleges that the pharmacists at the Respondent pharmacy shorted her twenty (20) tablets of her pain medication. In response to the complaint, PIC, DPh and technician all deny the allegations. PIC states that all of his controlled drugs are double counted. DPh states that the Complainant's medication was double counted and it was correctly counted before it was given to the Complainant's husband.

Recommendation: Dismiss

Dr. Julie Frazier motioned to **accept** counsel's recommendation; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

24. Case No.: L06-PHR-RBS-200603831

Complainant alleges that her daughter's prescription for Methadate was shorted ten (10) tablets. PIC denies the allegations. PIC states that when the Complainant contacted the pharmacy claiming that she was shorted ten (10) pills, the staff pharmacist checked the on-hand quantity and found that the count was correct. PIC attempted to contact the Complainant to address the problem and she did not receive a call back.

Recommendation: Dismiss

Mrs. Monica Franklin motioned to **accept** counsel's recommendation; seconded by Dr. Todd Bess. All were in favor and the motion carried.

25. Case No.: L07-PHR-RBS-200602735

Complainant alleges that the Respondent wrote prescriptions for herself and her sister for NuvaRing without a hard copy prescription or authorizing refills without consulting with the physician. Respondent admitted to authorizing refills without consulting with a physician. Investigation revealed that there was a January, 2006 prescription for Respondent's sister filled without physician authorization. Subsequent to the January incident, both the Respondent and Respondent's sister obtained valid prescriptions for NuvaRing in March, 2006.

Recommendation: Authorize Formal Hearing; 1 year term of probation (do not fill scripts for herself or her family members)

Dr. Todd Bess motioned to **accept counsel's recommendation and the PIC will be involved with the Consent Order** and it is her responsibility to advise any future employer that they are on probation; seconded by Mrs. Monica Franklin. All were in favor and the motion carried.

WAIVERS

JIM GAY, DPH PHARMERICA

Interim Executive Director, Dr. Terry Grinder, received a regulatory e-mail inquiry from Pharmerica regarding an Electronic Medication Administration Record and Order Entry System for the transmission of an order from a long term care facility to the pharmacy provider. Dr. Grinder noted by using the electronic system, the nurse enters the order into the system via a desktop computer that is connected to the pharmacy via a Virtual Private Network (VPN). The order is transmitted in an encrypted format to the pharmacy directly and the order is printed at the pharmacy for processing. Pharmerica is inquiring whether the Board would accept this order as a means of conveying the authority to fill the prescription. Dr. Robert Mitchell motioned "yes"; seconded by Mrs. Monica Franklin. All were in favor and the motion carried.

BRYAN JONES, DPH SOUTHERN TENNESSEE MEDICAL CENTER 185 Hospital Road Winchester, TN 37398

Dr. Bryan Jones is requesting a waiver of Tennessee Board of Pharmacy Rule 1140-3-.14 (12) relevant to being the designated pharmacist in charge of more than one (1) pharmacy practice site. Dr. Jones is currently the PIC at Southern Tennessee Medical Center in Winchester and is requesting to be PIC at Emerald-Hodgson Hospital in Sewanee, Tennessee. After board discussion, Dr. Julie Frazier motioned to **grant for a period of time as the previous request (six (6) months)**. Mrs. Monica Franklin seconded the motion. All were in favor and the motion carried.

WAYNE SMITH, DPH TRI-MED PHARMACY SERVICES 260 W. Main Street #217

Hendersonville, TN 37075

Dr. Wayne Smith is requesting a waiver of Rule 1140- 1-.12 (3) (d) relevant to the square footage requirement for Tri-Med Pharmacy Services. Dr. Robert Mitchell motioned to obtain further information; seconded by Mrs. Monica Franklin. The motion died for lack of a vote. After board discussion, Mrs. Monica Franklin motioned to **approve** the request; seconded by Dr. Robert Mitchell. All were in favor and the motion carried. The Board requested a letter be sent to Tri-Med explaining some of the guidelines.

**DIRECTOR'S REPORT
LEGISLATIVE INITIATIVES**

President, Dr. Sheila Mitchell reminded the board members that an individual board member can not make any comments to the media on behalf of the Board. Mrs. Alison Cleaves, chief legal counsel, stated one (1) member can not speak for the whole Board but the Board can discuss and either respond to the Legislature or the entire Board can appear before the Legislature.

Interim Executive Director, Dr. Terry Grinder, reviewed the following legislative matters with the Board.

Senate Bill No. 887 / House Bill No. 364

- Tennessee Affordable Drug Act of 2005

Senate Bill No. 2172 / House Bill No. 2234

- Access to Controlled Substance Monitoring Database

Senate Bill No. 2192 / House Bill No. 2249

- Controlled Substance Monitoring Act of 2002

Senate Bill No. 297

- Safeguarding and Monitoring of Prescription Drugs

Senate Bill No. 756 / House Bill No. 549

- Board of Pharmacy

Senate Bill No. 1197 / House Bill No. 1190

- "Safe Prescription Drug Act of 2007"

Senate Bill No. 661

- "Providing Prescriptive Authority for Psychologists"

Senate Bill No. 779 / House Bill No. 777

- Dispensing of Certain Drugs by Nurses

Senate Bill No. 2216 / House Bill No. 2267

- Scheduling of Controlled Substances

Senate Bill No. 2038 / House Bill No. 1853

- Controlled Substances

Senate Bill No. 1179 / House Bill No. 392

- Sale of Immediate Methamphetamine Precursors

Senate Bill No. 442 / House Bill No. 121

- Prescription Drugs for Epilepsy Patients

Senate Bill No. 68

- Prescription Drugs

Senate Bill No. 1412 / House Bill No. 633

- Information to be Posted

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

Interim Executive Director, Dr. Terry Grinder, advised a policy statement was issued in reference to a pharmacist board member being allowed to attend meetings at the board's expense. Dr. Larry Hill, Dr. Todd Bess and Dr. Sheila Mitchell have expressed an interest in attending NABP's 103rd Annual Meeting in Portland, Oregon on May 19 - 22, 2007.

Dr. Todd Bess suggested the Board review the policy it established for the board members attending NABP meetings at the next board meeting. Dr. Julie Frazier motioned to review the board policy; seconded by Dr. Todd Bess. All were In favor and the motion carried.

Dr. Larry Hill nominated Dr. Sheila Mitchell as the Board's Delegate at NABP's 103rd Annual Meeting to be held in Portland, Oregon on May 19 - 22, 2007, seconded by Dr. Todd Bess. All were in favor and the motion carried. Dr. Todd Bess was chosen as an Alternate.

SUSAN M. STEIN, MS, DPH
Associate Dean
PACIFIC UNIVERSITY SCHOOL OF PHARMACY
222 SE 8th Avenue #451
Hillsboro, OR 97123

Dr. Susan Stein, Associate Dean, is requesting recognition of Pacific University School of Pharmacy "Pharm D" Program. Pacific University was granted Pre-Candidate status in June, 2006. The Board noted it does not recognize special programs other than those recognized by ACPE.

TIMOTHY SMITH, DPH
FORT SANDERS REGIONAL MEDICAL CENTER
1901 Clinch Avenue
Knoxville, TN 37916

Dr. Timothy Smith with Fort Sanders Regional Medical Center submitted for the Board's approval a summary of operation and policy and procedures relevant to the central fill of employee's prescriptions for Covenant Health in Knoxville, Tennessee. The Board noted a pharmacist was not available during the prescription drop-off/pick-up and expressed concerned with patient counseling. Mrs. Alison Cleaves, chief legal counsel, stated the policy and procedures outlined falls outside the Board of Pharmacy rules.

ADJOURNMENT

Tennessee Board of Pharmacy
March 29 - 30, 2007

Dr. Julie Frazier motioned to adjourn the meeting on Thursday, March 29, 2007 at 4:55 p.m. CDT; seconded by Mrs. Monica Franklin. All were in favor and the motion carried.

RECONVENED

The Board of Pharmacy reconvened on Friday, March 30, 2007 at 9:00 a.m. CDT in Room 160 of the Davy Crockett Tower, Nashville, Tennessee. A quorum of the members being present, President Sheila Mitchell called the meeting to order. Dr. Sheila Mitchell noted for the record, Dr. Todd Bess has not arrived and Dr. Bettie Wilson will not be in attendance.

**TARIQ WAQAR, DPH
6096 Brentwood Chase Drive
Brentwood, TN 37027**

Dr. Tariq Waqar personally appeared before the Board to request reconsideration of Rule 1140-3-14 (12) in regards to being the pharmacist in charge of more than one (1) pharmacy practice site as the Board denied the waiver request at the January 30 - 31, 2007 meeting due to the number of hours scheduled at each location. Dr. Waqar is interested in opening a closed-door compounding pharmacy and plans to work seven (7) to eight (8) hours a day in addition to being PIC at Kroger Pharmacy #515. After board discussion, Dr. Julie Frazier motioned to **grant the waiver for a period of six (6) months and requested Dr. Waqar to either reappear before the Board or send a letter in regards to the status of his jobs.** Dr. Robert Mitchell seconded the motion. All were in favor and the motion carried.

**ZLB BEHRING, LLC
Rt. 50 North
Bradley, IL 60915**

and

**ZLB BEHRING, LLC
195 Bradford Drive
Bradley, IL 60916**

Mr. Kevin Hickman, Senior Manager - North America Distribution with ZLB Behring, LLC, and Mr. David Steed, Counsel with Cornelius and Collins, LLP, appeared before the Board to

request reconsideration of the Board's action taken at the November 7 - 8, 2006 meeting in which the ZLB Behring, LLC, manufacturer wholesale distributor applications were denied as there was no expunge date listed on the FDA Consent Decree, which was imposed in 1997. At the August 29, 2006 meeting, the Board deferred approval of the applications pending further review from the Board's legal counsel. Mr. Steed advised the Board ZLB is a distributor of blood and plasma products. In early to mid-1990's, the FDA conducted two inspections of the facility and identified a number of observations designated as "significant".

In 1996, a shipment of plasma products was handled roughly at the site prior to distribution which resulted in a number of broken and cracked vials. These vials were discarded but appropriate steps were not taken to inspect all of the vials for "visible" defects and were released for distribution. The error was identified when patients became ill subsequent to treatment using the "compromised" vials.

Mr. Steed noted the FDA is requiring numerous audits to ensure no further instances of this nature and have been under the Consent Decree for the past eleven (11) years. After board discussion, Dr. Robert Mitchell motioned to **grant** approval of the licenses; seconded by Dr. Larry Hill. All were in favor and the motion carried.

**JOHN ATWELL, DPH – REQUEST FOR REINSTATEMENT OF LICENSE
LENOIR CITY, TN**

Dr. John Atwell appeared before the Board along with TPRN advocates, Dr. Edwin Bills and Dr. Janet Hicks. Dr. Terry Grinder, interim executive director, noted there was no Consent Order for the Indefinite Suspension of license as Dr. Atwell sought treatment on his own. Dr. Atwell stated in 2002 he was diagnosed with rheumatoid arthritis and became addicted to Hydrocodone. In 2004, Dr. Atwell stated he suffered chest pains and was prescribed Percocet. A friend of Dr. Atwell's recommended he contact Cornerstone for treatment. TPRN advocate, Dr. Edwin Bills, stated Dr. Atwell attends Caduceus meetings and has completed the 90/90

meetings. Dr. Janet Hicks noted Dr. Atwell is compliant with TRPN recommendations and he enjoys being with individuals and is volunteering at Cornerstone. After board discussion, Dr. Todd Bess motioned:

1. Respondent does hereby agree to the reinstatement of license number **7510** with the following probationary conditions. Said probation shall remain in effect for a period of five (5) years, from **March 30, 2007 to March 30, 2012.**
 - a) The Respondent shall completely abstain from the consumption of alcohol or any other drugs, except as specified in (b);
 - b) Respondent shall be able to consume legend drugs or controlled substances prescribed by the Respondent's primary physician, Jean Murphy, MD, except in the case of an emergency or upon a proper referral from the Respondent's primary physician. The Respondent shall immediately notify the Board office in writing of the name of the Respondent's primary physician each time the Respondent changes primary physicians;
 - c) The Respondent shall not obtain or attempt to obtain any prescriptions in the respondent's name for any legend drugs, controlled substances or devices containing same from a physician other than the Respondent's primary physician or from any other health care provider, such as a nurse practitioner, physician's assistant or psychiatrist;
 - d) The Respondent shall destroy any unused controlled substances prescribed under the provisions of subsection (b) no later than thirty (30) days following the completion of the prescribed course of treatment;

- e) The Respondent shall report to the Board, in writing, the ingestion of any and all legend drugs or controlled substances (a copy of the prescription will satisfy the requirement);
- f) The Respondent shall submit to random sampling of urine, blood or bodily tissues for the presence of drugs and alcohol, at the Respondent's own expense, by agents of the Board, such as the Tennessee Pharmacists Recovery Network for as long as the Respondent has an active license. In the event that the sampling indicates the presence of drugs for which the Respondent does not have a valid prescription or the sampling indicates the presence of alcohol, then formal disciplinary charges may be brought against the Respondent which could result in the revocation of the Respondent's remaining term of probation or the suspension or revocation of the Respondent's license to engage in the practice of pharmacy. Prior to such disciplinary charges being heard by the Board, the Respondent's license may be summarily suspended;
- g) The Respondent shall comply with all of the terms and conditions of the extended aftercare contract he or she entered into with Tennessee Pharmacists Recovery Network. Respondent shall return a copy of said contract with this Consent Order to the Board office;
- h) The Respondent shall not serve as pharmacist-in-charge for a period of three (3) years, however, after a period of two (2) years, the Respondent may petition the Board for a modification of this Consent Order to remove the restrictions upon a show of good cause. The Respondent shall not work as a "floater" for a period of three (3) years, meaning that the

Respondent shall not work at more than one (1) pharmacy location at the same time without the permission of the Board.

- i) Section (i) was not included as a part of the Consent Order.

Mrs. Monica Franklin seconded the motion. All were in favor and the motion carried.

**AMELIA FLANDERS, DPH – REQUEST FOR REINSTATEMENT OF LICENSE
CROSSVILLE, TN**

Dr. Amelia Flanders appeared before the Board to request the reinstatement of her pharmacist license along with TPRN advocates, Dr. Edwin Bills and Dr. Janet Hicks. Interim Executive Director, Dr. Terry Grinder, advised the Board on March 4, 2006,

Loss Prevention intervened and terminated Dr. Flanders and two (2) pharmacy technicians and filed criminal charges for prescription fraud and diversion. Dr. Flanders stated she suffered from anxiety during periods of her life and began diverting and forging prescriptions for herself. Advocate, Dr. Edwin Bills stated Dr. Flanders is compliant with the TPRN recommendations. Dr. Janet Hicks stated Dr. Flanders attends AA/NA meetings, Caduceus and Aftercare and has a support network in place. After board discussion, Dr. Julie Frazier motioned:

1. Respondent does hereby agree to the reinstatement of license number **3540** with the following probationary conditions. Said probation shall remain in effect for a period of five (5) years, from **March 30, 2007 to March 30, 2012.**

- a) The Respondent shall completely abstain from the consumption of alcohol or any other drugs, except as specified in (b).
- b) Respondent shall be able to consume legend drugs or controlled substances prescribed by the Respondent's primary physician, Rodney McMillin, MD, except in the case of an emergency or upon a proper referral from the Respondent's primary physician. The Respondent shall immediately notify the Board office in writing of the name of the Respondent's primary physician each time the

Respondent changes primary physicians;

- c) The Respondent shall not obtain or attempt to obtain any prescriptions in the respondent's name for any legend drugs, controlled substances or devices containing same from a physician other than the Respondent's primary physician or from any other health care provider, such as a nurse practitioner, physician's assistant or psychiatrist;
- d) The Respondent shall destroy any unused controlled substances prescribed under the provisions of subsection (b) no later than thirty (30) days following the completion of the prescribed course of treatment;
- e) The Respondent shall report to the Board, in writing, the ingestion of any and all legend drugs or controlled substances (a copy of the prescription will satisfy the requirement);
- f) The Respondent shall submit to random sampling of urine, blood or bodily tissues for the presence of drugs and alcohol, at the Respondent's own expense, by agents of the Board, such as the Tennessee Pharmacists Recovery Network for as long as the Respondent has an active license. In the event that the sampling indicates the presence of drugs for which the Respondent does not have a valid prescription or the sampling indicates the presence of alcohol, then formal disciplinary charges may be brought against the Respondent which could result in the revocation of the Respondent's remaining term of probation or the suspension or revocation of the Respondent's license to engage in the practice of pharmacy. Prior to

such disciplinary charges being heard by the Board, the Respondent's license may be summarily suspended;

- g) The Respondent shall comply with all of the terms and conditions of the extended aftercare contract he or she entered into with Tennessee Pharmacists Recovery Network. Respondent shall return a copy of said contract with this Consent Order to the Board office;
- h) The Respondent shall not serve as pharmacist-in-charge for a period of three (3) years, however, after a period of two (2) years, the Respondent may petition the Board for a modification of this Consent Order to remove the restrictions upon a show of good cause. The Respondent shall not work as a "floater" for a period of three (3) years, meaning that the Respondent shall not work at more than one (1) pharmacy location at the same time without the permission of the Board;
- (i) If the license has been inactive, delinquent, suspended or revoked:
 - Less than one (1) year, the pharmacist shall:**
 - I. Provide written notice requesting an active license;
 - II. Satisfy all past due continuing pharmaceutical education; and
 - III. Pay all cumulative license renewal fees and any applicable penalties.

Mrs. Monica Franklin seconded the motion. All were in favor and the motion carried.

CHARITABLE CLINIC PHARMACY – APPROVAL OF CONTRACT BETWEEN CLINIC AND PHARMACY

Chief legal counsel, Mrs. Alison Cleaves, has requested a further review of the Charitable Clinic Pharmacy Contract Between Clinic and Pharmacy.

REQUEST FOR APPROVAL OF PHARMACY APPLICATION

CINCINNATI CLINICAL INTERVENTION CENTER 9482 Meridian Way West Chester, OH 45069

Mrs. Alison Cleaves, chief legal counsel, stated Cincinnati Clinical Intervention Clinic is seeking licensure as a pharmacy in the State of Tennessee. Cincinnati Clinical is a consulting pharmacy and makes recommendations to prescribers for potential therapeutic interchange. The Ohio Board of Pharmacy commented in the Inspection Report that there are no dangerous drugs at this site; the facility has multiple entrances and all employees are in possession of the keys to the pharmacy. Dr. Julie Frazier recused herself. Dr. Robert Mitchell motioned to approve the application; seconded by Mrs. Monica Franklin. All were in favor and the motion carried.

REQUEST FOR APPROVAL OF PHARMACY TECHNICIAN APPLICATIONS

MILES DANIEL BEARDEN 232 Flintville School Road Elora, TN 37328

Chief legal counsel, Mrs. Alison Cleaves, stated Mr. Miles Bearden responded “yes” to being convicted to a misdemeanor charge on his pharmacy technician application.

In September, 2004, Mr. Bearden pled guilty to possession of drug paraphernalia, and was sentenced to 11 months 29 days – all suspended, was placed on supervised probation and paid a \$150 fine. On June 18, 2005, Mr. Bearden was arrested for contributing to the delinquency of a minor – the matter was “retired” upon completion of A6 hours, which was fulfilled on July 28, 2005. On October 17, 2004, Mr. Bearden was arrested for having a suspended driver’s license. The charge was amended to “no operators” license in his possession. Mr. Bearden pled guilty to the amended charge and was sentenced to thirty (30) days – all suspended and paid a \$50 fine. Dr. Julie Frazier motioned to **approve** the

application if probation has been completed. Dr. Todd Bess seconded the motion. All were in favor and the motion carried.

ANITA HARRIS
5885 Shelby Oaks Drive #239
Memphis, TN 38134

Mrs. Alison Cleaves, chief legal counsel, advised the Board Ms. Harris indicated “yes” to being convicted of a felony on her pharmacy technician application. Ms. Harris was working under a grant for a position. When the funding for the position ceased, she became unemployed and sought assistance from a welfare agency. Ms. Harris later gained employment but she did not discontinue the welfare benefits. Ms. Harris was placed on probation and required to make monthly payments to her probation officer. When Ms. Harris failed to make the monthly payments to her probation officer; the Judge made an example out of her and sentenced her to one and one-half years in prison. In 2000, Mrs. Harris obtained certification as a pharmacy technician and is gainfully employed. Dr. Julie Frazier motioned to **grant** approval of the registration; seconded by Mrs. Monica Franklin. There were two (2) nay votes.

A roll call vote was taken by the Board:

Sheila Mitchell	Yes
Julie Frazier	Yes
Monica Franklin	Yes
Todd Bess	No
Robert Mitchell	No
Larry Hill	Yes

The motion carried.

KEONA KARRENE MENIFEE
325 Warrior Drive #9
Murfreesboro, TN 37128

Mrs. Alison Cleaves, chief legal counsel, stated Ms. Keona Meniffee marked "yes" to a question on the pharmacy technician application, "Are there ANY charges pending against you?" Ms. Meniffee responded she made an incorrect mark on the application and pled guilty to shoplifting in 2002. Mrs. Cleaves, chief legal counsel, advised Ms. Meniffee paid a \$25 fine and was placed on six (6) months probation. Dr. Julie Frazier motioned to **grant** approval, seconded by Dr. Larry Hill. All were in favor the motion carried.

JOSHUA MICHAEL MCNABB
2337 Highland Avenue #23
Knoxville, TN 37916

Chief legal counsel, Mrs. Alison Cleaves noted Mr. Joshua McNabb indicated he has a pending DUI charge after being involved in an automobile accident. Mrs. Cleaves advised a General Sessions Court document dated December 16, 2006, states Mr. McNabb was placed on a Court ordered probation with conditions to pay a \$350 fine; exhibit good conduct, attend DUI School plus spend twenty-four (24) hours in a detention center. Mrs. Monica Franklin motioned to **grant** approval of the application; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

TANGELA RENA PAYNE
722 Hart Avenue
Nashville, TN 37206

Mrs. Alison Cleaves, chief legal counsel, stated Ms. Tangela Payne admitted to a felony conviction charge on her pharmacy technician application. Mrs. Cleaves noted in 2002, Ms. Payne was charged with Theft of Merchandise - greater than \$500, but less than \$1,000, but was convicted of Theft of Merchandise - \$500 or less. Ms. Payne received a sentence of 11 months 29 days, which was suspended and made restitution of \$776. In 1996, Ms. Payne pled guilty to Theft by Shoplifting, and in 1997, pled guilty to Theft of Property. Dr. Julie Frazier motioned to **deny** approval of the pharmacy technician registration; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

ANTONIO RUSSELL
2858 Coach Drive #2
Memphis, TN 38128

Chief legal counsel, Mrs. Alison Cleaves, noted Mr. Antonio Russell marked on his pharmacy technician registration that there were charges pending against him. The Board office received an "HTS" report which reflected charges on November 7, 2006 of bodily assault and resisting an officer, which were dismissed. Dr. Robert Mitchell motioned to **obtain Mr. Russell's employment history** since this incident; seconded by Mrs. Monica Franklin. All were in favor and the motion carried.

MELISSA R. SAWICKI
843 Sky Blue Drive
Knoxville, TN 37923

Mrs. Alison Cleaves, chief legal counsel, stated Ms. Melissa Sawicki indicated on her pharmacy technician application that she had charges in another state. In August, 2006, Ms. Sawicki was charged with Check Deception in Indiana. Ms. Sawicki pled guilty; made restitution of \$52.50; paid court costs and a term of probation. Dr. Julie Frazier motioned to **grant** approval of the application; seconded by Mrs. Monica Franklin. All were in favor and the motion carried.

VALENCIA WALKER
4404 Wooddale Avenue
Memphis, TN 38118

Chief legal counsel, Mrs. Alison Cleaves, advised the Board that Ms. Valencia Walker submitted a pharmacy technician registration in which she indicated "yes" to being convicted of a misdemeanor. The application was placed on hold pending additional information and fees. While awaiting response, the employer submitted another application, and Ms. Walker answered all the questions contained in the "Violations" section "no" and was approved. In 1996, Ms. Walker was employed at a department store and was charged with Theft of Property - \$500 or less. Ms. Walker stated some friends had shoplifted items and she was

charged with the offense. Ms. Walker stated she pled guilty to the charge upon the advice of legal counsel to avoid further action. In April, 1998, Ms. Walker pled guilty to an assault charge and paid a fine of \$250. Dr. Robert Mitchell motioned to **deny** the application; seconded by Dr. Todd Bess. There was one (1) nay vote. The motion carried.

JENNIFER A. TAYLOR
334 Hermitage Avenue
Cookeville, TN 38501

Chief legal counsel, Mrs. Alison Cleaves, stated at the November 7 - 8, 2006 board meeting, the Board requested Ms. Taylor provide evidence that she had completed the requirements imposed by the Court for two (2) DUI convictions in 2003 and 2004. The Board received documents and letters of recommendation and is compliant with the Court's order. Mrs. Monica Franklin motioned to **grant** approval of the technician application; seconded by Dr. Larry Hill. All were in favor and the motion carried.

DISCIPLINED IN ANOTHER STATE

JUDITH V. INGALA, DPH
1804 Waters Edge
Johnson City, TN 37601

Chief legal counsel, Mrs. Alison Cleaves, stated Dr. Judith Ingala was disciplined by the Kentucky Board of Pharmacy for an HIV continuing education violation. Dr. Ingala paid a \$500 civil penalty and was required to complete additional CE hours. Dr. Ingala reported the CE deficiency when she contacted the Kentucky Board and was advised that the CE course offered by Duke University would not be accepted. Dr. Julie Frazier motioned to **grant** the processing of the reciprocity application; seconded by Dr. Todd Bess. All were in favor and the motion carried.

MICHAEL DRAKE MASON, DPH

**3009 N. Halifax Avenue #A-31
Daytona Beach, FL 32118**

Chief legal counsel, Mrs. Alison Cleaves, noted Dr. Mike Mason answered “yes” on his reciprocal application to a misdemeanor charge in September 1988 for reckless conduct in Georgia. Dr. Mason was placed on twelve (12) months unsupervised probation; and paid a \$500 civil penalty. The Georgia Board did not take any action against his license. Dr. Todd Bess motioned to **approve** the licensing of the reciprocal applicant; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

**CHIEMEZIE P. OTI, DPH
2550 Corona Redonda
Bullhead City, AZ 86442**

Chief legal counsel, Mrs. Alison Cleaves, stated Dr. Chiemezie Oti indicated on his reciprocal application that he had been disciplined in 2002 by the Florida Board of Pharmacy for a prescription that was improperly labeled. Dr. Oti paid a \$250 civil penalty and attended a Prescription Error Course. Mrs. Monica Franklin motioned to **approve** the reciprocal application for Dr. Oti; seconded by Dr. Todd Bess. All were in favor and the motion carried.

MODIFICATION TO CONSENT ORDER

**ROY L. KINNEY, DPH
8579 Sandpoint Drive
Germantown, TN 38139**

Mrs. Alison Cleaves, chief legal counsel, presented a request from Dr. Roy Kinney for a Modification of the Consent Order he entered into with the Board on January 17 - 18, 2006, to allow him to be the PIC. Dr. Kinney was placed on a two-year term of probation from the date the Consent Order was executed on November 25, 2005 and will expire on November 25, 2007 for the consumption of alcohol while practicing pharmacy. Mrs. Monica Franklin motioned to **deny** the Modification to Consent Order; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

AD HOC RULES COMMITTEE

Dr. Sheila Mitchell, president, appointed an ad hoc rules committee relevant to the USP 797 Best Compounding Practices of Dr. Terry Grinder, Dr. Julie Frazier, Dr. Todd Bess and herself.

PHARMACIST II VACANCY

Dr. Terry Grinder, interim executive director, noted an interview was conducted for the Pharmacist II vacancy but the process is still ongoing.

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Chief legal counsel, Mrs. Alison Cleaves, noted at the January 30 - 31, 2007, board meeting, a complaint was presented in which a pharmacist was indicted with conspiracy to sell stolen prescriptions. The pharmacist pled guilty to that charge and is awaiting sentencing. The Board authorized a formal hearing /consent order for revocation.

The pharmacist was sentenced to four years on February 14, 2007. When responding to the pharmacist of the Board's intent, the office received several letters supporting the pharmacist for his involvement in the community and his professional ability. Upon discussion, Mrs. Monica Franklin motioned to **reconfirm the previous motion made by the Board**; seconded by Dr. Todd Bess. All were in favor and the motion carried.

ADJOURNED

Mrs. Monica Franklin motioned to adjourn the Board of Pharmacy meeting on Friday, March 30, 2007, at 12:20 p.m. CDT; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

The Board of Pharmacy approved the March 29 - 30, 2007 minutes at the September 11 - 12, 2007 board meeting.