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Ohio State Board of Pharmacy 77 South High Street, Room 1702 Columbus, Ohio 43215-6126 telephone: 614-466-4143 fax: 614-752-4836 email: exec@bop.state.oh.us

Minutes of the February 8, 2006 Meeting of the Ohio State Board of Pharmacy

WEDNESDAY, FEBRUARY 8, 2006

10:00 a.m. The Ohio State Board of Pharmacy convened in Room East B, 31st Floor, of the Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio, with the following members present:

Suzanne R. Eastman, R.Ph., *President*, James E. Turner, R.Ph., *Vice-President*, Robert P. Giacalone, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; Kevin J. Mitchell, R.Ph.; and Dorothy S. Teater, Public Member.

Also present were William T. Winsley, *Executive Director*, Timothy Benedict, *Assistant Executive Director*, William McMillen, *Licensing Administrator*, Mark Keeley, *Legislative Affairs Administrator*, David Rowland, *Legal Affairs Administrator*, Danna Droz, *Prescription Monitoring Program Administrator*, and Sally Ann Steuk, *Assistant Attorney General*.

10:10 a.m. Board member Gregory Braylock, R.Ph., arrived and joined the meeting in progress.

10:12 a.m. Mrs. Gregg moved that the Board go into Executive Session for the purpose of the investigation of complaints regarding licensees and registrants pursuant to Section 121.22(G)(1) of the Ohio Revised Code and for the purpose of conferring with an attorney for the Board regarding pending or imminent court action pursuant to Section 121.22(G)(3) of the Ohio Revised Code. The motion was seconded by Mr. Lipsyc and a roll-call vote was taken by President Eastman as follows: Braylock – yes; Giacalone – yes; Gregg – yes; Lipsyc – yes; Mitchell – yes; Teater – yes; and Turner – yes.

10:48 a.m. The Executive Session ended and the meeting was opened to the public.

R-2006-126 Mrs. Gregg moved that the Board issue the following Cease and Desist order in the matter of Heartland Veterinary Supply and Pharmacy. The motion was seconded by Mrs. Teater and approved by the Board: Aye – 7.

CEASE AND DESIST

Heartland Veterinary Supply and Pharmacy 5052 West 12th Street Hastings, Nebraska 68901

To Whom It May Concern:

Ohio State Board of Pharmacy records indicate that Heartland Veterinary Supply and Pharmacy advertises to distribute, and distributes dangerous drugs and compounded drugs into the State of Ohio.

Please be reminded that Section 4729.51(C) of the Ohio Revised Code states in pertinent part: "[except for a licensed terminal distributor whose conduct is in accordance with Chapters 3719., 4729., and 4731. of the Ohio Revised Code] no

person shall sell at retail dangerous drugs." Violation of this provision is a felony, and is punishable by a fine of up to Ten Thousand Dollars (\$10,000.00) and incarceration up to five (5) years for an individual, and is punishable by a fine of Fifteen Thousand Dollars (\$15,000.00) for an organization.

In addition, Section 2925.03 of the Ohio Revised Code prohibits the sale of controlled substances unless the seller is acting in accordance with Chapters 3719. and 4729. of the Ohio Revised Code, each of which requires licensure. A violation of this section is a felony depending upon the amount of the substance, and is punishable by a mandatory fine of up to Twenty Thousand (\$20,000.00) and incarceration up to the lifetime of the offender for an individual, and is punishable by a fine of Twenty-Five Thousand Dollars (\$25,000.00) for an organization. Heartland Veterinary Supply and Pharmacy is not so licensed and therefore cannot legally distribute dangerous drugs into Ohio. To do so is in violation of Ohio law.

Various provisions of Ohio law prohibit compounding dangerous drugs unless done so "patient-specific." This means that a pharmacy must have a valid prescription, issued by an authorized prescriber for a specific patient. Absent such a scenario, compounding drugs may give rise to federal prohibitions for manufacturing, and they could be deemed selling a drug not approved by the FDA in violation of Section 3715.65 of the Ohio Revised Code, a misdemeanor of the 4th degree.

YOU ARE HEREBY ADVISED that pursuant to Section 4729.25(B) of the Ohio Revised Code, the Ohio State Board of Pharmacy may issue notice or warning to an alleged offender of any of the provisions of Chapter 4729. of the Ohio Revised Code; thus, you are hereby notified to immediately CEASE distribution, sale or delivery of dangerous drugs into the State of Ohio unless you are properly licensed to do so, and DESIST from any further violations of Chapter 4729. of the Ohio Revised Code.

If you desire to become licensed in order to continue distributing dangerous drugs and/or controlled substances at wholesale, or at retail pursuant to Section 4729.551 of the Ohio Revised Code, please contact the licensing division of the Board, the address and phone number being listed above, and information will be sent to you.

If you have questions or comments, feel free to correspond by telephone, mail, or electronic mail (e-mail).

BY ORDER OF THE STATE BOARD OF PHARMACY

- R-2006-127 Mr. Braylock moved that the Board accept a request from John Mileti, R.Ph., for a delay in the due date for payment of the fine assessed as part of his Board order until twelve months after the date of his Board order. The motion was seconded by Mr. Mitchell and approved by the Board: Aye 7.
- **R-2006-128** Mr. Giacalone moved that the Board accept the settlement offer presented in the matter of **Heather Moran,** R.Ph., by her attorney. Mrs. Gregg seconded the motion and it was approved by the Board: *Aye* 7.
- **R-2006-129** Mr. Mitchell moved that, pursuant to Section 3719.121 of the Ohio Revised Code, the Board summarily suspend the license to practice pharmacy as a pharmacy intern belonging to **Danielle Lyn Timkovich**, (06-0-03803), because a continuation of her professional practice presents a danger of immediate and serious harm to others. The motion was seconded by Mrs. Gregg and approved by the Board: *Aye* 7.

10:51 a.m. Mr. Braylock left the meeting for personal reasons. Mrs. Droz presented her report on the progress of the Prescription Monitoring Program to the Board.

Mr. McMillen then reported that the following candidates for licensure by reciprocity had participated in a discussion of pharmacy laws and rules with Mr. McMillen on Tuesday, February 7, 2006. Following that discussion the candidates were presented their pharmacist identification cards:

Hany Marwan Boutros	03-3-27089	Michigan
Irina Carothers	03-3-27094	Michigan
James Edwin Lynn	03-3-27082	Pennsylvania
Cynthia Ann Peterson	03-3-27078	New Hampshire
Sajaitha Salvaji	03-3-27084	Michigan
Kimberly Ann Valz	03-3-27099	Kentucky

Mr. Benedict presented the Medical Board Prescribing Committee Report.

- **R-2006-130** Mr. Turner moved that the NAPLEX/MPJE letter of agreement with NABP be approved for signing. Mrs. Gregg seconded the motion and it was approved by the Board: *Aye* 6.
- **R-2006-131** The Board then considered a request for an exemption to OAC Rule 4729-5-10 (Prescription pick-up station) received from **Teregen Laboratories** for the following sites:

Teregen Laboratories (02-1235150) Various Offices as listed on the letter of request

After discussion, Mrs. Gregg moved that the Board approve the request as long as the parties to the request comply with the requirements in the rule for such an exemption. The motion was seconded by Mr. Lipsyc and approved by the Board: Aye - 6.

R-2006-132 The Board considered a request for an exemption to OAC Rule 4729-5-10 (Prescription pick-up station) received for the following sites:

Mount Carmel Medical Center Hospital Pharmacy (02-0975550) **Central Admixture Pharmacy Services** (02-1312700)

After discussion, Mrs. Gregg moved that the Board approve the request as long as the parties to the request comply with the requirements in the rule for such an exemption. The motion was seconded by Mr. Turner and approved by the Board: *Aye* – 6.

Mr. Winsley reported on the upcoming NABP Annual meeting and discussed the Executive Committee election information he had recently received from NABP.

- <u>R-2006-133</u> Mr. Keeley presented a request from the **University of Toledo** for Board approval of an updated immunization course. After discussion, Mrs. Gregg moved that the Board accept the proposal. Mr. Turner seconded the motion and it was approved by the Board: Aye 6.
- R-2006-134 The Board discussed a proposal received from **BioPassword**, **Inc.** for consideration of a proposed method to meet the Board's positive identification requirements. Mr. Lipsyc moved that the proposal be held for further consideration by the Board after further testing and review by Board staff. The motion was seconded by Mr. Turner and approved by the Board: Aye 6.
- R-2006-135 Mr. Keeley discussed a proposed new document management system, **DocuTrack (**LTC Pharmacy order transmission system). Mrs. Gregg moved that the system be considered approvable pending a successful final inspection of the installed product. Mr. Lipsyc seconded the motion and it was approved by the Board: *Aye* 6.
- 12:09 p.m. Board member Gregory Braylock, R.Ph., rejoined the meeting in progress.

12:10 p.m. The Board recessed for lunch.

1:17 p.m. The Ohio State Board of Pharmacy reconvened in Room East B, 31st Floor, of the Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio, with the following members present:

Suzanne R. Eastman, R.Ph., *President*, James E. Turner, R.Ph., *Vice-President*, Gregory Braylock, R. Ph.; Robert P. Giacalone, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; Kevin J. Mitchell, R.Ph.; and Dorothy S. Teater, Public Member.

The Board was joined by Assistant Attorney General Sally Ann Steuk to create a record in accordance with Ohio Revised Code Chapters 119. and 4729. in the matter of **Yu-Ping Lee**, R.Ph.

1:37 p.m. The record was closed.

1:39 p.m. The Board was joined by Assistant Attorney General Sally Ann Steuk to create a record in accordance with Ohio Revised Code Chapters 119. and 4729. in the matter of **Direct Pharmacy, Inc.**

1:54 p.m. The record was closed.

2:00 p.m. The Board then met with the Board of Directors of the Ohio Society of Health-System Pharmacists (OSHP). During this meeting, Mr. McMillen discussed his Licensing Report with the Board and the Board of Directors of OSHP. Mr. Keeley discussed his Legislative Report and Mrs. Droz discussed the Prescription Drug Monitoring Program.

Other items of mutual interest to the two groups were discussed. There were no issues requiring official action by the Board.

3:52 p.m. The meeting with the OSHP Board of Directors ended.

Mr. Braylock reported that there had been no meeting of the Nursing Board's Committee on Prescriptive Governance during the past month.

3:55 p.m. The Board recessed briefly.

4:05 p.m.

R-2006-136 The meeting resumed and, after discussion, Mrs. Gregg moved that the minutes of the January 31, 2006 Conference Call be accepted as written. Mrs. Teater seconded the motion and it was approved by the Board: Aye-7.

R-2006-137
 Mrs. Gregg then moved that the minutes of the January, 2006, meeting be approved as amended. The motion was seconded by Mr. Lipsyc and approved by the Board: Aye – 7.

4:16 p.m. Mrs. Gregg moved that the Board go into Executive Session for the purpose of the investigation of complaints regarding licensees and registrants pursuant to Section 121.22(G)(1) of the Ohio Revised Code. The motion was seconded by Mr. Braylock and a roll-call vote was conducted by President Eastman as follows: Braylock – yes; Giacalone – yes; Gregg – yes; Lipsyc – yes; Mitchell – yes; Turner – yes; and Teater – yes.

4:34 p.m. The Executive Session ended and the meeting was opened to the public. Mr. Mitchell moved that the Board adopt the following order in the matter of **Direct Pharmacy, Inc**.

R-2006-138 ORDER OF THE STATE BOARD OF PHARMACY

Docket Number D-051215-050

in the matter of:

DIRECT PHARMACY, INC.

c/o Stephen J. McMurtrey, CEO 1033 State Road 436, Suite 201 Casselberry, Florida 32707

INTRODUCTION

The matter of Direct Pharmacy, INC. came for consideration on February 8, 2006, before the following members of the Board: Suzanne R. Eastman, R.Ph. (presiding); GregorY Braylock, R.Ph.; Robert P. Giacalone, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; Kevin J. Mitchell, R.Ph.; Dorothy S. Teater, Public Member; and James E. Turner, R.Ph.

Stephen J. McMurtrey was not present nor was Direct Pharmacy, INC. represented by counsel nor was a representative present. The State of Ohio was represented by Sally Ann Steuk, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witness: Timothy J. Benedict, R.Ph.,

Ohio State Board of Pharmacy

Respondent's Witnesses: None

State's Exhibits:

1. Proposal to Deny/Notice of Opportunity For Hearing letter [12-15-05]

- 2. Application for Registration As A Terminal Distributor of Dangerous Drugs with attachments and with Stephen J. McMurtrey signing as CEO [06-21-05]
- 3. Ten facsimiles of Prescription Authorization Requests [05-09-05 to 01-02-06]
- 4. Direct Pharmacy, Inc. Computer Online Website, DirectDietPills.com [06-22-05]

Respondent's Exhibits: None

FINDINGS OF FACT

After having heard the testimony, observed the demeanor of the witness, considered the evidence, and weighed the credibility of each, the State Board of Pharmacy finds the following to be fact:

- (1) On December 15, 2005, Direct Pharmacy, Inc. was notified by letter of its right to a hearing, its rights in such hearing, and its right to submit any contentions in writing.
- (2) As demonstrated by return receipt dated December 19, 2005, signed by A. Redcove, Stephen J. McMurtrey, CEO received the letter of December 15, 2005, informing him of the allegations and the proposal to deny Direct Pharmacy, Inc.'s application for registration as a Terminal Distributor of Dangerous Drugs and its rights.
- (3) Stephen J. McMurtrey has not responded in any manner to the letter of December 15, 2005, and has not requested a hearing in this matter, therefore the matter was referred to the Board for consideration.
- (4) Records of the State Board of Pharmacy indicate that on or about June 21, 2005, Stephen J. McMurtrey was the CEO of Direct Pharmacy, Inc., and that on June 21, 2005, Direct Pharmacy, Inc. applied for registration as a Terminal Distributor of Dangerous Drugs.

(5) Direct Pharmacy, Inc. has not furnished satisfactory proof to the Board pursuant to Section 4729.55 of the Ohio Revised Code that it is equipped as to land, buildings, and equipment to properly carry on the business of a terminal distributor of dangerous drugs within the category of licensure approved by the board. Specifically, Direct Pharmacy, Inc., a mail-order pharmacy sells diet medications for illegitimate use beyond time limitations set forth by FDA-approved labeling and prohibited by the Ohio Administrative Code. Additionally, Direct Pharmacy, Inc. has sold drugs into Ohio by deception, to wit: when asked for its Ohio licensure information as required by Ohio law, Direct Pharmacy, Inc. indicated that it and its pharmacists are licensed in Ohio, and provided false license numbers to deceive the purchasers.

CONCLUSIONS OF LAW

- (1) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraph (5) of the Findings of Fact constitutes failure to meet the qualifications set forth in Section 4729.53(A) of the Ohio Revised Code.
- (2) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraph (5) of the Findings of Fact constitutes failure to furnish satisfactory proof to the Board that granting a registration certificate to Direct Pharmacy, Inc. is in the public interest as provided in Section 4729.53(B) of the Ohio Revised Code.

DECISION OF THE BOARD

Pursuant to Section 4729.55(A) of the Ohio Revised Code, the State Board of Pharmacy hereby refuses to register Direct Pharmacy, Inc. and, therefore, denies the Application for Registration as a Terminal Distributor of Dangerous Drugs submitted by Stephen J. McMurtrey and received by the Board on June 21, 2005.

The motion was seconded by Mr. Braylock and approved by the Board: Aye - 7.

Mr. Braylock then moved that the Board adopt the following order in the matter of **Yu-Ping Lee**, R.Ph.

R-2006-139

ORDER OF THE STATE BOARD OF PHARMACY

Docket Number D-051013-038

in the matter of:

YU-PING LEE, R.PH. 903 Redspire Drive Union, New Jersey 07083

R.Ph. Number 03-3-19844

INTRODUCTION

The matter of Yu-Ping Lee came for consideration on February 8, 2006, before the following members of the Board: Suzanne R. Eastman, R.Ph. (*presiding*); Gregory Braylock, R.Ph.; Robert P. Giacalone, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; Kevin J. Mitchell, R.Ph.; Dorothy S. Teater, Public Member; and James E. Turner, R.Ph.

Yu-Ping Lee was not present nor was she represented by counsel. The State of Ohio was represented by Sally Ann Steuk, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witness: Timothy J. Benedict, R.Ph., Ohio State Board of

Pharmacy

Respondent's Witnesses: None

State's Exhibits:

Notice of Opportunity For Hearing letter [12-14-05]
 1A. Procedural

- 2. Renewal Application for Pharmacist License of Yu-Ping Lee [08-14-04]
- 3. Copy of Settlement Agreement Between Missouri State Board of Pharmacy and Yu-Ping Lee [02-24-04]
- 4. The Children's Mercy Hospital Doctor's Order Sheet for Treatment [11-18-02]
- 5. Children's Mercy Pharmacy PHA Order [11-22-02 to 11-23-02]
- 6. Mix Check Report with notes [12-20-02]
- 7. Mix Check Report with notes [11-22-02]
- 8. Copy of Compounded Label from TPN Bag [date illegible]

Respondent's Exhibits: None

FINDINGS OF FACT

After having heard the testimony, observed the demeanor of the witness, considered the evidence, and weighed the credibility of each, the State Board of Pharmacy finds the following to be fact:

- (1) On December 14, 2005, Yu-Ping Lee was notified by letter of her right to a hearing, her rights in such hearing, and her right to submit any contentions in writing.
- (2) As demonstrated by return receipt dated December 17, 2005, Yu-Ping Lee received the letter of December 14, 2005, informing her of the allegations against her and her rights.
- (3) Yu-Ping Lee returned her identification card to the Board, but has not requested a hearing in this matter, therefore the matter was referred to the Board for consideration.
- (4) Records of the State Board of Pharmacy indicate that Yu-Ping Lee was originally licensed by the State of Ohio as a pharmacist on July 28, 1993, pursuant to examination, and is currently licensed to practice pharmacy in Ohio.
- (5) Effective fifteen days from February 24, 2004, Yu-Ping Lee's license to practice pharmacy in the State of Missouri was disciplined by the Missouri Board of Pharmacy through a Settlement Agreement. Yu-Ping Lee's license was suspended for thirty days, she was placed on probation for five years, and was required to obtain six hours of additional continuing education in the area of error prevention. Such settlement/discipline constitutes being disciplined by a board of pharmacy within the meaning of Rule 4729-5-04 of the Ohio Administrative Code, and not meeting the requirements for licensure in the State of Ohio pursuant to Sections 4729.08 and 4729.12 of the Ohio Revised Code.

CONCLUSION OF LAW

The State Board of Pharmacy concludes that paragraph (5) of the Findings of Fact constitutes having been disciplined by any board of pharmacy as provided in paragraph (F) of Rule 4729-5-04 of the Ohio Administrative Code.

DECISION OF THE BOARD

Pursuant to Section 4729.16 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby notes the disciplinary action of the Missouri Board of Pharmacy in the matter of Yu-Ping Lee.

The motion was seconded by Mrs. Gregg and approved by the Board: Aye - 7.

- 4:35 p.m. Mr. Lipsyc left the meeting for personal reasons.
- 4:36 p.m. Mrs. Gregg moved that the Board go into Executive Session for the purpose of the investigation of complaints regarding licensees and registrants pursuant to Section 121.22(G)(1) of the Ohio Revised Code. The motion was seconded by Mr. Braylock and a roll-call vote was conducted by President Eastman as follows: Braylock yes; Giacalone yes; Gregg yes; Mitchell yes; Turner yes; and Teater yes.
- 6:22 p.m. The Executive Session ended and the meeting was opened to the public.

Mrs. Gregg moved that the Board receive Per Diem as follows:

PER DIEM	<u>2/8</u>	<u>Total</u>
G. Braylock	1	1
S. Eastman	1	1
R. Giacalone	1	1
E. Gregg	1	1
L. Kost	-	-
N. Lipsyc	1	1
K. Mitchell	1	1
D. Teater	1	1
J. Turner	1	1

Mr. Braylock seconded the motion and it was approved by the Board: Aye – 6.

6:23 p.m. Mrs. Gregg moved that the meeting be adjourned. The motion was seconded by Mr. Braylock and approved by the Board: Aye – 6.

THE OHIO STATE BOARD OF PHARMACY APPROVED THESE MINUTES MARCH 7, 2006