

**NOTE: The following Minutes are provided for informational purposes only.**  
*If you would like to obtain an official copy of these Minutes, please contact the State Board of Pharmacy at 614/466-4143 for instructions and fee.*

STATE BOARD OF PHARMACY; 77 SOUTH HIGH STREET, ROOM 1702; COLUMBUS, OHIO 43215-6126  
 Tel: 614/466-4143 Fax: 614/752-4836 Email: [exec@bop.state.oh.us](mailto:exec@bop.state.oh.us)

## **Minutes Of The Meeting**

Ohio State Board of Pharmacy  
 May 3, 4, 5, 2004

### **MONDAY, MAY 3, 2004**

10:05 a.m. ROLL CALL

The State Board of Pharmacy convened in the Medical Sciences Building-E701, University of Cincinnati, Cincinnati, Ohio with the following members present:

Robert P. Giacalone, R.Ph. (President); Lawrence J. Kost, R.Ph. (Vice-President); Diane C. Adelman, R.Ph.; Gregory Braylock, R.Ph.; Suzanne R. Eastman, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, 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; and Sally Ann Steuk, Assistant Attorney General.

This meeting was held at the University of Cincinnati so that the students from the College of Pharmacy could attend. President Giacalone, Board members, and Board staff introduced themselves to the students and a brief explanation of the meeting process was given.

10:17 a.m.

**R-2004-186**

Mr. Winsley presented a settlement offer to the Board that had been received in the matter of Terrell L. Mundhenk, R.Ph. After discussion, Mr. Braylock moved that the settlement offer be denied and that the hearing scheduled for that afternoon proceed. The motion was seconded by Mr. Kost and approved by the Board (Aye-7/Nay-0).

Mr. Keeley presented a detailed legislative report to the Board.

Mr. McMillen presented a detailed licensing report to the Board.

11:30 a.m.

The Board recessed for lunch.

1:09 p.m.

The Board reconvened in the Medical Sciences Building-E701, University of Cincinnati, Cincinnati, Ohio with the following members present:

Robert P. Giacalone, R.Ph. (President); Lawrence J. Kost, R.Ph. (Vice-President); Diane C. Adelman, R.Ph.; Gregory Braylock, R.Ph.; Suzanne R. Eastman, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; and Dorothy S. Teater, Public Member.

The Board was joined by Assistant Attorney General Sally Ann Steuk for the purpose of conducting an adjudication hearing in accordance with Ohio Revised Code Chapters 119. and 4729. in the matter of Anthony Kornokovich, R.Ph., Timberlake. Mr. Lipsyc recused himself from the hearing and the resulting deliberations.

2:25 p.m.

The hearing ended and the record was closed. The Board took a brief recess.

3:00 p.m.

The Board was joined by Assistant Attorney General Sally Ann Steuk for the purpose of conducting an adjudication hearing in accordance with Ohio Revised Code Chapters 119. and 4729. in the matter of Terrell L. Mundhenk, R.Ph., Centerville.

5:40 p.m.

The hearing ended and the record was closed. The Board meeting recessed until Tuesday, May 4, 2004.

## **TUESDAY, MAY 4, 2004**

8:10 a.m. ROLL CALL

The State Board of Pharmacy convened in Room West-B&C, 31st Floor, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio with the following members present:

Robert P. Giacalone, R.Ph. (President); Lawrence J. Kost, R.Ph. (Vice-President); Diane C. Adelman, R.Ph.; Gregory Braylock, R.Ph.; Suzanne R. Eastman, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; Dorothy S. Teater, Public Member; and James E. Turner, R.Ph.

Mr. Rowland announced that the following settlement agreements for Stephen A. Summers, R.Ph. and Elaine Woll, R.Ph. had been signed and were effective.

*R-2004-187*

### **SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY**

(Docket No. D-040211-059)

In The Matter Of:

**STEPHEN ANDREW SUMMERS, R.Ph.**

9597 Pence Jones Road  
Waynesville, Ohio 45068  
(R.Ph. No. 03-2-16556)

This Settlement Agreement is entered into by and between Stephen Andrew Summers and the Ohio State Board of Pharmacy, a state agency charged with enforcing the Pharmacy Practice Act and Dangerous Drug Distribution Act, Chapter 4729. of the Ohio Revised Code.

Stephen Andrew Summers voluntarily enters into this Agreement being fully informed of his rights afforded under Chapter 119. of the Ohio Revised Code, including the right to representation by counsel, the right to a formal adjudication hearing on the issues contained herein, and the right to appeal. Stephen Andrew Summers acknowledges that by entering into this agreement he has waived his rights under Chapter 119. of the Revised Code.

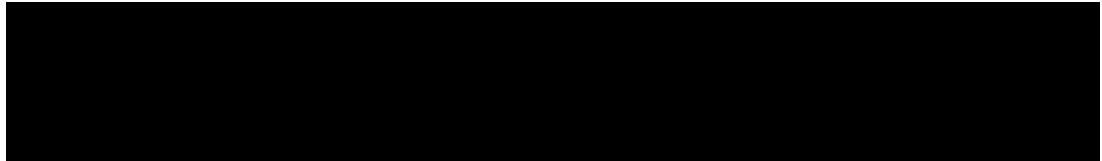
Whereas, the Board is empowered by Section 4729.16 of the Ohio Revised Code to suspend, revoke, place on probation, refuse to grant or renew an identification card or enforce a monetary penalty on the license holder for violation of any of the enumerated grounds therein.

Whereas, Stephen Andrew Summers is licensed to practice pharmacy in the State of Ohio.

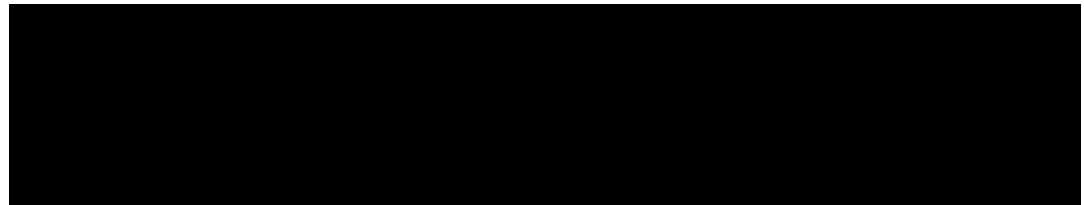
Whereas, on or about February 11, 2004, pursuant to Chapter 119. of the Ohio Revised Code, Stephen Andrew Summers was notified of the allegations or charges against him, his right to a hearing, his rights in such hearing, and his right to submit contentions in writing. Stephen Andrew Summers requested a hearing; it was scheduled and continued. The February 11, 2004, Notice of Opportunity for Hearing contains the following allegations or charges:

(1) Records of the Board of Pharmacy indicate that Stephen Andrew Summers was originally licensed in the State of Ohio on August 6, 1986, pursuant to examination, and is currently licensed to practice pharmacy in the State of Ohio.

(2)



(3)



Stephen Andrew Summers neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated January 7, 2004; however, the Board has evidence sufficient to sustain the allegations and hereby adjudicates the same.

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of a formal hearing at this time, Stephen Andrew Summers knowingly and voluntarily agrees with the State Board of Pharmacy to the following:

- (A) Stephen Andrew Summer's pharmacist identification card, No. 03-2-16556, will be placed on probation for two years, effective from the date of this Agreement.
- (B) Stephen Andrew Summers agrees to the imposition of a monetary penalty of two thousand five hundred dollars (\$2,500.00) due and owing within thirty days from the effective date of this Agreement. Checks should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 South High Street, Room 1702, Columbus, Ohio 43215-6126
- (C) The terms of probation are as follows:
  - (1) The State Board of Pharmacy hereby declares that Stephen Andrew Summer's pharmacist identification card is not in good standing and thereby denies the privilege of being a preceptor and training pharmacy interns pursuant to paragraph (D)(1) of Rule 4729-3-01 of the Ohio Administrative Code.
  - (2) Stephen Andrew Summers may not serve as a responsible pharmacist.
  - (3) Stephen Andrew Summers must, during the period of probation, notify any future employers of his probation and its terms.
  - (4) Stephen Andrew Summers may destroy, assist in, or witness the destruction of controlled substances.
  - (5) Stephen Andrew Summers must not violate the drug laws of the State of Ohio, any other state, or the federal government.

(6) Stephen Andrew Summers must abide by the rules of the Ohio State Board of Pharmacy.

(7) Stephen Andrew Summers must comply with the terms of this Agreement.

If, in the judgment of the Board, Stephen Andrew Summers appears to have violated or breached any terms or conditions of this Agreement, the Ohio State Board of Pharmacy reserves the right to, at any time, revoke probation, modify the conditions of probation, and reduce or extend the period of probation, and/or the Board may institute formal disciplinary proceedings for any and all possible violations or breaches, including but not limited to, alleged violation of the laws of Ohio occurring before the effective date of this Agreement.

Stephen Andrew Summers acknowledges that he has had an opportunity to ask questions concerning the terms of this agreement and that all questions asked have been answered in a satisfactory manner. Any action initiated by the Board based on alleged violation of this Agreement shall comply with the Administrative Procedure Act, Chapter 119. of the Ohio Revised Code.

Stephen Andrew Summers waives any and all claims or causes of action he may have against the State of Ohio or the Board, and members, officers, employees, and/or agents of either, arising out of matters which are the subject of this Agreement. Stephen Andrew Summers waives any rights of appeal pursuant to Chapter 119. of the Ohio Revised Code.

This Settlement Agreement shall be considered a public record, as that term is used in Section 149.43 of the Ohio Revised Code, and shall become effective upon the date of the Board President's signature below.

<u>/s/ S A Summers</u>	<u>/d/ 4/21/04</u>
Stephen Andrew Summers, R.Ph., Respondent	Date of Signature
<u>/s/ J D Revelson</u>	<u>/d/ 04/21/04</u>
Jay D. Revelson, Attorney for Respondent	Date of Signature
<u>/s/ Robert P. Giacalone</u>	<u>/d/ 5/4/04</u>
Robert P. Giacalone, President, Ohio State Board of Pharmacy	Date of Signature
<u>/s/ Sally Ann Steuk</u>	<u>/d/ 5-5-04</u>
Sally Ann Steuk, Ohio Assistant Attorney General	Date of Signature

R-2004-188

**SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY**

(Docket No. D-040107-051)

In The Matter Of:

**ELAINE L. WOLL, R.Ph.**  
4468 Classic Drive  
Cincinnati, Ohio 45241  
(R.Ph. No. 03-2-13136)

This Settlement Agreement is entered into by and between Elaine L. Woll and the Ohio State Board of Pharmacy, a state agency charged with enforcing the Pharmacy Practice Act and Dangerous Drug Distribution Act, Chapter 4729. of the Ohio Revised Code.

Elaine L. Woll voluntarily enters into this Agreement being fully informed of her rights afforded under Chapter 119. of the Ohio Revised Code, including the right to representation by counsel, the right to a formal adjudication hearing on the issues contained herein, and the right to appeal. Elaine L. Woll acknowledges that by entering into this agreement she has waived her rights under Chapter 119. of the Revised Code.

Whereas, the Board is empowered by Section 4729.16 of the Ohio Revised Code to suspend, revoke, place on probation, refuse to grant or renew an identification card or enforce a monetary penalty on the license holder for violation of any of the enumerated grounds therein.

Whereas, Elaine L. Woll is licensed to practice pharmacy in the State of Ohio.

Whereas, on or about January 7, 2004, pursuant to Chapter 119. of the Ohio Revised Code, Elaine L. Woll was notified of the allegations or charges against her, her right to a hearing, her rights in such hearing, and her right to submit contentions in writing. Elaine L. Woll requested a hearing; it was scheduled and continued. The January 7, 2004, Notice of Opportunity for Hearing contains the following allegations or charges:

- (1) Records of the Board of Pharmacy indicate that Elaine L. Woll was originally licensed in the State of Ohio on August 9, 1978, pursuant to examination, and is currently licensed to practice pharmacy in the State of Ohio.
- (2) Elaine L. Woll did, on or about April 8, 2003, with purpose to deprive, knowingly obtain or exert control over dangerous drugs, the property of University Hospital, Cincinnati, Ohio, beyond the express or implied consent of the owner, to wit: Elaine L. Woll admittedly stole a bottle of 100 tablets of Toprol XL 25 mg to give to a family member. Such conduct is in violation of Section 2913.02 of the Ohio Revised Code.
- (3) Elaine L. Woll did, on or about April 15, 2003, with purpose to deprive, knowingly obtain or exert control over dangerous drugs, the property of Lincoln Heights Health Center Pharmacy, Cincinnati, Ohio, beyond the express or implied consent of the owner, to wit: Elaine L. Woll admittedly stole a bottle of 100 tablets of Toprol XL 50 mg to give to a family member. Such conduct is in violation of Section 2913.02 of the Ohio Revised Code.
- (4) Elaine L. Woll did, on or about April 22, 2003, with purpose to deprive, knowingly obtain or exert control over dangerous drugs, the property of University Hospital, Cincinnati, Ohio, beyond the express or implied consent of the owner, to wit: Elaine L. Woll admittedly stole a bottle of 100 tablets of Toprol XL 25 mg to give to a family member. Such conduct is in violation of Section 2913.02 of the Ohio Revised Code.
- (5) Elaine L. Woll did, on or about September 3, 2003, with purpose to deprive, knowingly obtain or exert control over dangerous drugs, the property of Lincoln Heights Health Center Pharmacy, Cincinnati, Ohio, beyond the express or implied consent of the owner, to wit: Elaine L. Woll admittedly stole a bottle of 100 tablets of Toprol XL 25 mg to give to a family member. Such conduct is in violation of Section 2913.02 of the Ohio Revised Code.

Elaine L. Woll neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated January 7, 2004; however, the Board has evidence sufficient to sustain the allegations and hereby adjudicates the same.

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of a formal hearing at this time, Elaine L. Woll knowingly and voluntarily agrees with the State Board of Pharmacy to the following:

- (A) Elaine L. Woll's pharmacist identification card, No. 03-2-13136, will be placed on probation for two years, effective from the date of this Agreement.
- (B) Elaine L. Woll agrees to the imposition of a monetary penalty of five thousand dollars (\$5,000.00) due and owing within thirty days from the effective date of this Agreement. Checks should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 South High Street, Room 1702, Columbus, Ohio 43215-6126
- (C) Elaine L. Woll must demonstrate to the Board that she has made full restitution.
- (D) The terms of probation are as follows:
  - (1) The State Board of Pharmacy hereby declares that Elaine L. Woll's pharmacist identification card is not in good standing.

- (2) Elaine L. Woll must, during the period of probation, notify any future employers of her probation and its terms.
- (3) Elaine L. Woll must not violate the drug laws of the State of Ohio, any other state, or the federal government.
- (4) Elaine L. Woll must abide by the rules of the Ohio State Board of Pharmacy.
- (5) Elaine L. Woll must comply with the terms of this Agreement.

If, in the judgment of the Board, Elaine L. Woll appears to have violated or breached any terms or conditions of this Agreement, the Ohio State Board of Pharmacy reserves the right to, at any time, revoke probation, modify the conditions of probation, and reduce or extend the period of probation, and/or the Board may institute formal disciplinary proceedings for any and all possible violations or breaches, including but not limited to, alleged violation of the laws of Ohio occurring before the effective date of this Agreement.

Elaine L. Woll acknowledges that she has had an opportunity to ask questions concerning the terms of this agreement and that all questions asked have been answered in a satisfactory manner. Any action initiated by the Board based on alleged violation of this Agreement shall comply with the Administrative Procedure Act, Chapter 119. of the Ohio Revised Code.

Elaine L. Woll waives any and all claims or causes of action she may have against the State of Ohio or the Board, and members, officers, employees, and/or agents of either, arising out of matters which are the subject of this Agreement. Elaine L. Woll waives any rights of appeal pursuant to Chapter 119. of the Ohio Revised Code.

This Settlement Agreement shall be considered a public record, as that term is used in Section 149.43 of the Ohio Revised Code, and shall become effective upon the date of the Board President's signature below.

<u>/s/ Elaine L. Woll</u>	<u>/d/ 4/19/04</u>
Elaine L. Woll, R.Ph., Respondent	Date of Signature
<u>/s/ Peter Rosenwald</u>	<u>/d/ 20 Apr 04</u>
Peter Rosenwald, Attorney for Respondent	Date of Signature
<u>/s/ Robert P. Giacalone</u>	<u>/d/ 5/4/04</u>
Robert P. Giacalone, President, Ohio State Board of Pharmacy	Date of Signature
<u>/s/ Sally Ann Steuk</u>	<u>/d/ 5-5-04</u>
Sally Ann Steuk, Ohio Assistant Attorney General	Date of Signature

8:12 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 Revised Code. The motion was seconded by Mr. Braylock and a roll call vote was conducted by President Giacalone as follows: Adelman-Yes, Braylock-Yes, Eastman-Yes, Gregg-Yes, Kost-Yes, Lipsyc-Yes, Teater-Yes, and Turner-Yes.

9:00 a.m.

**R-2004-189**

The Executive Session ended and the meeting was opened to the public. Mr. Kost moved that the Board adopt the following Order in the matter of Anthony Kornokovich, R.Ph.:

**ORDER OF THE STATE BOARD OF PHARMACY**  
(Docket No. D-031016-021)

In The Matter Of:

**ANTHONY KORNOKOVICH, R.Ph.**  
86 Eastshore Boulevard  
Timberlake, Ohio 44095  
(R.Ph. No. 03-3-16986)

INTRODUCTION

THE MATTER OF ANTHONY KORNOKOVICH CAME FOR HEARING ON MAY 3, 2004, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: ROBERT P. GIACALONE, R.Ph. (presiding); DIANE C. ADELMAN, R.Ph.; GREGORY BRAYLOCK, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; ELIZABETH I. GREGG, R.Ph.; LAWRENCE J. KOST, R.Ph.; DOROTHY S. TEATER, PUBLIC MEMBER.

ANTHONY KORNOKOVICH WAS REPRESENTED BY JOHN R. IRWIN, M.D. AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCEState's Witnesses

None

Respondent's Witnesses

1. Anthony Kornokovich, R.Ph., Respondent
2. Christopher M. Holzman, R.Ph.

State's Exhibits

1. Reinstatement Hearing Request letter from John R. Irwin, M.D. [10-07-03]  
1A-1E. Procedurals
- 2A. Copy of State Board of Pharmacy Order in re Anthony Kornokovich, R.Ph. [05-15-03]
2. Willoughby Police Department Records for Incident No. 02-02326 in re Anthony J. Kornokovich [09-27-02]
3. Copy of Statement by Anthony Kornokovich [09-27-02]
4. Copy of Statement by Kimberly K. Kornokovich [09-27-02]
5. Medic Drug #304 Loss Calculation Sheet [08-26-01 to 09-30-02]; copy of letter from Michael Bukach [not dated]
6. Notarized Statement of Anthony J. Kornokovich [10-02-02]
7. Bill of Information, State of Ohio vs. Anthony J. Kornokovich, Case 02-CR-000678, Lake County Common Pleas Court [12-20-02]
8. Judgment Entry [03-11-03]

Respondent's Exhibits

- A1-A3. Facsimile copy of PRO Pharmacist's Recovery Contract for Tony Kornokovich [12-10-02]
- B. Support Group Attendance Verification cover letter from Anthony Kornokovich [04-28-04]
- C1-C13. Calendar pages for April 2003 to April 2004
- D1-D21. Support Group Attendance Records [04-04-03 to 04-28-04]
- E1-E14. Support Group Attendance Records [05-13-03 to 04-28-04]
- F. Letter from Anthony J. Kornokovich [04-29-04]
- G1-G15. Calendar pages for February 2003 to April 2004
- H1-H3. Compass Vision Licensee Summary Report [02-10-03 to 03-02-04]
- I1-I2. Compass Vision Drug Screen Report [04-23-04]
- J. Letter from Michael D. Quigley, R.Ph. [04-30-04]
- K1-K2. Letter from Lake County Adult Probation Officer Evelyn A. Porter [04-21-04]; Release of Information letter from Anthony Joseph Kornokovich [04-19-04]
- L. Letter from Lake County Adult Probation Fiscal Officer Kathy L. Cummings [04-19-04]
- M. Receipt No. 2840, Lake County Adult Probation Department, stamped Paid in Full [04-19-04]
- N. Receipt No. C83943, Lake County Court of Common Pleas, showing zero balance due [04-19-04]
- O. Copy of letter from Anthony Kornokovich regarding Restitution to Medic Drug [not dated]
- P. Purchaser's Receipt of Official Check No. 2786120 payable to Medic [03-31-04]
- Q. United States Postal Service Certified Mail Return Receipt for Article No. 7003 3110 0002 8871 6412 [04-02-04]

- R. Ohio Bureau of Motor Vehicles Notification/Reinstatement Requirement for Driver License Status of Anthony J. Kornokovich [03-18-04]  
S1-S2. Copy of Cleveland Clinic Progress Reports [04-06-04 and 04-19-04]  
S3-S4. The Cleveland Clinic Foundation letter confirming Vicodin prescription [10-24-03]; copy of Rx #970949 [10-24-03]  
S5. Treatment Compliance letter from Stacey B. Foerstner, Ph.D. [not dated]  
S6-S7. Letters of Support [04-28-04 and 04-30-04]  
T1-T33. Continuing Pharmaceutical Education Credits and Certificates [12-10-00 to 04-25-04]

#### FINDING OF FACT

After having heard the testimony, observed the demeanor of the witnesses, considered the evidence, and weighed the credibility of each, the State Board of Pharmacy finds that Anthony Kornokovich has complied with the terms set forth in the Order of the State Board of Pharmacy, Docket No. D-021016-020, effective May 15, 2003.

#### DECISION OF THE BOARD

On the basis of the Finding of Fact set forth above, and after consideration of the record as a whole, the State Board of Pharmacy hereby approves the reinstatement of the pharmacist identification card, No. 03-3-16986, held by Anthony Kornokovich to practice pharmacy in Ohio and places Anthony Kornokovich on probation for five years beginning on the effective date of this Order, with the following conditions:

(A) Anthony Kornokovich must enter into a new contract, signed within thirty days after the effective date of this Order, with an Ohio Department of Alcohol and Drug Addiction Services (ODADAS) treatment provider or a treatment provider acceptable to the Board for a period of not less than five years and submit a copy of the signed contract to the Board office before his pharmacist identification card is issued. The contract must provide that:

(1) Random, observed urine drug screens shall be conducted at least once each month for the first year and then at least once every three months for the remaining four years.

(a) The urine sample must be given within twelve hours of notification. The urine drug screen must include testing for creatinine or specific gravity of the sample as the dilutional standard.

(b) Soma, Valium, Fioricet, Vicodin, Lortab, and Ultram must be added to the standard urine drug screen.

(c) Results of all drug screens must be negative. Any positive results, including those that may have resulted from ingestion of food, but excluding false positives that resulted from medication legitimately prescribed, indicate a violation of probation.

(d) Refusals of urine screens or diluted urine screens are equivalent to a positive result and indicate a violation of probation.

(2) The intervener/sponsor shall provide copies of all drug screen reports to the Board in a timely fashion.

(3) Attendance is required a minimum of three times per week at an Alcoholics Anonymous, Narcotics Anonymous, and/or similar support group meeting.

(4) The program shall immediately report to the Board any violations of the contract and/or lack of cooperation.



(B) Anthony Kornokovich must submit quarterly progress reports to the Board (due January 10, April 10, July 10, and October 10 of each year of probation) that include:

- (1) The written report and documentation provided by the treatment program pursuant to the contract, and
- (2) A written description of Anthony Kornokovich's progress towards recovery and what Anthony Kornokovich has been doing during the previous three months.

(C) Other terms of probation are as follows:

- (1) The State Board of Pharmacy hereby declares that Anthony Kornokovich's pharmacist identification card is not in good standing and thereby denies the privilege of being a preceptor and training pharmacy interns pursuant to paragraph (D)(1) of Rule 4729-3-01 of the Ohio Administrative Code.
- (2) Anthony Kornokovich may not serve as a responsible pharmacist.
- (3) Anthony Kornokovich may not destroy, assist in, or witness the destruction of controlled substances.
- (4) Anthony Kornokovich may not work in a pharmacy more than 40 hours per week during the first twelve months of practice.
- (5) Anthony Kornokovich must abide by the contract with his treatment provider and must immediately report any violation of the contract to the Board.
- (6) Anthony Kornokovich must not violate the drug laws of Ohio, any other state, or the federal government.
- (7) Anthony Kornokovich must abide by the rules of the State Board of Pharmacy.
- (8) Anthony Kornokovich must comply with the terms of this Order.
- (9) Anthony Kornokovich's license is deemed not in good standing until successful completion of the probationary period.

(D) Any violation of probation may result in a Board hearing to consider alternative or additional sanctions under Section 4729.16 of the Ohio Revised Code.

Anthony Kornokovich is hereby advised that the Board may at any time revoke probation for cause, modify the conditions of probation, and reduce or extend the period of probation. At any time during this period of probation, the Board may revoke probation for a violation occurring during the probation period.

THIS ORDER WAS APPROVED BY A VOTE OF THE STATE BOARD OF PHARMACY.

MOTION CARRIED.

SO ORDERED.

The motion was seconded by Mrs. Gregg and approved by the Board (Aye-6/Nay-0/Abstain-2[Lipsyc, Turner]).

**R-2004-190** Mr. Braylock then moved that the Board adopt the following Order in the matter of Terrell L. Mundhenk, R.Ph.:

**ORDER OF THE STATE BOARD OF PHARMACY**  
(Docket No. D-031024-026 and D-040218-061)

In The Matter Of:

**TERRELL L. MUNDHENK, R.Ph.**  
7571 Cloverbrook Park Drive  
Centerville, Ohio 45459  
(R.Ph. No. 03-3-08732)

**INTRODUCTION**

THE MATTER OF TERRELL L. MUNDHENK CAME FOR HEARING ON MAY 3, 2004, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: ROBERT P. GIACALONE, R.Ph. (presiding); DIANE C. ADELMAN, R.Ph.; GREGORY BRAYLOCK, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; ELIZABETH I. GREGG, R.Ph.; LAWRENCE J. KOST, R.Ph.; NATHAN S. LIPSYC, R.Ph.; AND DOROTHY S. TEATER, PUBLIC MEMBER.

TERRELL L. MUNDHENK WAS REPRESENTED BY RAY A. COX AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

**SUMMARY OF EVIDENCE**

**State's Witnesses**

1. Jesse Wimberly, Ohio State Board of Pharmacy

**Respondent's Witnesses**

1. Robert A. Blair, R.Ph.
2. Julia K. Wharff, Pastor
3. Terrell Mundhenk, R.Ph., Respondent

**State's Exhibits**

1. Copy of Notice of Opportunity For Hearing letter [10-24-03]  
1A-1E. Procedurals  
1F. Copy of Summary Suspension Order/Notice of Opportunity For Hearing letter [02-18-04]  
1G. Procedural
2. Copy of e-mail letter from Cassie to Brent Kovalyak [07-25-03]
3. Copy of Statement of Terrell Mundhenk [09-04-03]
4. Copy of letter from Edmund Choroski [03-22-04]; copy of record of Ann Mundhenk's prescriptions [10-21-02 to 08-30-03]; copy of record of Terrell Mundhenk's prescriptions [10-31-02 to 05-30-03]; copy of letter from Audrey J. Aronsohn [03-23-04]
5. Copy of Walgreens Prescription Refill Request for Ann Mundhenk [07-23-03]; copy of Walgreens Second Prescription Refill Request for Ann Mundhenk [07-25-03]
6. Copy of twenty-three page Prescription Profile for Ann Mundhenk [05-20-02 to 09-02-03]
7. Copy of Statement of J. Koren, D.O. [09-04-03]
8. Copy of nineteen page Prescription Profile for Amy Mundhenk [05-20-02 to 09-02-03]
9. Copy of Statement of S. Lee, M.D. [09-04-03]
10. Copy of eleven page Prescription Profile for Terrell L. Mundhenk [05-20-02 to 09-02-03]
11. Indictment [11-06-03]; Entry of Plea of Not Guilty [11-20-03]; Motion for Intervention in Lieu of Conviction [12-02-03]; Decision and Order of Intervention in Lieu of Conviction [02-04-04]  
**State of Ohio vs. Terrell L. Mundhenk**, Case No. 2003 CR 03614, Montgomery County Common Pleas Court

Respondent's Exhibits

- A. Letter from Robert Blair, R.Ph., [04-27-04]
- B. Letter from Ronald E. Seigla, R.Ph. [not dated]
- C. Letter from William M. Powers, Jr. [04-26-04]
- D. Letter from Julia K. Wharff, Pastor [04-27-04]
- E. Copy of Demand for Payment letter from Civil Recovery Services [11-10-03]; copy of Section 2307.61 (Damages Recoverable For Willful Damage Or theft; Demand; Agreement for Payment; Procedure) of the Ohio Revised Code [10-13-97]; copy of United States Postal Service Money Order Receipt, No. 04611184402 [12-08-03]; copy of U.S. Postal Service Certified Mail Receipt No. 7003 1680 0004 2120 8811 [02-26-04]
- F. Copy of Miami Valley Pharmacists Association *MVPA Newsletter* [not dated]
- G. Letter from James H. Davis, M.D. [04-22-04]
- H. Letter from James A. Derksen, M.D., FAAFP [04-28-04]

FINDINGS OF FACT

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

(1) Records of the State Board of Pharmacy indicate that Terrell L. Mundhenk was originally licensed by the State of Ohio as a pharmacist on February 13, 1967, pursuant to examination, and that his license to practice pharmacy in Ohio was summarily suspended effective February 18, 2004.

(2) Terrell L. Mundhenk did, on or about the following dates, intentionally create and/or knowingly possess a false or forged prescription, to wit: Terrell L. Mundhenk created the following documents to obtain drugs for his wife without authorization from a prescriber:

<u>Rx #</u>	<u>Drug</u>	<u>Qty.</u>	<u>Date</u>
147619	Aciphex 20 mg	30	03/21/03
147798	ranitidine 150 mg	60	03/24/03
149156	Levoxyl .05 mg	60	04/04/03
150308	Allegra-D	60	04/14/03
150424	ranitidine 150 mg	60	04/15/03
150835	chlordiazepoxide	90	04/18/03
152046	clotrimazole/Cream 1%	45	04/30/03
152937	ranitidine 150 mg	60	05/07/03
155498	ranitidine 150 mg	60	05/30/03
156034	Levoxyl .05 mg	60	06/05/03
156417	Aciphex 20 mg	30	06/09/03
160993	Allegra-D	60	07/23/03

Such conduct violates Section 2925.23(B) of the Ohio Revised Code.

(3) Terrell L. Mundhenk did, on or about the following dates, intentionally create and/or knowingly possess a false or forged prescription, to wit: Terrell L. Mundhenk created the following documents to obtain drugs for his daughter, in order to "keep her calm and stable," without authorization from a prescriber:

<u>Rx #</u>	<u>Drug</u>	<u>Qty.</u>	<u>Date</u>
144286	omeprazole 20 mg	30	01/09/03
148655	omeprazole 20 mg	30	03/31/03
150303	fluoxetine 20 mg	30	04/14/03
150304	clonazepam 1 mg	60	04/14/03
150306	hydrocodone/APAP 5/500	40	04/14/03
153135	clonazepam 1 mg	60	05/09/03
153136	hydrocodone/APAP 5/500	40	05/09/03
155905	hydrocodone/APAP 5/500	40	06/04/03
156429	clonazepam 1 mg	60	06/09/03
157479	fluoxetine 20 mg	30	06/19/03
159212	hydrocodone/APAP 5/500	40	07/07/03
159213	mirtazapine 15 mg	30	07/07/03

Such conduct violates Section 2925.23(B) of the Ohio Revised Code.

(4) Terrell L. Mundhenk did, on or about the following dates, intentionally create and/or knowingly possess a false or forged prescription, to wit: Terrell L. Mundhenk created the following documents to obtain drugs for himself without authorization from a prescriber:

<u>Rx #</u>	<u>Drug</u>	<u>Qty.</u>	<u>Date</u>
145453	Paxil 20 mg	30	02/02/03
155499	omeprazole 20 mg	30	05/30/03
153289	Glucotrol XL 5 mg	30	03/04/02
153291	Paxil 20 mg	30	04/11/02
152617	Actos 15 mg	30	06/17/02
157882	Actos 15 mg	30	07/19/02
158231	Paxil 20 mg	60	07/21/02
158232	Glucotrol XL 5mg	30	07/21/02
164240	Paxil 20 mg	30	08/26/02
164242	Actos 15 mg	30	08/26/02
170288	Glucotrol XL 5 mg	30	09/30/02
170289	Paxil 20 mg	30	09/30/02
170290	Actos 15 mg	30	09/30/02
172395	Nexium 40 mg	7	10/10/02
175781	Paxil 20 mg	30	10/31/02
175782	Glucotrol XL 5 mg	30	10/31/02
175783	Actos 15 mg	30	10/31/02
179535	Nexium 40 mg	30	11/19/02
180875	Paxil 20 mg	30	11/26/02
180876	Actos 15 mg	30	11/26/02
180877	Glucotrol XL 5 mg	30	11/26/02
186862	Actos 15 mg	30	01/01/03
186863	Paxil 20 Mg	30	01/01/03
186864	Glucotrol XL 5mg	30	01/01/03

Such conduct violates Section 2925.23(B) of the Ohio Revised Code.

(5) Terrell L. Mundhenk did, on or about the following dates, by deception, procure the dispensing of a dangerous drug, to wit: by creating false or forged prescriptions to disguise the illegitimacy of his actions, Terrell L. Mundhenk procured the following dispensings of dangerous drugs:

<u>Rx #</u>	<u>Drug</u>	<u>Qty.</u>	<u>Date</u>
147619	Aciphex 20 mg	30	03/21/03
147798	ranitidine 150 mg	60	03/24/03
149156	Levoxyl .05 mg	60	04/04/03
150308	Allegra-D	60	04/14/03
150424	ranitidine 150 mg	60	04/15/03
150835	chlordiazepoxide	90	04/18/03
152046	clotrimazole/Cream 1%	45	04/30/03
152937	ranitidine 150 mg	60	05/07/03
155498	ranitidine 150 mg	60	05/30/03
156034	Levoxyl .05 mg	60	06/05/03
156417	Aciphex 20 mg	30	06/09/03
160993	Allegra-D	60	07/23/03
144286	omeprazole 20 mg	30	01/09/03
148655	omeprazole 20 mg	30	03/31/03
150303	fluoxetine 20 mg	30	04/14/03
150304	clonazepam 1 mg	60	04/14/03
150306	hydrocodone/APAP 5/500	40	04/14/03
153135	clonazepam 1 mg	60	05/09/03
153136	hydrocodone/APAP 5/500	40	05/09/03
155905	hydrocodone/APAP 5/500	40	06/04/03
156429	clonazepam 1 mg	60	06/09/03
157479	fluoxetine 20 mg	30	06/19/03
159212	hydrocodone/APAP 5/500	40	07/07/03
159213	mirtazapine 15 mg	30	07/07/03
145453	Paxil 20 mg	30	02/02/03
155499	omeprazole 20 mg	30	05/30/03
153289	Glucotrol XL 5 mg	30	03/04/02
153291	Paxil 20 mg	30	04/11/02
152617	Actos 15 mg	30	06/17/02
157882	Actos 15 mg	30	07/19/02
158231	Paxil 20 mg	60	07/21/02
158232	Glucotrol XL 5mg	30	07/21/02
164240	Paxil 20 mg	30	08/26/02
164242	Actos 15 mg	30	08/26/02

<u>Rx #</u>	<u>Drug</u>	<u>Qty.</u>	<u>Date</u>
170288	Glucotrol XL 5 mg	30	09/30/02
170289	Paxil 20 mg	30	09/30/02
170290	Actos 15 mg	30	09/30/02
172395	Nexium 40 mg	7	10/10/02
175781	Paxil 20 mg	30	10/31/02
175782	Glucotrol XL 5 mg	30	10/31/02
175783	Actos 15 mg	30	10/31/02
179535	Nexium 40 mg	30	11/19/02
180875	Paxil 20 mg	30	11/26/02
180876	Actos 15 mg	30	11/26/02
180877	Glucotrol XL 5 mg	30	11/26/02
186862	Actos 15 mg	30	01/01/03
186863	Paxil 20 Mg	30	01/01/03
186864	Glucotrol XL 5mg	30	01/01/03

Such conduct violates Section 2925.22 of the Ohio Revised Code.

(6) In accordance with Section 2929.24 of the Ohio Revised Code, the office of the Prosecuting Attorney of Montgomery County, Ohio, submitted to this Board information which indicates that on February 4, 2004, Terrell L. Mundhenk was found by a court to be eligible for Intervention in Lieu of Conviction, State of Ohio vs. Terrell L. Mundhenk, Case No. 2003 CR 03614, Montgomery County Common Pleas Court.

#### CONCLUSIONS OF LAW

(1) The State Board of Pharmacy concludes that paragraphs (2) through (5) of the Findings of Fact constitute being guilty of gross immorality as provided in Division (A)(1) of Section 4729.16 of the Ohio Revised Code.

(2) The State Board of Pharmacy concludes that paragraphs (2) through (5) of the Findings of Fact constitute being guilty of dishonesty and unprofessional conduct in the practice of pharmacy as provided in Division (A)(2) of Section 4729.16 of the Ohio Revised Code.

(3) The State Board of Pharmacy concludes that paragraphs (2) through (6) of the Findings of Fact constitutes being guilty of willfully violating, conspiring to violate, attempting to violate, or aiding and abetting the violation of provisions of Chapter 2925. of the Revised Code as provided in Division (A)(5) of Section 4729.16 of the Ohio Revised Code.

DECISION OF THE BOARD

Pursuant to Section 3719.121 of the Ohio Revised Code, the State Board of Pharmacy hereby removes the Summary Suspension Order issued to Terrell L. Mundhenk on February 18, 2004.

Pursuant to Section 4729.16 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy adjudicates the matter of Terrell L. Mundhenk as follows:

(A) On the basis of the Findings of Fact and the Conclusions of Law set forth above, the State Board of Pharmacy hereby suspends for one year the pharmacist identification card, No. 03-3-08732, held by Terrell L. Mundhenk effective as of the date of the mailing of this Order. Further, the Board suspends the suspension and places his identification card on probation for three years, with the following conditions:

(1) Terrell L. Mundhenk may not dispense prescriptions for himself or for any member of his family.

(2) The State Board of Pharmacy hereby declares that Terrell L. Mundhenk's pharmacist identification card is not in good standing and thereby denies the privilege of being a preceptor and training pharmacy interns pursuant to paragraph (D)(1) of Rule 4729-3-01 of the Ohio Administrative Code.

(3) Terrell L. Mundhenk may not serve as a responsible pharmacist.

(4) Terrell L. Mundhenk must not violate the drug laws of Ohio, any other state, or the federal government.

(5) Terrell L. Mundhenk must abide by the rules of the State Board of Pharmacy.

(6) Terrell L. Mundhenk must comply with the terms of this Order.

(7) Terrell L. Mundhenk's license is deemed not in good standing until successful completion of the probationary period.

(8) Any violation of probation may result in a Board hearing to consider alternative or additional sanctions under Section 4729.16 of the Ohio Revised Code.

(B) On the basis of the Findings of Fact and Conclusions of Law set forth above, the State Board of Pharmacy hereby imposes on Terrell L. Mundhenk a monetary penalty of five thousand dollars (\$5,000.00) due and owing within thirty days of the issuance of this Order. The monetary penalty should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 South High Street, Room 1702, Columbus, Ohio 43215-6126.

Terrell L. Mundhenk is hereby advised that the Board may at any time revoke probation for cause, modify the conditions of probation, and reduce or extend the period of probation. At any time during this period of probation, the Board may revoke probation for a violation occurring during the probation period.

THIS ORDER WAS APPROVED BY A VOTE OF THE STATE BOARD OF PHARMACY.

MOTION CARRIED.

SO ORDERED.

The motion was seconded by Mr. Lipsyc and approved by the Board (Aye-7/Nay-0/Abstain-1[Turner]).

9:15 a.m.

The Board was joined by Assistant Attorney General Sally Ann Steuk for the purpose of conducting an adjudication hearing in accordance with Ohio Revised Code Chapters 119. and 4729. in the matters of Christopher Kiel, R.Ph., Sagamore Hills; Teregen Labs, T.D., Willoughby; and Teregen Labs, W.D., Willoughby.

11:15 a.m.

The hearing was recessed for lunch.

12:30 p.m.

The hearing resumed.

1:30 p.m.

**R-2004-191**

While the hearing continued, the following candidates for licensure by reciprocity participated in a discussion of pharmacy laws and rules with Mr. McMillen in Room South-A, 31st Floor, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio, and were then presented with their pharmacist identification cards.

LINO DIMATTEO	03-1-26154	NEW JERSEY
CLAYTON DAVID EDWARDS	03-1-26199	PENNSYLVANIA
KARISSA YOONSOOK KIM	03-1-26173	NEVADA
JOHN PATRICK MAHONEY	03-1-26108	ARIZONA
JAMES JOSEPH McDONALD	03-1-26165	TEXAS
ANDREA LEIGH RAFTERY	03-1-26141	MISSOURI
RODD A. REINHART	03-1-26076	OREGON
THOMAS J. VIGNA	03-1-26194	PENNSYLVANIA
REBECCA JEAN WRIGHT	03-1-26171	MISSOURI

8:27 p.m.

The hearing ended and the record was closed. The Board took a brief recess.

8:37 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 Revised Code. The motion was seconded by Mrs. Adelman and a roll call vote was conducted by President Giacalone as follows: Adelman-Yes, Braylock-Yes, Eastman-Yes, Gregg-Yes, Kost-Yes, Lipsyc-Yes, Teater-Yes, and Turner-Yes.

9:50 p.m.

**R-2004-192**

The Executive Session ended. Mr. Turner moved that the Board adopt the following Order in the matter of Teregen Labs, W.D.:

**ORDER OF THE STATE BOARD OF PHARMACY**

(Docket No. D-031110-033)

In The Matter Of:

**TEREGEN LABS**

c/o George Fiderio, President  
38320 Western Parkway  
Willoughby, Ohio 44094  
(W.D. No. 01-0361600)

**INTRODUCTION**

THE MATTER OF TEREGEN LABS CAME FOR HEARING ON MAY 4, 2004, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: ROBERT P. GIACALONE, R.Ph. (presiding); DIANE C. ADELMAN, R.Ph.; GREGORY BRAYLOCK, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; ELIZABETH I. GREGG, R.Ph.; LAWRENCE J. KOST, R.Ph.; NATHAN S. LIPSYC, R.Ph.; DOROTHY S. TEATER, PUBLIC MEMBER; AND JAMES E. TURNER, R.Ph.

TEREGEN LABS WAS REPRESENTED BY JOSEPH W. DIEMERT, JR. AND DIANE A. CALTA AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCEState's Witnesses

1. Joann Predina, R.Ph., Ohio State Board of Pharmacy
2. Frederick Lochner, U.S. Food and Drug Administration (FDA)

Respondent's Witnesses

1. Christopher Kiel, R.Ph.

State's Exhibits

- 1W. Copy of Notice of Opportunity For Hearing letter [11-10-03]
  - 1A-1W-E. Procedurals
  - 1W-F. Copy of Amendment Notice [03-03-04]
  - 1G-1W-K. Procedurals
2. Copy of Ohio State Board of Pharmacy Compliance Bulletin 93-002 [09-15-93]
  - 2A. Copy of letter from Joseph Diemert, Jr. to Debra Grille [11-29-00]
  - 2B. Copy of letter from Joseph W. Diemert, Jr. to Timothy Benedict [12-08-00]
  - 2C. Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 02-1235150, with attachments [12-14-00]
  - 2D. Copy of letter from Charles S. Price to Diane A. Calta [01-02-01]
3. Facsimile copy of Rx #201315, Rx #201316, Rx #201317, and Rx #201318 [01-08-01]
  - 3A. Copy of letter from Joseph W. Diemert, Jr. to George Fiderio [01-12-01]
  - 3B. Copy of Purchase Order from Nevada Dermatology [12-04-01]
4. Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 02-1235150 [08-19-03]
- 4A. Copy of Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 01-0361600 [08-19-03]
5. Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 02-1235150 [08-21-03]
- 5A. Pink Sheet Response with enclosures from Diane Calta and Christopher Kiel, R.Ph. to William T. Winsley [09-09-03]
6. Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 01-0361600 [08-21-03]
- 6A. Pink Sheet Response with enclosures from Diane Calta and George V. Fiderio to William T. Winsley [09-09-03]
7. Vial of Dexamethasone Acetate Suspension 8 mg/mL [not dated]
- 7A. New Hampshire Board of Pharmacy Possessed Property Report with invoice attachments [09-23-03]
- 8-8K. One sheet of Teregen Vial Labels [03-10-04] and Teregen Package Inserts for Betamethasone, Brompheniramine, Dexamethasone acetate, Dexamethasone Na phosphate, Estradiol cypionate, Estradiol valerate, Estrone, Methylprednisolone acetate, Pyridoxine HCl, Triamcinolone acetate, and Triamcinolone diacetate [Feb 2001 to Feb 2003]
9. Building layout for Teregen (WD & TD) and Drug World Compounding Pharmacy [not dated]
  - 9A. Clean room layout of Teregen Labs [not dated]
  - 9B. Ten photographs of Clean room [not dated]
10. Report of Vials Produced Per Month at Teregen Labs [08-19-03]
  - 10A. Copy of Inventory On Hand at Teregen Labs [08-20-03]
  - 10B. Sales History of Teregen-Produced Sterile Product [12-00 to 09-03]
  - 10C. Teregen Labs In-Stock Warehouse Inventory [10-01-03]
11. Copy of letter with enclosures from Diane A. Calta to Fred L. Dailey [09-03-03]
  - 11A. Copy of letter from William A. Hopper, Jr. to Diane A. Calta [09-19-03]
  - 11B. Copy of letter with attachments from Christopher Kiel, R.Ph. to Mr. Hopper [09-24-03]
  - 11C. Copy of letter from Steven Silverman to William T. Winsley, M.S., R.Ph. [11-13-03]
  - 11C-1. Copy of letter from Carol A. Heppe to Steven C. LaTourette, Congressman [03-17-04]
  - 11D. Copy of letter from Fred L. Dailey to Diane A. Calta [11-21-03]



12. *Ohio State Board of Pharmacy News*, November 2003
13. Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 02-1235150 [03-11-04]
- 13A. Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 01-0361600 [03-11-04]
- 13B. Copy of Productivity Record [03-10-04]
- 13C. Teregen Labs Production Records [10-27-03 to 03-03-04]
14. Teregen Labs 2001 Physician Orders, Total Quantity Purchased [03-25-04]
- 14A. Copy of Betamethasone Distribution Records [11-28-01]
- 14B. Copy of Brompheniramine Distribution Records [02-21-01]
- 14C. Copy of Dexamethasone Acetate Distribution Records [10-17-01]
- 14D. Copy of Dexamethasone Na Phosphate Distribution Records [09-26-01]
- 14E. Copy of Estradiol Cypionate Distribution Records [03-23-01]
- 14F. Copy of Estradiol Valerate Distribution Records [07-25-01]
- 14G. Copy of Estrone Distribution Records [02-21-01]
- 14H. Copy of Methylprednisolone Acetate Distribution Records [12-04-01]
- 14I. Copy of Pyridoxine HCl Distribution Records [12-03-01]
- 14J. Copy of Triamcinolone Acetonide Distribution Records [02-05-01]
- 14K. Copy of Triamcinolone Diacetate Distribution Records [11-27-01]
- 14L. Dexamethasone Acetate Batch Records [10-10-01]
15. Teregen Labs 2002 Physician Orders, Total Quantity Purchased [03-25-04]
- 15A. Copy of Betamethasone Distribution Records [09-12-02]
- 15B. Copy of Brompheniramine Distribution Records [05-13-02]
- 15C. Copy of Dexamethasone Acetate Distribution Records [07-01-02]
- 15D. Copy of Dexamethasone Na Phosphate Distribution Records [09-27-02]
- 15E. Copy of Estradiol Cypionate Distribution Records [03-06-02]
- 15F. Copy of Estradiol Valerate Distribution Records [12-13-02]
- 15G. Copy of Estrone Distribution Records [09-20-02]
- 15H. Copy of Methylprednisolone Acetate Distribution Records [07-30-02]
- 15I. Copy of Pyridoxine HCl Distribution Records [09-25-02]
- 15J. Copy of Triamcinolone Acetonide Distribution Records [04-09-02]
- 15K. Copy of Triamcinolone Diacetate Distribution Records [09-26-02]
- 15L. Dexamethasone Acetate Batch Records [06-18-02]
16. Teregen Labs 2003 Physician Orders, Total Quantity Purchased [03-25-04]
- 16A. Copy of Betamethasone Distribution Records [09-10-03]
- 16B. Copy of Brompheniramine Distribution Records [06-09-03]
- 16C. Copy of Dexamethasone Acetate Distribution Records [05-15-03]
- 16D. Copy of Dexamethasone Na Phosphate Distribution Records [04-22-03]
- 16E. Copy of Estradiol Cypionate Distribution Records [06-24-03]
- 16F. Copy of Estradiol Valerate Distribution Record [08-20-03]
- 16G. Copy of Estrone Distribution Records [01-14-03]
- 16H. Copy of Methylprednisolone Acetate Distribution Records [04-28-03]
- 16I. Copy of Pyridoxine HCl Distribution Records [06-26-03]
- 16J. Copy of Triamcinolone Acetonide Distribution Records [08-28-03]
- 16K. Copy of Triamcinolone Diacetate Distribution Records [06-20-03]
- 16L. Dexamethasone Acetate Batch Records [04-25-03]
17. Rx #818899 [02-10-03]
- 17A. Teregen Labs Rx #818899 Label [02-10-03]
- 17B. Copy of Tax Insurance Summary for Drug World Pharmacy [01-01-01 to 11-05-03]
18. Rx #819878 [06-03-03]
19. Rx #817388 [07-03-02]
20. Letter with enclosures from Regina C. Hamlin, M.D. to Joann D. Predina, MBA, R.Ph. [11-02-03]
21. Copy of Ohio Revised Code (ORC) Section 3715.65 (Application for new drugs) [07-22-98]
- 21A. Copy of Division (A)(10) of ORC Section 3715.01 (Definitions) defining "New drug" [not dated]
- 21B. Copy of Division (C) of ORC Section 4729.01 (Definitions) defining "Compounding" [not dated]
- 21C. Copy of Division (H) of ORC Section 4729.01 (Definitions) defining "Prescription" [not dated]

- 21D. Copy of paragraph (B) of Ohio Administrative Code (OAC) Rule 4729-5-01 (Definitions) defining "Dispense" [not dated]
- 21E. Copy of OAC Rule 4729-5-30 (Manner of issuance of a prescription) [not dated]
- 21F. Copy of OAC Rule 4729-9-21 (Drugs compounded in a pharmacy) [03-01-99]
- 22. FDA Inspectional Observations (Form FDA 483) for Gentere Inc. [03-10-04 to 03-19-04]

#### Respondent's Exhibits

- A. Pink Sheet Response with enclosures from Diane Calta and George V. Fiderio to William T. Winsley [09-09-03]
- B. Notice of Opportunity for Hearing letter to Teregen Labs, License No. 01-0361600 [11-10-03]
- C. Copy of Amendment Notice letter To Teregen Labs, License No. 01-0361600 [03-03-04]
- D. Copy of Pink Sheet Response with enclosures from Diane Calta and Christopher Kiel, R.Ph. to William T. Winsley [09-09-03]
- E. Notice of Opportunity for Hearing letter to Teregen Labs, License No. 02-1235150 [11-10-03]
- F. Amendment Notice letter to Teregen Labs, License No. 02-1235150 [03-03-04]
- G. Copy of Pink Sheet Response from Christopher Kiel, R.Ph. to Ohio State Board of Pharmacy [08-25-03]
- H. Copy of Notice of Opportunity for Hearing letter to Christopher Kiel, R.Ph. [11-10-03]
- I. Copy of Amendment Notice letter to Christopher Kiel, R.Ph. [03-03-04]
- J. Copy of letter with enclosures from Diane A. Calta to William A. Hopper, Jr. [09-30-03]
- K. Letter with enclosure from William A. Hopper, Jr. to Diane A. Calta, Esq. [11-21-03]
- L. Copy of letter from Steven Silverman to William T. Winsley, M.S., R.Ph. [11-13-03]
- M. Copy of e-mail letter from Bill Winsley to Betty Hiner [10-23-03]
- N. Copy of Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 02-1235150 [12-14-00]
- O. Copy of letter from Joseph W. Diemert, Jr. to Debra Grille [11-29-00]; copy of Fax Cover Sheet from Diane Calta to Tim Benedict [11-30-00]
- P. Copy of letter from Joseph W. Diemert, Jr. to Timothy Benedict [12-08-00]
- Q. Copy of letter from Charles S. Price to Diane A. Calta [12-28-00]
- R. Copy of letter with enclosure from Joseph W. Diemert, Jr. to George Fiderio [01-12-01]
- S. Copy by Westlaw of Ohio Revised Code (ORC) Section 4729.01 (Definitions) [06-26-03]
- T. Copy by Westlaw of ORC Section 4729.29 (Exceptions to certain provisions) [03-09-99]
- U. Copy by Westlaw of Ohio Administrative Code (OAC) Rule 4729-5-30 (Manner of issuance of a prescription) [02-01-03]
- V. Copy by Westlaw of OAC Rule 4729-5-01 (Definitions) [01-01-04]
- W. Copy by Westlaw of OAC Rule 4729-9-12 (Verification of license as a distributor of dangerous drugs or exempt status of a prescriber) [03-01-99]
- X. Copy by Westlaw of ORC Sections 3715.01 (Definitions) [11-21-01] and 3715.65 (Application for new drugs) [07-22-98]
- Y. Copy of Guidance for FDA Staff and Industry Compliance Policy Guides Manual, Section 460.200 (Pharmacy Compounding) [05-29-02]
- Z. Six photographs of Teregen Laboratory Facility [not dated]
- AA. Copy by Westlaw of 2003 Ohio Senate Bill 196 (SN) As Introduced [02-12-04]; Bill Analysis by the Ohio Legislative Service Commission of S.B. 196 As Introduced [02-26-04]
- BB. Copy of pages 2498 through 2501 of the United States Pharmacopeial (USP) for Section 1075 (Good Compounding Practices) [not dated]
- CC. Copy of letter from David L. Rosen, B.S. Pharm, J.D. to Carol A. Heppe [04-27-04]

#### FINDINGS OF FACT

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

- (1) Records of the State Board of Pharmacy indicate that Teregen Labs, 38320 Western Parkway, Willoughby, Ohio, is registered as a Wholesale Distributor of Dangerous Drugs, No. 01-0361600, and George Fiderio is the president and contact person pursuant to Section 4729.53(A)(5) of the Ohio Revised Code within the meaning of Section 4729.56 of the Ohio Revised Code.

(2) Teregen Labs did, on or about the following dates in 2001, sell a new drug without an application with respect to the drug having become effective under Section 505 of the Federal Food, Drug, and Cosmetic Act, to wit: after having received verbal and written warning against doing so, the facility sold dangerous drugs, the following being representative examples, without obtaining patient-specific orders for the products:

<u>Invoice#</u>	<u>Date</u>	<u>Qty</u>	<u>Drug</u>
30486	11/28/01	25 vials	betamethasone Na phos & acetate 6 mg/ml inj.-5 ml
26495	02/21/01	12 vials	brompheniramine maleate 10 mg/ml inj.-10 ml
29925	10/17/01	30 vials	dexamethasone acetate 8 mg/ml inj.-5 ml
29631	09/26/01	12 vials	dexamethasone Na phos. 4 mg/ml inj.-5 ml
26810	03/23/01	4 vials	estradiol cypionate 5 mg/ml inj.-10 ml
28680	07/25/01	2 vials	estradiol valerate 40 mg/ml inj.-10 ml
26490	02/21/01	10 vials	estrone 5 mg/ml inj.-10 ml
30547	12/04/01	15 vials	methylprednisolone acetate 40 mg/ml inj.-10 ml
30529	12/03/01	200 vials	pyridoxine HCl 100 mg/ml inj.- 30 ml
26333	02/05/01	30 vials	triamcinolone acetonide 40 mg/ml inj.- 5 ml
30466	11/27/01	2 vials	triamcinolone diacetate 40 mg/ml inj.-5 ml

Such conduct violates Section 3715.65 of the Ohio Revised Code.

(3) Teregen Labs did, on or about the following dates in 2002, sell a new drug without an application with respect to the drug having become effective under Section 505 of the Federal Food, Drug, and Cosmetic Act, to wit: after having received verbal and written warning against doing so, the facility sold dangerous drugs, the following being representative examples, without obtaining patient-specific orders for the products:

<u>Invoice#</u>	<u>Date</u>	<u>Qty</u>	<u>Drug</u>
34259	09/12/02	4 vials	betamethasone Na phos. & acetate 6 mg/ml inj.-5 ml
32613	05/13/02	2 vials	brompheniramine maleate 10 mg/ml inj.-10 ml
33265	07/01/02	300 vials	dexamethasone acetate 8 mg/ml inj.-5 ml
34467	09/27/02	20 vials	dexamethasone Na phos. 4 mg/ml inj.-5 ml
31704	03/06/02	2 vials	estradiol cypionate 5 mg/ml inj.-10 ml
35410	12/13/02	4 vials	estradiol valerate 40 mg/ml inj.-10 ml
34380	09/20/02	5 vials	estrone 5 mg/ml inj.- 10 ml
33660	07/30/02	12 vials	methylprednisolone acetate 40 mg/ml inj.-10 ml
34433	09/25/02	6 vials	pyridoxine HCl 100 mg/ml inj.-30 ml
32162	04/09/02	8 vials	triamcinolone acetonide 40 mg/ml inj.-5 ml
34455	09/26/02	8 vials	triamcinolone diacetate 40 mg/ml inj.-5 ml

Such conduct violates Section 3715.65 of the Ohio Revised Code.

(4) Teregen Labs did, on or about the following dates in 2003, sell a new drug without an application with respect to the drug having become effective under Section 505 of the Federal Food, Drug, and Cosmetic Act, to wit: after having received verbal and written warning against doing so, the facility sold dangerous drugs, the following being representative examples, without obtaining patient-specific orders for the products:

<u>Invoice#</u>	<u>Date</u>	<u>Qty</u>	<u>Drug</u>
38531	09/10/03	40 vials	betamethasone Na phos. & acetate 6 mg/ml inj.-5 ml
37430	06/09/03	10 vials	brompheniramine maleate 10 mg/ml inj.- 10 ml
37145	05/15/03	12 vials	dexamethasone acetate 8 mg/ml inj.-5 ml
36851	04/22/03	12 vials	dexamethasone Na phos. 4 mg/ml inj.-5 ml
37617	06/24/03	3 vials	estradiol cypionate 5 mg/ml inj.-10 ml
38287	08/20/03	4 vials	estradiol valerate 40 mg/ml inj.-10 ml
35702	01/14/03	10 vials	estrone 5 mg/ml inj.-10 ml
36929	04/28/03	15 vials	methylprednisolone acetate 40 mg/ml inj.-10 ml
37639	06/26/03	600 vials	pyridoxine HCl 100 mg/ml inj.-30 ml
38379	08/28/03	30 vials	triamcinolone acetonide 40 mg/ml inj.-5 ml
37569	06/20/03	4 vials	triamcinolone diacetate 40 mg/ml inj.-5 ml

Such conduct violates Section 3715.65 of the Ohio Revised Code.

CONCLUSION OF LAW

The State Board of Pharmacy concludes that paragraphs (2) through (4) of the Findings of Fact constitutes being guilty of violating any federal, state, or local drug law or any provision of Chapter 3715. of the Revised Code as provided in Division (A)(2) of Section 4729.56 of the Ohio Revised Code.

DECISION OF THE BOARD

Pursuant to Section 4729.56 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy adjudicates the matter of Teregen Labs, Wholesale Distributor Registration No. 01-0361600, as follows:

(A) On the basis of the Findings of Fact and Conclusions of Law set forth above, the State Board of Pharmacy hereby imposes a monetary penalty of six thousand dollars (\$6,000.00) on Teregen Labs, Wholesale Distributor Registration No. 01-0361600, and payment of the monetary penalty is due and owing within thirty days of the mailing of this Order. The remittance should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 South High Street, Room 1702, Columbus, Ohio 43215-6126.

(B) Teregen Labs, Wholesale Distributor Registration No. 01-0361600, must cease distributing drugs that are not approved by the FDA effective as of the date of the mailing of this Order.

THIS ORDER WAS APPROVED BY A VOTE OF THE STATE BOARD OF PHARMACY.

MOTION CARRIED.

SO ORDERED.

The motion was seconded by Mr. Braylock and approved by the Board (Aye-8/Nay-0).

**R-2004-193** Mr. Braylock then moved that the Board adopt the following Order in the matter of Teregen Labs, T.D.:

ORDER OF THE STATE BOARD OF PHARMACY

(Docket No. D-031110-038)

In The Matter Of:

**TEREGEN LABS**

c/o Christopher Kiel, R.Ph.  
38320 Western Parkway  
Willoughby, Ohio 44094  
(T.D. No. 02-1235150)

INTRODUCTION

THE MATTER OF TEREGEN LABS CAME FOR HEARING ON MAY 4, 2004, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: ROBERT P. GIACALONE, R.Ph. (presiding); DIANE C. ADELMAN, R.Ph.; GREGORY BRAYLOCK, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; ELIZABETH I. GREGG, R.Ph.; LAWRENCE J. KOST, R.Ph.; NATHAN S. LIPSYC, R.Ph.; DOROTHY S. TEATER, PUBLIC MEMBER; AND JAMES E. TURNER, R.Ph.

TEREGEN LABS WAS REPRESENTED BY JOSEPH W. DIEMERT, JR. AND DIANE A. CALTA AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCEState's Witnesses

1. Joann Predina, R.Ph., Ohio State Board of Pharmacy
2. Frederick Lochner, U.S. Food and Drug Administration (FDA)

Respondent's Witnesses

1. Christopher Kiel, R.Ph.

State's Exhibits

- 1T. Copy of Notice of Opportunity For Hearing letter [11-10-03]
  - 1A-1T-E. Procedurals
  - 1T-F. Copy of Amendment Notice [03-03-04]
  - 1G-1T-K. Procedurals
2. Copy of Ohio State Board of Pharmacy Compliance Bulletin 93-002 [09-15-93]
  - 2A. Copy of letter from Joseph Diemert, Jr. to Debra Grille [11-29-00]
  - 2B. Copy of letter from Joseph W. Diemert, Jr. to Timothy Benedict [12-08-00]
  - 2C. Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 02-1235150, with attachments [12-14-00]
  - 2D. Copy of letter from Charles S. Price to Diane A. Calta [01-02-01]
3. Facsimile copy of Rx #201315, Rx #201316, Rx #201317, and Rx #201318 [01-08-01]
  - 3A. Copy of letter from Joseph W. Diemert, Jr. to George Fiderio [01-12-01]
  - 3B. Copy of Purchase Order from Nevada Dermatology [12-04-01]
4. Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 02-1235150 [08-19-03]
- 4A. Copy of Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 01-0361600 [08-19-03]
5. Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 02-1235150 [08-21-03]
- 5A. Pink Sheet Response with enclosures from Diane Calta and Christopher Kiel, R.Ph. to William T. Winsley [09-09-03]
6. Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 01-0361600 [08-21-03]
- 6A. Pink Sheet Response with enclosures from Diane Calta and George V. Fiderio to William T. Winsley [09-09-03]
7. Vial of Dexamethasone Acetate Suspension 8 mg/mL [not dated]
- 7A. New Hampshire Board of Pharmacy Possessed Property Report with invoice attachments [09-23-03]
- 8-8K. One sheet of Teregen Vial Labels [03-10-04] and Teregen Package Inserts for Betamethasone, Brompheniramine, Dexamethasone acetate, Dexamethasone Na phosphate, Estradiol cypionate, Estradiol valerate, Estrone, Methylprednisolone acetate, Pyridoxine HCl, Triamcinolone acetate, and Triamcinolone diacetate [Feb 2001 to Feb 2003]
9. Building layout for Teregen (WD & TD) and Drug World Compounding Pharmacy [not dated]
  - 9A. Clean room layout of Teregen Labs [not dated]
  - 9B. Ten photographs of Clean room [not dated]
10. Report of Vials Produced Per Month at Teregen Labs [08-19-03]
  - 10A. Copy of Inventory On Hand at Teregen Labs [08-20-03]
  - 10B. Sales History of Teregen-Produced Sterile Product [12-00 to 09-03]
  - 10C. Teregen Labs In-Stock Warehouse Inventory [10-01-03]
11. Copy of letter with enclosures from Diane A. Calta to Fred L. Dailey [09-03-03]
  - 11A. Copy of letter from William A. Hopper, Jr. to Diane A. Calta [09-19-03]
  - 11B. Copy of letter with attachments from Christopher Kiel, R.Ph. to Mr. Hopper [09-24-03]
  - 11C. Copy of letter from Steven Silverman to William T. Winsley, M.S., R.Ph. [11-13-03]
  - 11C-1. Copy of letter from Carol A. Heppe to Steven C. LaTourette, Congressman [03-17-04]
  - 11D. Copy of letter from Fred L. Dailey to Diane A. Calta [11-21-03]

12. *Ohio State Board of Pharmacy News*, November 2003
13. Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 02-1235150 [03-11-04]
- 13A. Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 01-0361600 [03-11-04]
- 13B. Copy of Productivity Record [03-10-04]
- 13C. Teregen Labs Production Records [10-27-03 to 03-03-04]
14. Teregen Labs 2001 Physician Orders, Total Quantity Purchased [03-25-04]
- 14A. Copy of Betamethasone Distribution Records [11-28-01]
- 14B. Copy of Brompheniramine Distribution Records [02-21-01]
- 14C. Copy of Dexamethasone Acetate Distribution Records [10-17-01]
- 14D. Copy of Dexamethasone Na Phosphate Distribution Records [09-26-01]
- 14E. Copy of Estradiol Cypionate Distribution Records [03-23-01]
- 14F. Copy of Estradiol Valerate Distribution Records [07-25-01]
- 14G. Copy of Estrone Distribution Records [02-21-01]
- 14H. Copy of Methylprednisolone Acetate Distribution Records [12-04-01]
- 14I. Copy of Pyridoxine HCl Distribution Records [12-03-01]
- 14J. Copy of Triamcinolone Acetonide Distribution Records [02-05-01]
- 14K. Copy of Triamcinolone Diacetate Distribution Records [11-27-01]
- 14L. Dexamethasone Acetate Batch Records [10-10-01]
15. Teregen Labs 2002 Physician Orders, Total Quantity Purchased [03-25-04]
- 15A. Copy of Betamethasone Distribution Records [09-12-02]
- 15B. Copy of Brompheniramine Distribution Records [05-13-02]
- 15C. Copy of Dexamethasone Acetate Distribution Records [07-01-02]
- 15D. Copy of Dexamethasone Na Phosphate Distribution Records [09-27-02]
- 15E. Copy of Estradiol Cypionate Distribution Records [03-06-02]
- 15F. Copy of Estradiol Valerate Distribution Records [12-13-02]
- 15G. Copy of Estrone Distribution Records [09-20-02]
- 15H. Copy of Methylprednisolone Acetate Distribution Records [07-30-02]
- 15I. Copy of Pyridoxine HCl Distribution Records [09-25-02]
- 15J. Copy of Triamcinolone Acetonide Distribution Records [04-09-02]
- 15K. Copy of Triamcinolone Diacetate Distribution Records [09-26-02]
- 15L. Dexamethasone Acetate Batch Records [06-18-02]
16. Teregen Labs 2003 Physician Orders, Total Quantity Purchased [03-25-04]
- 16A. Copy of Betamethasone Distribution Records [09-10-03]
- 16B. Copy of Brompheniramine Distribution Records [06-09-03]
- 16C. Copy of Dexamethasone Acetate Distribution Records [05-15-03]
- 16D. Copy of Dexamethasone Na Phosphate Distribution Records [04-22-03]
- 16E. Copy of Estradiol Cypionate Distribution Records [06-24-03]
- 16F. Copy of Estradiol Valerate Distribution Record [08-20-03]
- 16G. Copy of Estrone Distribution Records [01-14-03]
- 16H. Copy of Methylprednisolone Acetate Distribution Records [04-28-03]
- 16I. Copy of Pyridoxine HCl Distribution Records [06-26-03]
- 16J. Copy of Triamcinolone Acetonide Distribution Records [08-28-03]
- 16K. Copy of Triamcinolone Diacetate Distribution Records [06-20-03]
- 16L. Dexamethasone Acetate Batch Records [04-25-03]
17. Rx #818899 [02-10-03]
- 17A. Teregen Labs Rx #818899 Label [02-10-03]
- 17B. Copy of Tax Insurance Summary for Drug World Pharmacy [01-01-01 to 11-05-03]
18. Rx #819878 [06-03-03]
19. Rx #817388 [07-03-02]
20. Letter with enclosures from Regina C. Hamlin, M.D. to Joann D. Predina, MBA, R.Ph. [11-02-03]
21. Copy of Ohio Revised Code (ORC) Section 3715.65 (Application for new drugs) [07-22-98]
- 21A. Copy of Division (A)(10) of ORC Section 3715.01 (Definitions) defining "New drug" [not dated]
- 21B. Copy of Division (C) of ORC Section 4729.01 (Definitions) defining "Compounding" [not dated]
- 21C. Copy of Division (H) of ORC Section 4729.01 (Definitions) defining "Prescription" [not dated]

- 21D. Copy of paragraph (B) of Ohio Administrative Code (OAC) Rule 4729-5-01 (Definitions) defining "Dispense" [not dated]
- 21E. Copy of OAC Rule 4729-5-30 (Manner of issuance of a prescription) [not dated]
- 21F. Copy of OAC Rule 4729-9-21 (Drugs compounded in a pharmacy) [03-01-99]
- 22. FDA Inspectional Observations (Form FDA 483) for Gentere Inc. [03-10-04 to 03-19-04]

#### Respondent's Exhibits

- A. Pink Sheet Response with enclosures from Diane Calta and George V. Fiderio to William T. Winsley [09-09-03]
- B. Notice of Opportunity for Hearing letter to Teregen Labs, License No. 01-0361600 [11-10-03]
- C. Copy of Amendment Notice letter To Teregen Labs, License No. 01-0361600 [03-03-04]
- D. Copy of Pink Sheet Response with enclosures from Diane Calta and Christopher Kiel, R.Ph. to William T. Winsley [09-09-03]
- E. Notice of Opportunity for Hearing letter to Teregen Labs, License No. 02-1235150 [11-10-03]
- F. Amendment Notice letter to Teregen Labs, License No. 02-1235150 [03-03-04]
- G. Copy of Pink Sheet Response from Christopher Kiel, R.Ph. to Ohio State Board of Pharmacy [08-25-03]
- H. Copy of Notice of Opportunity for Hearing letter to Christopher Kiel, R.Ph. [11-10-03]
- I. Copy of Amendment Notice letter to Christopher Kiel, R.Ph. [03-03-04]
- J. Copy of letter with enclosures from Diane A. Calta to William A. Hopper, Jr. [09-30-03]
- K. Letter with enclosure from William A. Hopper, Jr. to Diane A. Calta, Esq. [11-21-03]
- L. Copy of letter from Steven Silverman to William T. Winsley, M.S., R.Ph. [11-13-03]
- M. Copy of e-mail letter from Bill Winsley to Betty Hiner [10-23-03]
- N. Copy of Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 02-1235150 [12-14-00]
- O. Copy of letter from Joseph W. Diemert, Jr. to Debra Grille [11-29-00]; copy of Fax Cover Sheet from Diane Calta to Tim Benedict [11-30-00]
- P. Copy of letter from Joseph W. Diemert, Jr. to Timothy Benedict [12-08-00]
- Q. Copy of letter from Charles S. Price to Diane A. Calta [12-28-00]
- R. Copy of letter with enclosure from Joseph W. Diemert, Jr. to George Fiderio [01-12-01]
- S. Copy by Westlaw of Ohio Revised Code (ORC) Section 4729.01 (Definitions) [06-26-03]
- T. Copy by Westlaw of ORC Section 4729.29 (Exceptions to certain provisions) [03-09-99]
- U. Copy by Westlaw of Ohio Administrative Code (OAC) Rule 4729-5-30 (Manner of issuance of a prescription) [02-01-03]
- V. Copy by Westlaw of OAC Rule 4729-5-01 (Definitions) [01-01-04]
- W. Copy by Westlaw of OAC Rule 4729-9-12 (Verification of license as a distributor of dangerous drugs or exempt status of a prescriber) [03-01-99]
- X. Copy by Westlaw of ORC Sections 3715.01 (Definitions) [11-21-01] and 3715.65 (Application for new drugs) [07-22-98]
- Y. Copy of Guidance for FDA Staff and Industry Compliance Policy Guides Manual, Section 460.200 (Pharmacy Compounding) [05-29-02]
- Z. Six photographs of Teregen Laboratory Facility [not dated]
- AA. Copy by Westlaw of 2003 Ohio Senate Bill 196 (SN) As Introduced [02-12-04]; Bill Analysis by the Ohio Legislative Service Commission of S.B. 196 As Introduced [02-26-04]
- BB. Copy of pages 2498 through 2501 of the United States Pharmacopeial (USP) for Section 1075 (Good Compounding Practices) [not dated]
- CC. Copy of letter from David L. Rosen, B.S. Pharm, J.D. to Carol A. Heppe [04-27-04]

#### FINDINGS OF FACT

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

- (1) Records of the State Board of Pharmacy indicate that Teregen Labs, 38320 Western Parkway, Willoughby, Ohio, is licensed as a Terminal Distributor of Dangerous Drugs, No. 02-1235150, and Christopher Kiel is the Responsible Pharmacist pursuant to Rule 4729-5-11 of the Ohio Administrative Code and Sections 4729.27 and 4729.55 of the Ohio Revised Code.

(2) Teregen Labs did, on or about the following dates in 2001, sell a new drug without an application with respect to the drug having become effective under Section 505 of the Federal Food, Drug, and Cosmetic Act, to wit: after having received verbal and written warning against doing so, the pharmacy sold dangerous drugs, the following being representative examples, without obtaining patient-specific orders for the products:

<u>Invoice#</u>	<u>Date</u>	<u>Qty</u>	<u>Drug</u>
30486	11/28/01	25 vials	betamethasone Na phos. & acetate 6 mg/ml inj.-5 ml
26495	02/21/01	12 vials	brompheniramine maleate 10 mg/ml inj.-10 ml
29925	10/17/01	30 vials	dexamethasone acetate 8 mg/ml inj.-5 ml
29631	09/26/01	12 vials	dexamethasone Na phos. 4 mg/ml inj.-5 ml
26810	03/23/01	4 vials	estradiol cypionate 5 mg/ml inj.-10 ml
28680	07/25/01	2 vials	estradiol valerate 40 mg/ml inj.-10 ml
26490	02/21/01	10 vials	estrone 5 mg/ml inj.-10 ml
30547	12/04/01	15 vials	methylprednisolone acetate 40 mg/ml inj.-10 ml
30529	12/03/01	200 vials	pyridoxine HCl 100 mg/ml inj.- 30 ml
26333	02/05/01	30 vials	triamcinolone acetonide 40 mg/ml inj.- 5 ml
30466	11/27/01	2 vials	triamcinolone diacetate 40 mg/ml inj.-5 ml

Such conduct violates Section 3715.65 of the Ohio Revised Code.

(3) Teregen Labs did, on or about the following dates in 2002, sell a new drug without an application with respect to the drug having become effective under Section 505 of the Federal Food, Drug, and Cosmetic Act, to wit: after having received verbal and written warning against doing so, the pharmacy sold dangerous drugs, the following being representative examples, without obtaining patient-specific orders for the products:

<u>Invoice#</u>	<u>Date</u>	<u>Qty</u>	<u>Drug</u>
34259	09/12/02	4 vials	betamethasone Na phos. & acetate 6 mg/ml inj.-5 ml
32613	05/13/02	2 vials	brompheniramine maleate 10 mg/ml inj.-10 ml
33265	07/01/02	300 vials	dexamethasone acetate 8 mg/ml inj.-5 ml
34467	09/27/02	20 vials	dexamethasone Na phos. 4 mg/ml inj.-5 ml
31704	03/06/02	2 vials	estradiol cypionate 5 mg/ml inj.-10 ml
35410	12/13/02	4 vials	estradiol valerate 40 mg/ml inj.-10 ml
34380	09/20/02	5 vials	estrone 5 mg/ml inj.- 10 ml
33660	07/30/02	12 vials	methylprednisolone acetate 40 mg/ml inj.-10 ml
34433	09/25/02	6 vials	pyridoxine HCl 100 mg/ml inj.-30 ml
32162	04/09/02	8 vials	triamcinolone acetonide 40 mg/ml inj.-5 ml
34455	09/26/02	8 vials	triamcinolone diacetate 40 mg/ml inj.-5 ml

Such conduct violates Section 3715.65 of the Ohio Revised Code.

(4) Teregen Labs did, on or about the following dates in 2003, sell a new drug without an application with respect to the drug having become effective under Section 505 of the Federal Food, Drug, and Cosmetic Act, to wit: after having received verbal and written warning against doing so, the pharmacy sold dangerous drugs, the following being representative examples, without obtaining patient-specific orders for the products:

<u>Invoice#</u>	<u>Date</u>	<u>Qty</u>	<u>Drug</u>
38531	09/10/03	40 vials	betamethasone Na phos. & acetate 6 mg/ml inj.-5 ml
37430	06/09/03	10 vials	brompheniramine maleate 10 mg/ml inj.- 10 ml
37145	05/15/03	12 vials	dexamethasone acetate 8 mg/ml inj.-5 ml
36851	04/22/03	12 vials	dexamethasone Na phos. 4 mg/ml inj.-5 ml
37617	06/24/03	3 vials	estradiol cypionate 5 mg/ml inj.-10 ml
38287	08/20/03	4 vials	estradiol valerate 40 mg/ml inj.-10 ml
35702	01/14/03	10 vials	estrone 5 mg/ml inj.-10 ml
36929	04/28/03	15 vials	methylprednisolone acetate 40 mg/ml inj.-10 ml
37639	06/26/03	600 vials	pyridoxine HCl 100 mg/ml inj.-30 ml
38379	08/28/03	30 vials	triamcinolone acetonide 40 mg/ml inj.-5 ml
37569	06/20/03	4 vials	triamcinolone diacetate 40 mg/ml inj.-5 ml

Such conduct violates Section 3715.65 of the Ohio Revised Code.



(5) Teregen Labs did, on or about the following dates in 2001, compound and sell prescription drugs when not pursuant to specific orders for individual patients issued by prescribers and not in limited quantities in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns, to wit: the pharmacy compounded and sold dangerous drugs, the following being representative examples:

<u>Invoice#</u>	<u>Date</u>	<u>Qty</u>	<u>Drug</u>
30486	11/28/01	25 vials	betamethasone Na phos & acetate 6 mg/ml inj.-5 ml
26495	02/21/01	12 vials	brompheniramine maleate 10 mg/ml inj.-10 ml
29925	10/17/01	30 vials	dexamethasone acetate 8 mg/ml inj.-5 ml
29631	09/26/01	12 vials	dexamethasone Na phos. 4 mg/ml inj.-5 ml
26810	03/23/01	4 vials	estradiol cypionate 5 mg/ml inj.-10 ml
28680	07/25/01	2 vials	estradiol valerate 40 mg/ml inj.-10 ml
26490	02/21/01	10 vials	estrone 5 mg/ml inj.-10 ml
30547	12/04/01	15 vials	methylprednisolone acetate 40 mg/ml inj.-10 ml
30529	12/03/01	200 vials	pyridoxine HCl 100 mg/ml inj.- 30 ml
26333	02/05/01	30 vials	triamcinolone acetonide 40 mg/ml inj.- 5 ml
30466	11/27/01	2 vials	triamcinolone diacetate 40 mg/ml inj.-5 ml

Such conduct violates Rule 4729-9-21 of the Ohio Administrative Code.

(6) Teregen Labs did, on or about the following dates in 2002, compound and sell prescription drugs when not pursuant to specific orders for individual patients issued by prescribers and not in limited quantities in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns, to wit: the pharmacy compounded and sold dangerous drugs, the following being representative examples:

<u>Invoice#</u>	<u>Date</u>	<u>Qty</u>	<u>Drug</u>
34259	09/12/02	4 vials	betamethasone Na phos. & acetate 6 mg/ml inj.-5 ml
32613	05/13/02	2 vials	brompheniramine maleate 10 mg/ml inj.-10 ml
33265	07/01/02	300 vials	dexamethasone acetate 8 mg/ml inj.-5 ml
34467	09/27/02	20 vials	dexamethasone Na phos. 4 mg/ml inj.-5 ml
31704	03/06/02	2 vials	estradiol cypionate 5 mg/ml inj.-10 ml
35410	12/13/02	4 vials	estradiol valerate 40 mg/ml inj.-10 ml
34380	09/20/02	5 vials	estrone 5 mg/ml inj.- 10 ml
33660	07/30/02	12 vials	methylprednisolone acetate 40 mg/ml inj.-10 ml
34433	09/25/02	6 vials	pyridoxine HCl 100 mg/ml inj.-30 ml
32162	04/09/02	8 vials	triamcinolone acetonide 40 mg/ml inj.-5 ml
34455	09/26/02	8 vials	triamcinolone diacetate 40 mg/ml inj.-5 ml

Such conduct violates Rule 4729-9-21 of the Ohio Administrative Code.

(7) Teregen Labs did, on or about the following dates in 2003, compound and sell prescription drugs when not pursuant to specific orders for individual patients issued by prescribers and not in limited quantities in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns, to wit: the pharmacy compounded and sold dangerous drugs, the following being representative examples:

<u>Invoice#</u>	<u>Date</u>	<u>Qty</u>	<u>Drug</u>
38531	09/10/03	40 vials	betamethasone Na phos. & acetate 6 mg/ml inj.-5 ml
37430	06/09/03	10 vials	brompheniramine maleate 10 mg/ml inj.- 10 ml
37145	05/15/03	12 vials	dexamethasone acetate 8 mg/ml inj.-5 ml
36851	04/22/03	12 vials	dexamethasone Na phos. 4 mg/ml inj.-5 ml
37617	06/24/03	3 vials	estradiol cypionate 5 mg/ml inj.-10 ml
38287	08/20/03	4 vials	estradiol valerate 40 mg/ml inj.-10 ml
35702	01/14/03	10 vials	estrone 5 mg/ml inj.-10 ml
36929	04/28/03	15 vials	methylprednisolone acetate 40 mg/ml inj.-10 ml
37639	06/26/03	600 vials	pyridoxine HCl 100 mg/ml inj.-30 ml
38379	08/28/03	30 vials	triamcinolone acetonide 40 mg/ml inj.-5 ml
37569	06/20/03	4 vials	triamcinolone diacetate 40 mg/ml inj.-5 ml

Such conduct violates Rule 4729-9-21 of the Ohio Administrative Code.

(8) Teregen Labs did, on or about February 10, 2003, dispense a drug from a prescription which had been sent to the pharmacy by facsimile directly from the patient, to wit: the pharmacy dispensed prescription no. 818899 for Celestone Soluspan 6 mg/ml, 5cc, which had been faxed directly from the patient. Such conduct violates Rule 4729-5-30(F) of the Ohio Administrative Code.

(9) Teregen Labs did, on or about September 2, 2003, dispense a drug from a prescription which had been sent to the pharmacy by facsimile directly from the patient, to wit: the pharmacy dispensed prescription no. 819878 for Celestone Soluspan 6 mg/ml, 5cc, which had been faxed directly from the patient. Such conduct violates Rule 4729-5-30(F) of the Ohio Administrative Code.

(10) Teregen Labs did, on or about September 16, 2002, dispense a drug from a prescription which had been sent to the pharmacy by facsimile directly from the patient, to wit: the pharmacy dispensed prescription no. 817388 for Celestone Soluspan 6 mg/ml, 5cc, which had been faxed directly from the patient. Such conduct violates Rule 4729-5-30(F) of the Ohio Administrative Code.

(11) Teregen Labs did, on or about May 2, 2003, sell a dangerous drug when not in accordance with Chapters 4729, and 4731, of the Ohio Revised Code, to wit: after the pharmacy had received prescription no. 818899, written for Celestone Soluspan 6 mg/ml, 5cc, refill 2 times, the drug was dispensed again without additional authorization from a prescriber. Such conduct violates Section 4729.51(C) of the Ohio Revised Code.

(12) Teregen Labs did, on or about August 4, 2003, sell a dangerous drug when not in accordance with Chapters 4729, and 4731, of the Ohio Revised Code, to wit: after the pharmacy had received prescription no. 818899, written for Celestone Soluspan 6 mg/ml, 5cc, refill 2 times, the drug was dispensed again without additional authorization from a prescriber. Such conduct violates Section 4729.51(C) of the Ohio Revised Code.

#### CONCLUSIONS OF LAW

(1) The State Board of Pharmacy concludes that paragraphs (5) through (10) of the Findings of Fact constitute being guilty of violating any rule of the Board as provided in Division (A)(2) of Section 4729.57 of the Ohio Revised Code.

(2) The State Board of Pharmacy concludes that paragraphs (11) and (12) of the Findings of Fact constitute being guilty of violating any provision of Chapter 4729, of the Revised Code as provided in Division (A)(3) of Section 4729.57 of the Ohio Revised Code.

(3) The State Board of Pharmacy concludes that paragraphs (2) through (4) of the Findings of Fact constitute being guilty of violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), U.S.C.A. 301, or Chapter 3715, of the Revised Code as provided in Division (A)(4) of Section 4729.57 of the Ohio Revised Code.

#### DECISION OF THE BOARD

Pursuant to Section 4729.57 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy adjudicates the matter of Teregen Labs, Terminal Distributor License No. 02-1235150, as follows:

(A) On the basis of the Findings of Fact and Conclusions of Law set forth above, the State Board of Pharmacy hereby revokes the Terminal Distributor license, No. 02-1235150, held by Teregen Labs effective as of the date of the mailing of this Order. Further, the Board suspends the revocation provided Teregen Labs compounds and sells only patient-specific orders.

(B) On the basis of the Findings of Fact and Conclusions of Law set forth above, the State Board of Pharmacy hereby imposes a monetary penalty of twenty-five thousand dollars (\$25,000.00) on Teregen Labs, Terminal Distributor License No. 02-1235150, and payment of the monetary penalty is due and owing within thirty days of the mailing of this Order. The remittance should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 South High Street, Room 1702, Columbus, Ohio 43215-6126.

THIS ORDER WAS APPROVED BY A VOTE OF THE STATE BOARD OF PHARMACY.

MOTION CARRIED.

SO ORDERED.

The motion was seconded by Mrs. Gregg and approved by the Board (Aye-8/Nay-0).

**R-2004-194** Mr. Kost then moved that the Board adopt the following Order in the matter of Christopher Kiel, R.Ph.:

**ORDER OF THE STATE BOARD OF PHARMACY**

(Docket No. D-031110-034)

In The Matter Of:

**CHRISTOPHER KIEL, R.Ph.**  
8260 Cyrus Lane  
Sagamore Hills, Ohio 44067  
(R.Ph. No. 03-1-12367)

**INTRODUCTION**

THE MATTER OF CHRISTOPHER KIEL CAME FOR HEARING ON MAY 4, 2004, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: ROBERT P. GIACALONE, R.Ph. (presiding); DIANE C. ADELMAN, R.Ph.; GREGORY BRAYLOCK, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; ELIZABETH I. GREGG, R.Ph.; LAWRENCE J. KOST, R.Ph.; NATHAN S. LIPSYC, R.Ph.; DOROTHY S. TEATER, PUBLIC MEMBER; AND JAMES E. TURNER, R.Ph.

CHRISTOPHER KIEL WAS REPRESENTED BY JOSEPH W. DIEMERT, JR. AND DIANE A. CALTA AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

**SUMMARY OF EVIDENCE**

**State's Witnesses**

1. Joann Predina, R.Ph., Ohio State Board of Pharmacy
2. Frederick Lochner, U.S. Food and Drug Administration (FDA)

**Respondent's Witnesses**

1. Christopher Kiel, R.Ph., Respondent

**State's Exhibits**

- 1K. Copy of Notice of Opportunity For Hearing letter [11-10-03]
  - 1A-1K-E. Procedurals
  - 1K-F. Copy of Amendment Notice [03-03-04]
  - 1G-1K-K. Procedurals
2. Copy of Ohio State Board of Pharmacy Compliance Bulletin 93-002 [09-15-93]
  - 2A. Copy of letter from Joseph Diemert, Jr. to Debra Grille [11-29-00]
  - 2B. Copy of letter from Joseph W. Diemert, Jr. to Timothy Benedict [12-08-00]
  - 2C. Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 02-1235150, with attachments [12-14-00]
  - 2D. Copy of letter from Charles S. Price to Diane A. Calta [01-02-01]

3. Facsimile copy of Rx #201315, Rx #201316, Rx #201317, and Rx #201318 [01-08-01]
- 3A. Copy of letter from Joseph W. Diemert, Jr. to George Fiderio [01-12-01]
- 3B. Copy of Purchase Order from Nevada Dermatology [12-04-01]
4. Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 02-1235150 [08-19-03]
- 4A. Copy of Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 01-0361600 [08-19-03]
5. Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 02-1235150 [08-21-03]
- 5A. Pink Sheet Response with enclosures from Diane Calta and Christopher Kiel, R.Ph. to William T. Winsley [09-09-03]
6. Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 01-0361600 [08-21-03]
- 6A. Pink Sheet Response with enclosures from Diane Calta and George V. Fiderio to William T. Winsley [09-09-03]
7. Vial of Dexamethasone Acetate Suspension 8 mg/mL [not dated]
- 7A. New Hampshire Board of Pharmacy Possessed Property Report with invoice attachments [09-23-03]
- 8-8K. One sheet of Teregen Vial Labels [03-10-04] and Teregen Package Inserts for Betamethasone, Brompheniramine, Dexamethasone acetate, Dexamethasone Na phosphate, Estradiol cypionate, Estradiol valerate, Estrone, Methylprednisolone acetate, Pyridoxine HCl, Triamcinolone acetate, and Triamcinolone diacetate [Feb 2001 to Feb 2003]
9. Building layout for Teregen (WD & TD) and Drug World Compounding Pharmacy [not dated]
- 9A. Clean room layout of Teregen Labs [not dated]
- 9B. Ten photographs of Clean room [not dated]
10. Report of Vials Produced Per Month at Teregen Labs [08-19-03]
- 10A. Copy of Inventory On Hand at Teregen Labs [08-20-03]
- 10B. Sales History of Teregen-Produced Sterile Product [12-00 to 09-03]
- 10C. Teregen Labs In-Stock Warehouse Inventory [10-01-03]
11. Copy of letter with enclosures from Diane A. Calta to Fred L. Dailey [09-03-03]
- 11A. Copy of letter from William A. Hopper, Jr. to Diane A. Calta [09-19-03]
- 11B. Copy of letter with attachments from Christopher Kiel, R.Ph. to Mr. Hopper [09-24-03]
- 11C. Copy of letter from Steven Silverman to William T. Winsley, M.S., R.Ph. [11-13-03]
- 11C-1. Copy of letter from Carol A. Heppe to Steven C. LaTourette, Congressman [03-17-04]
- 11D. Copy of letter from Fred L. Dailey to Diane A. Calta [11-21-03]
12. *Ohio State Board of Pharmacy News*, November 2003
13. Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 02-1235150 [03-11-04]
- 13A. Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 01-0361600 [03-11-04]
- 13B. Copy of Productivity Record [03-10-04]
- 13C. Teregen Labs Production Records [10-27-03 to 03-03-04]
14. Teregen Labs 2001 Physician Orders, Total Quantity Purchased [03-25-04]
- 14A. Copy of Betamethasone Distribution Records [11-28-01]
- 14B. Copy of Brompheniramine Distribution Records [02-21-01]
- 14C. Copy of Dexamethasone Acetate Distribution Records [10-17-01]
- 14D. Copy of Dexamethasone Na Phosphate Distribution Records [09-26-01]
- 14E. Copy of Estradiol Cypionate Distribution Records [03-23-01]
- 14F. Copy of Estradiol Valerate Distribution Records [07-25-01]
- 14G. Copy of Estrone Distribution Records [02-21-01]
- 14H. Copy of Methylprednisolone Acetate Distribution Records [12-04-01]
- 14I. Copy of Pyridoxine HCl Distribution Records [12-03-01]
- 14J. Copy of Triamcinolone Acetonide Distribution Records [02-05-01]
- 14K. Copy of Triamcinolone Diacetate Distribution Records [11-27-01]
- 14L. Dexamethasone Acetate Batch Records [10-10-01]

- 15. Teregen Labs 2002 Physician Orders, Total Quantity Purchased [03-25-04]
- 15A. Copy of Betamethasone Distribution Records [09-12-02]
- 15B. Copy of Brompheniramine Distribution Records [05-13-02]
- 15C. Copy of Dexamethasone Acetate Distribution Records [07-01-02]
- 15D. Copy of Dexamethasone Na Phosphate Distribution Records [09-27-02]
- 15E. Copy of Estradiol Cypionate Distribution Records [03-06-02]
- 15F. Copy of Estradiol Valerate Distribution Records [12-13-02]
- 15G. Copy of Estrone Distribution Records [09-20-02]
- 15H. Copy of Methylprednisolone Acetate Distribution Records [07-30-02]
- 15I. Copy of Pyridoxine HCl Distribution Records [09-25-02]
- 15J. Copy of Triamcinolone Acetonide Distribution Records [04-09-02]
- 15K. Copy of Triamcinolone Diacetate Distribution Records [09-26-02]
- 15L. Dexamethasone Acetate Batch Records [06-18-02]
- 16. Teregen Labs 2003 Physician Orders, Total Quantity Purchased [03-25-04]
- 16A. Copy of Betamethasone Distribution Records [09-10-03]
- 16B. Copy of Brompheniramine Distribution Records [06-09-03]
- 16C. Copy of Dexamethasone Acetate Distribution Records [05-15-03]
- 16D. Copy of Dexamethasone Na Phosphate Distribution Records [04-22-03]
- 16E. Copy of Estradiol Cypionate Distribution Records [06-24-03]
- 16F. Copy of Estradiol Valerate Distribution Record [08-20-03]
- 16G. Copy of Estrone Distribution Records [01-14-03]
- 16H. Copy of Methylprednisolone Acetate Distribution Records [04-28-03]
- 16I. Copy of Pyridoxine HCl Distribution Records [06-26-03]
- 16J. Copy of Triamcinolone Acetonide Distribution Records [08-28-03]
- 16K. Copy of Triamcinolone Diacetate Distribution Records [06-20-03]
- 16L. Dexamethasone Acetate Batch Records [04-25-03]
- 17. Rx #818899 [02-10-03]
- 17A. Teregen Labs Rx #818899 Label [02-10-03]
- 17B. Copy of Tax Insurance Summary for Drug World Pharmacy [01-01-01 to 11-05-03]
- 18. Rx #819878 [06-03-03]
- 19. Rx #817388 [07-03-02]
- 20. Letter with enclosures from Regina C. Hamlin, M.D. to Joann D. Predina, MBA, R.Ph. [11-02-03]
- 21. Copy of Ohio Revised Code (ORC) Section 3715.65 (Application for new drugs) [07-22-98]
- 21A. Copy of Division (A)(10) of ORC Section 3715.01 (Definitions) defining "New drug" [not dated]
- 21B. Copy of Division (C) of ORC Section 4729.01 (Definitions) defining "Compounding" [not dated]
- 21C. Copy of Division (H) of ORC Section 4729.01 (Definitions) defining "Prescription" [not dated]
- 21D. Copy of paragraph (B) of Ohio Administrative Code (OAC) Rule 4729-5-01 (Definitions) defining "Dispense" [not dated]
- 21E. Copy of OAC Rule 4729-5-30 (Manner of issuance of a prescription) [not dated]
- 21F. Copy of OAC Rule 4729-9-21 (Drugs compounded in a pharmacy) [03-01-99]
- 22. FDA Inspectional Observations (Form FDA 483) for Gentere Inc. [03-10-04 to 03-19-04]

#### Respondent's Exhibits

- A. Pink Sheet Response with enclosures from Diane Calta and George V. Fiderio to William T. Winsley [09-09-03]
- B. Notice of Opportunity for Hearing letter to Teregen Labs, License No. 01-0361600 [11-10-03]
- C. Copy of Amendment Notice letter To Teregen Labs, License No. 01-0361600 [03-03-04]
- D. Copy of Pink Sheet Response with enclosures from Diane Calta and Christopher Kiel, R.Ph. to William T. Winsley [09-09-03]
- E. Notice of Opportunity for Hearing letter to Teregen Labs, License No. 02-1235150 [11-10-03]
- F. Amendment Notice letter to Teregen Labs, License No. 02-1235150 [03-03-04]
- G. Copy of Pink Sheet Response from Christopher Kiel, R.Ph. to Ohio State Board of Pharmacy [08-25-03]
- H. Copy of Notice of Opportunity for Hearing letter to Christopher Kiel, R.Ph. [11-10-03]
- I. Copy of Amendment Notice letter to Christopher Kiel, R.Ph. [03-03-04]

- J. Copy of letter with enclosures from Diane A. Calta to William A. Hopper, Jr. [09-30-03]
- K. Letter with enclosure from William A. Hopper, Jr. to Diane A. Calta, Esq. [11-21-03]
- L. Copy of letter from Steven Silverman to William T. Winsley, M.S., R.Ph. [11-13-03]
- M. Copy of e-mail letter from Bill Winsley to Betty Hiner [10-23-03]
- N. Copy of Dangerous Drug Distributor Inspection Report of Teregen Labs, License No. 02-1235150 [12-14-00]
- O. Copy of letter from Joseph W. Diemert, Jr. to Debra Grille [11-29-00]; copy of Fax Cover Sheet from Diane Calta to Tim Benedict [11-30-00]
- P. Copy of letter from Joseph W. Diemert, Jr. to Timothy Benedict [12-08-00]
- Q. Copy of letter from Charles S. Price to Diane A. Calta [12-28-00]
- R. Copy of letter with enclosure from Joseph W. Diemert, Jr. to George Fiderio [01-12-01]
- S. Copy by Westlaw of Ohio Revised Code (ORC) Section 4729.01 (Definitions) [06-26-03]
- T. Copy by Westlaw of ORC Section 4729.29 (Exceptions to certain provisions) [03-09-99]
- U. Copy by Westlaw of Ohio Administrative Code (OAC) Rule 4729-5-30 (Manner of issuance of a prescription) [02-01-03]
- V. Copy by Westlaw of OAC Rule 4729-5-01 (Definitions) [01-01-04]
- W. Copy by Westlaw of OAC Rule 4729-9-12 (Verification of license as a distributor of dangerous drugs or exempt status of a prescriber) [03-01-99]
- X. Copy by Westlaw of ORC Sections 3715.01 (Definitions) [11-21-01] and 3715.65 (Application for new drugs) [07-22-98]
- Y. Copy of Guidance for FDA Staff and Industry Compliance Policy Guides Manual, Section 460.200 (Pharmacy Compounding) [05-29-02]
- Z. Six photographs of Teregen Laboratory Facility [not dated]
- AA. Copy by Westlaw of 2003 Ohio Senate Bill 196 (SN) As Introduced [02-12-04]; Bill Analysis by the Ohio Legislative Service Commission of S.B. 196 As Introduced [02-26-04]
- BB. Copy of pages 2498 through 2501 of the United States Pharmacopeial (USP) for Section 1075 (Good Compounding Practices) [not dated]
- CC. Copy of letter from David L. Rosen, B.S. Pharm, J.D. to Carol A. Heppe [04-27-04]

#### FINDINGS OF FACT

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

(1) Records of the State Board of Pharmacy indicate that Christopher Kiel was originally licensed by the State of Ohio as a pharmacist on August 10, 1977, pursuant to examination, and is currently licensed to practice pharmacy in Ohio. Records further reflect that, during the relevant time periods stated herein, Christopher Kiel was the Responsible Pharmacist at Teregen Labs, 38320 Western Parkway, Willoughby, Ohio, pursuant to Rule 4729-5-11 of the Ohio Administrative Code and Sections 4729.27 and 4729.55 of the Ohio Revised Code.

(2) Christopher Kiel did, on or about the following dates in 2001, sell a new drug without an application with respect to the drug having become effective under Section 505 of the Federal Food, Drug, and Cosmetic Act, to wit: after having received verbal and written warning against doing so, the pharmacy sold dangerous drugs, the following being representative examples, without obtaining patient-specific orders for the products:

<u>Invoice#</u>	<u>Date</u>	<u>Qty</u>	<u>Drug</u>
30486	11/28/01	25 vials	betamethasone Na phos & acetate 6 mg/ml inj.-5 ml
26495	02/21/01	12 vials	brompheniramine maleate 10 mg/ml inj.-10 ml
29925	10/17/01	30 vials	dexamethasone acetate 8 mg/ml inj.-5 ml
29631	09/26/01	12 vials	dexamethasone Na phos. 4 mg/ml inj.-5 ml
26810	03/23/01	4 vials	estradiol cypionate 5 mg/ml inj.-10 ml
28680	07/25/01	2 vials	estradiol valerate 40 mg/ml inj.-10 ml
26490	02/21/01	10 vials	estrone 5 mg/ml inj.-10 ml
30547	12/04/01	15 vials	methylprednisolone acetate 40 mg/ml inj.-10 ml
30529	12/03/01	200 vials	pyridoxine HCl 100 mg/ml inj.- 30 ml
26333	02/05/01	30 vials	triamcinolone acetonide 40 mg/ml inj.- 5 ml
30466	11/27/01	2 vials	triamcinolone diacetate 40 mg/ml inj.-5 ml

Such conduct violates Section 3715.65 of the Ohio Revised Code.

(3) Christopher Kiel did, on or about the following dates in 2002, sell a new drug without an application with respect to the drug having become effective under Section 505 of the Federal Food, Drug, and Cosmetic Act, to wit: after having received verbal and written warning against doing so, the pharmacy sold dangerous drugs, the following being representative examples, without obtaining patient-specific orders for the products:

<u>Invoice#</u>	<u>Date</u>	<u>Qty</u>	<u>Drug</u>
34259	09/12/02	4 vials	betamethasone Na phos. & acetate 6 mg/ml inj.-5 ml
32613	05/13/02	2 vials	brompheniramine maleate 10 mg/ml inj.-10 ml
33265	07/01/02	300 vials	dexamethasone acetate 8 mg/ml inj.-5 ml
34467	09/27/02	20 vials	dexamethasone Na phos. 4 mg/ml inj.-5 ml
31704	03/06/02	2 vials	estradiol cypionate 5 mg/ml inj.-10 ml
35410	12/13/02	4 vials	estradiol valerate 40 mg/ml inj.-10 ml
34380	09/20/02	5 vials	estrone 5 mg/ml inj.- 10 ml
33660	07/30/02	12 vials	methylprednisolone acetate 40 mg/ml inj.-10 ml
34433	09/25/02	6 vials	pyridoxine HCl 100 mg/ml inj.-30 ml
32162	04/09/02	8 vials	triamcinolone acetonide 40 mg/ml inj.-5 ml
34455	09/26/02	8 vials	triamcinolone diacetate 40 mg/ml inj.-5 ml

Such conduct violates Rule 4729-9-21 of the Ohio Administrative Code.

(4) Christopher Kiel did, on or about the following dates in 2003, sell a new drug without an application with respect to the drug having become effective under Section 505 of the Federal Food, Drug, and Cosmetic Act, to wit: after having received verbal and written warning against doing so, the pharmacy sold dangerous drugs, the following being representative examples, without obtaining patient-specific orders for the products:

<u>Invoice#</u>	<u>Date</u>	<u>Qty</u>	<u>Drug</u>
38531	09/10/03	40 vials	betamethasone Na phos. & acetate 6 mg/ml inj.-5 ml
37430	06/09/03	10 vials	brompheniramine maleate 10 mg/ml inj.- 10 ml
37145	05/15/03	12 vials	dexamethasone acetate 8 mg/ml inj.-5 ml
36851	04/22/03	12 vials	dexamethasone Na phos. 4 mg/ml inj.-5 ml
37617	06/24/03	3 vials	estradiol cypionate 5 mg/ml inj.-10 ml
38287	08/20/03	4 vials	estradiol valerate 40 mg/ml inj.-10 ml
35702	01/14/03	10 vials	estrone 5 mg/ml inj.-10 ml
36929	04/28/03	15 vials	methylprednisolone acetate 40 mg/ml inj.-10 ml
37639	06/26/03	600 vials	pyridoxine HCl 100 mg/ml inj.-30 ml
38379	08/28/03	30 vials	triamcinolone acetonide 40 mg/ml inj.-5 ml
37569	06/20/03	4 vials	triamcinolone diacetate 40 mg/ml inj.-5 ml

Such conduct violates Rule 4729-9-21 of the Ohio Administrative Code.

(5) Christopher Kiel did, on or about the following dates in 2001, compound and sell prescription drugs when not pursuant to specific orders for individual patients issued by prescribers and not in limited quantities in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns, to wit: Christopher Kiel compounded and sold dangerous drugs, the following being representative examples:

<u>Invoice#</u>	<u>Date</u>	<u>Qty</u>	<u>Drug</u>
30486	11/28/01	25 vials	betamethasone NA phos & acetate 6 mg/ml inj.-5 ml
26495	02/21/01	12 vials	brompheniramine maleate 10 mg/ml inj.-10 ml
29925	10/17/01	30 vials	dexamethasone acetate 8 mg/ml inj.-5 ml
29631	09/26/01	12 vials	dexamethasone Na phos. 4 mg/ml inj.-5 ml
26810	03/23/01	4 vials	estradiol cypionate 5 mg/ml inj.-10 ml
28680	07/25/01	2 vials	estradiol valerate 40 mg/ml inj.-10 ml
26490	02/21/01	10 vials	estrone 5 mg/ml inj.-10 ml
30547	12/04/01	15 vials	methylprednisolone acetate 40 mg/ml inj.-10 ml
30529	12/03/01	200 vials	pyridoxine HCl 100 mg/ml inj.- 30 ml
26333	02/05/01	30 vials	triamcinolone acetonide 40 mg/ml inj.- 5 ml
30466	11/27/01	2 vials	triamcinolone diacetate 40 mg/ml inj.-5 ml

Such conduct violates Rule 4729-9-21 of the Ohio Administrative Code.

(6) Christopher Kiel did, on or about the following dates in 2002, compound and sell prescription drugs when not pursuant to specific orders for individual patients issued by prescribers and not in limited quantities in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns, to wit: Christopher Kiel compounded and sold dangerous drugs, the following being representative examples:

<u>Invoice#</u>	<u>Date</u>	<u>Qty</u>	<u>Drug</u>
34259	09/12/02	4 vials	betamethasone Na phos. & acetate 6 mg/ml inj.-5 ml
32613	05/13/02	2 vials	brompheniramine maleate 10 mg/ml inj.-10 ml
33265	07/01/02	300 vials	dexamethasone acetate 8 mg/ml inj.-5 ml
34467	09/27/02	20 vials	dexamethasone Na phos. 4 mg/ml inj.-5 ml
31704	03/06/02	2 vials	estradiol cypionate 5 mg/ml inj.-10 ml
35410	12/13/02	4 vials	estradiol valerate 40 mg/ml inj.-10 ml
34380	09/20/02	5 vials	estrone 5 mg/ml inj.- 10 ml
33660	07/30/02	12 vials	methylprednisolone acetate 40 mg/ml inj.-10 ml
34433	09/25/02	6 vials	pyridoxine HCl 100 mg/ml inj.-30 ml
32162	04/09/02	8 vials	triamcinolone acetonide 40 mg/ml inj.-5 ml
34455	09/26/02	8 vials	triamcinolone diacetate 40 mg/ml inj.-5 ml

Such conduct violates Rule 4729-9-21 of the Ohio Administrative.

(7) Christopher Kiel did, on or about the following dates in 2003, compound and sell prescription drugs when not pursuant to specific orders for individual patients issued by prescribers and not in limited quantities in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns, to wit: Christopher Kiel compounded and sold dangerous drugs, the following being representative examples:

<u>Invoice#</u>	<u>Date</u>	<u>Qty</u>	<u>Drug</u>
38531	09/10/03	40 vials	betamethasone Na phos. & acetate 6 mg/ml inj.-5 ml
37430	06/09/03	10 vials	brompheniramine maleate 10 mg/ml inj.- 10 ml
37145	05/15/03	12 vials	dexamethasone acetate 8 mg/ml inj.-5 ml
36851	04/22/03	12 vials	dexamethasone Na phos. 4 mg/ml inj.-5 ml
37617	06/24/03	3 vials	estradiol cypionate 5 mg/ml inj.-10 ml
38287	08/20/03	4 vials	estradiol valerate 40 mg/ml inj.-10 ml
35702	01/14/03	10 vials	estrone 5 mg/ml inj.-10 ml
36929	04/28/03	15 vials	methylprednisolone acetate 40 mg/ml inj.-10 ml
37639	06/26/03	600 vials	pyridoxine HCl 100 mg/ml inj.-30 ml
38379	08/28/03	30 vials	triamcinolone acetonide 40 mg/ml inj.-5 ml
37569	06/20/03	4 vials	triamcinolone diacetate 40 mg/ml inj.-5 ml

Such conduct violates Rule 4729-9-21 of the Ohio Administrative Code.

(8) Christopher Kiel did, on or about February 10, 2003, dispense a drug from a prescription which had been sent to the pharmacy by facsimile directly from the patient, to wit: the pharmacy dispensed Rx 818899 for Celestone Soluspan 6 mg/ml, 5cc, which had been faxed directly from the patient. Such conduct violates Rule 4729-5-30(F) of the Ohio Administrative Code.

(9) Christopher Kiel did, on or about September 2, 2003, dispense a drug from a prescription which had been sent to the pharmacy by facsimile directly from the patient, to wit: the pharmacy dispensed Rx 819878 for Celestone Soluspan 6 mg/ml, 5cc, which had been faxed directly from the patient. Such conduct violates Rule 4729-5-30(F) of the Ohio Administrative Code.

(10) Christopher Kiel did, on or about September 16, 2002, dispense a drug from a prescription which had been sent to the pharmacy by facsimile directly from the patient, to wit: the pharmacy dispensed Rx 817388 for Celestone Soluspan 6 mg/ml, 5cc, which had been faxed directly from the patient. Such conduct violates Rule 4729-5-30(F) of the Ohio Administrative Code.



(11) Christopher Kiel did, on or about May 2, 2003, sell a dangerous drug when not in accordance with Chapters 4729, and 4731, of the Ohio Revised Code, to wit: after the pharmacy had received Rx 818899, written for Celestone Soluspan 6 mg/ml, 5cc, refill 2 times, Christopher Kiel dispensed the drug again without additional authorization from a prescriber. Such conduct violates Section 4729.51(C) of the Ohio Revised Code.

(12) Christopher Kiel did, on or about August 4, 2003, sell a dangerous drug when not in accordance with Chapters 4729, and 4731, of the Ohio Revised Code, to wit: after the pharmacy had received Rx 818899, written for Celestone Soluspan 6 mg/ml, 5cc, refill 2 times, Christopher Kiel dispensed the drug again without additional authorization from a prescriber. Such conduct violates Section 4729.51(C) of the Ohio Revised Code.

#### CONCLUSIONS OF LAW

(1) The State Board of Pharmacy concludes that paragraphs (2) through (12) of the Findings of Fact constitute being guilty of gross immorality as provided in Division (A)(1) of Section 4729.16 of the Ohio Revised Code.

(2) The State Board of Pharmacy concludes that paragraphs (2) through (12) of the Findings of Fact constitute being guilty of dishonesty and unprofessional conduct in the practice of pharmacy as provided in Division (A)(2) of Section 4729.16 of the Ohio Revised Code.

(3) The State Board of Pharmacy concludes that paragraphs (2) through (12) of the Findings of Fact constitute being guilty of willfully violating, conspiring to violate, attempting to violate, or aiding and abetting the violation of provisions of Chapter 3715, or 4729, of the Revised Code or any rule adopted by the Board as provided in Division (A)(5) of Section 4729.16 of the Ohio Revised 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 adjudicates the matter of Christopher Kiel as follows:

(A) On the basis of the Findings of Fact and Conclusions of Law set forth above, the State Board of Pharmacy hereby suspends for six months the pharmacist identification card, No. 03-1-12367, held by Christopher Kiel and such suspension is effective as of the date of the mailing of this Order.

(1) Christopher Kiel, pursuant to Rule 4729-9-01(F) of the Ohio Administrative Code, may not be employed by or work in a facility licensed by the State Board of Pharmacy to possess or distribute dangerous drugs during such period of suspension.

(2) Christopher Kiel, pursuant to Section 4729.16(B) of the Ohio Revised Code, must return his identification card and license (wall certificate) to the office of the State Board of Pharmacy within ten days after receipt of this Order unless the Board office is already in possession of both. The identification card and wall certificate should be sent by certified mail, return receipt requested.

(B) On the basis of the Findings of Fact and Conclusions of Law set forth above, the State Board of Pharmacy hereby imposes a monetary penalty of ten thousand dollars (\$10,000.00) on Christopher Kiel and payment of the monetary penalty is due and owing within thirty days of the mailing of this Order. The remittance should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 South High Street, Room 1702, Columbus, Ohio 43215-6126.

(C) Beginning six months from the effective date of this Order, the State Board of Pharmacy places Christopher Kiel on probation for two years. The terms of probation are as follows:

- (1) The State Board of Pharmacy hereby declares that Christopher Kiel's pharmacist identification card is not in good standing and thereby denies the privilege of being a preceptor and training pharmacy interns pursuant to paragraph (D)(1) of Rule 4729-3-01 of the Ohio Administrative Code.
- (2) Christopher Kiel may not serve as a responsible pharmacist.
- (3) Christopher Kiel must not violate the drug laws of Ohio, any other state, or the federal government.
- (4) Christopher Kiel must abide by the rules of the State Board of Pharmacy.
- (5) Christopher Kiel must comply with the terms of this Order.
- (6) Christopher Kiel's license is deemed not in good standing until successful completion of the probationary period.
- (7) Any violation of probation may result in a Board hearing to consider alternative or additional sanctions under Section 4729.16 of the Ohio Revised Code.

Christopher Kiel is hereby advised that the Board may at any time revoke probation for cause, modify the conditions of probation, and reduce or extend the period of probation. At any time during this period of probation, the Board may revoke probation for a violation occurring during the probation period.

THIS ORDER WAS APPROVED BY A VOTE OF THE STATE BOARD OF PHARMACY.

MOTION CARRIED.

SO ORDERED.

The motion was seconded by Mrs. Adelman and approved by the Board (Aye-8/Nay-0).

9:15 p.m.

The Board meeting recessed until Wednesday, May 5, 2004.

### **WEDNESDAY, MAY 5, 2004**

9:00 a.m. ROLL CALL

The State Board of Pharmacy convened in Room West-B&C, 31st Floor, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio with the following members present:

Robert P. Giacalone, R.Ph. (President); Lawrence J. Kost, R.Ph. (Vice-President); Diane C. Adelman, R.Ph.; Gregory Braylock, R.Ph.; Suzanne R. Eastman, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; and Dorothy S. Teater, Public Member.

9:14 a.m.

The Board was joined by Assistant Attorney General Sally Ann Steuk for the purpose of conducting an adjudication hearing in accordance with Ohio Revised Code Chapters 119. and 4729. in the matter of Steven Ray Liles, R.Ph., Cold Spring, KY.

9:44 a.m.

The hearing ended and the record was closed.

9:47 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 Revised Code. The motion was seconded by Mr. Kost and a roll call vote was conducted by President Giacalone as follows: Adelman-Yes, Braylock-Yes, Eastman-Yes, Gregg-Yes, Lipsyc-Yes, Kost-Yes, and Teater-Yes.

10:20 a.m.

**R-2004-195**

The Executive Session ended and the meeting was opened to the public. Mrs. Gregg moved that the Board adopt the following Order in the matter of Steven Ray Liles, R.Ph.:

**ORDER OF THE STATE BOARD OF PHARMACY**

(Docket No. D-031215-044)

In The Matter Of:

**STEVEN RAY LILES, R.Ph.**  
908 Monterey Lane  
Cold Spring, Kentucky 41076  
(R.Ph. No. 03-1-14987)

**INTRODUCTION**

THE MATTER OF STEVEN RAY LILES CAME FOR HEARING ON MAY 5, 2004, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: ROBERT P. GIACALONE, R.Ph. (presiding); DIANE C. ADELMAN, R.Ph.; GREGORY BRAYLOCK, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; ELIZABETH I. GREGG, R.Ph.; LAWRENCE J. KOST, R.Ph.; NATHAN S. LIPSYC, R.Ph.; AND DOROTHY S. TEATER, PUBLIC MEMBER.

STEVEN RAY LILES WAS REPRESENTED BY ELIZABETH Y. COLLIS AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

**SUMMARY OF EVIDENCE**

**State's Witnesses**

None

**Respondent's Witnesses**

1. Steven Ray Liles, R.Ph., Respondent

**State's Exhibits**

1. Facsimile copy of Reinstatement Hearing Request letter from Steven Ray Liles [12-15-03]
  - 1A. Reinstatement Hearing Request letter from Elizabeth Y. Collis [12-15-03]
  - 1B-1C. Procedurals
  - 2A. Copy of State Board of Pharmacy Order in re Steven Ray Liles, R.Ph. [12-10-03]
2. Commonwealth of Kentucky Uniform Citation, Control No. C841762 [07-06-02]
3. DUI (Guilty Plea); Judgment Entry; Fine and Costs Pay Schedule; and Drug Education Program letter [08-05-02] Commonwealth of Kentucky vs. Steven Liles, Case No. 02M2158, Campbell District Court, 17th Judicial District, Second Division

**Respondent's Exhibits**

- A. Letter of Treatment Recommendation from Diane C. Brock, CCDC IIIe [01-02-04]
- B. Facsimile copy of Treatment Progress/Termination Report from Thomas Cox, MS, CCDC I [03-08-04]
- C. Letter from Daniel E. Kincaid, Esq. [05-04-04]
- D. Facsimile copy of Commonwealth of Kentucky Division of Substance Abuse Driving Under The Influence (DUI) Program Completion Form [10-23-02]; copy of Assessment Results for Steven Liles [08-14-02]

FINDING 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 that Steven Ray Liles has complied with the terms set forth in the Order of the State Board of Pharmacy, Docket No. D-030910-007, effective December 10, 2003.

DECISION OF THE BOARD

On the basis of the Finding of Fact set forth above, and after consideration of the record as a whole, the State Board of Pharmacy hereby approves the reinstatement of the pharmacist identification card, No. 03-1-14987, held by Steven Ray Liles to practice pharmacy in Ohio and places Steven Ray Liles on probation for one year beginning on the effective date of this Order, with the following conditions:

- (1) Random, observed urine drug screens, through an Ohio Department of Alcohol and Drug Addiction Services (ODADAS) approved program, shall be conducted at least once every three months.
  - (a) The urine sample must be given within twelve hours of notification. The urine drug screen must include testing for creatinine or specific gravity of the sample as the dilutional standard.
  - (b) Marijuana must be added to the standard urine drug screen.
  - (c) Results of all drug screens must be negative. Refusal of a drug screen or a diluted drug screen is equivalent to a positive result. Any positive results, including those which may have resulted from ingestion of food, but excluding false positives which resulted from medication legitimately prescribed, indicates a violation of probation.
- (2) The ODADAS program shall provide copies of all drug screen reports to the Board in a timely fashion and shall immediately report to the Board any violations and/or lack of cooperation.
- (3) The State Board of Pharmacy hereby declares that Steven Ray Liles' pharmacist identification card is not in good standing and thereby denies the privilege of being a preceptor and training pharmacy interns pursuant to paragraph (D)(1) of Rule 4729-3-01 of the Ohio Administrative Code.
- (4) Steven Ray Liles may not serve as a responsible pharmacist.
- (5) Steven Ray Liles may not destroy, assist in, or witness the destruction of controlled substances.
- (6) Steven Ray Liles must immediately report any violation of the ODADAS program to the Board.
- (7) Steven Ray Liles must not violate the drug laws of Ohio, any other state, or the federal government.
- (8) Steven Ray Liles must abide by the rules of the Ohio Board of Pharmacy.
- (9) Steven Ray Liles must comply with the terms of this Order.
- (10) Steven Ray Liles' license is deemed not in good standing until successful completion of the probationary period.
- (11) Any violation of probation may result in a Board hearing to consider alternative or additional sanctions under Section 4729.16 of the Ohio Revised Code.

Steven Ray Liles is hereby advised that the Board may at any time revoke probation for cause, modify the conditions of probation, and reduce or extend the period of probation. At any time during this period of probation, the Board may revoke probation for a violation occurring during the probation period.

THIS ORDER WAS APPROVED BY A VOTE OF THE STATE BOARD OF PHARMACY.

MOTION CARRIED.

SO ORDERED.

The motion was seconded by Mr. Braylock and approved by the Board (Aye-7/Nay-0).

After a discussion of the draft minutes from the April 5-7, 2004 meeting, Mrs. Gregg moved that the minutes be approved as amended. The motion was seconded by Mr. Braylock and approved by the Board (Aye-6/Nay-0/Abstain-1[Adelman]).

10:30 a.m.

The Board was joined by Assistant Attorney General Sally Ann Steuk for the purpose of conducting an adjudication hearing in accordance with Ohio Revised Code Chapters 119. and 4729. in the matter of Anita R. McDonald, R.Ph., Batavia.

10:44 a.m.

The hearing ended and the record was closed.

10:45 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 Revised Code. The motion was seconded by Mr. Braylock and a roll call vote was conducted by President Giacalone as follows: Adelman-Yes, Braylock-Yes, Eastman-Yes, Gregg-Yes, Lipsyc-Yes, Kost-Yes, and Teater-Yes.

11:08 a.m.

**R-2004-196**

The Executive Session ended and the meeting was opened to the public. Mr. Kost moved that the Board adopt the following Order in the matter of Anita R. McDonald, R.Ph.:

**ORDER OF THE STATE BOARD OF PHARMACY**

(Docket No. D-031208-041)

In The Matter Of:

**ANITA R. McDONALD, R.Ph.**

1220 Rosemont Avenue  
Cincinnati, Ohio 45205  
(R.Ph. No. 03-2-23614)

**INTRODUCTION**

THE MATTER OF ANITA R. McDONALD CAME FOR HEARING ON MAY 5, 2004, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: ROBERT P. GIACALONE, R.Ph. (presiding); DIANE C. ADELMAN, R.Ph.; GREGORY BRAYLOCK, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; ELIZABETH I. GREGG, R.Ph.; LAWRENCE J. KOST, R.Ph.; NATHAN S. LIPSYC, R.Ph.; AND DOROTHY S. TEATER, PUBLIC MEMBER.

ANITA R. McDONALD WAS NOT REPRESENTED BY COUNSEL AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

**SUMMARY OF EVIDENCE**

**State's Witnesses**

1. Rick Haun, Ohio State Board of Pharmacy

**Respondent's Witnesses**

2. Anita R. McDonald, R.Ph., Respondent

State's Exhibits

1. Copy of Notice of Opportunity For Hearing letter [12-09-03]  
1A-1C. Procedurals
2. Rx #4427309 [10-03-03]
3. Rx #4427312 [10-03-03]
4. Rx #4429346 [10-16-03]
5. Rx #4429345 [10-16-03]
6. Rx #2207705 [10-16-03]
7. Rx #2207706 [10-16-03]
8. Rx #2207707 [10-16-03]

Respondent's Exhibits

- A. Decree of Dissolution of Marriage, Anita Rose McDonald vs. Thomas Patrick McDonald, Case No. 03OR28043, Warren County Common Pleas Court [11-10-03]
- B. Copy of Hyde Park Internists, Inc. Medical Record No. 3708 for Anita R. McDonald [09-24-03]
- C. Copy of Hyde Park Internists, Inc. Medical Record No. 12835 for Anita R. McDonald [12-01-03]
- D. Resume of Anita R. McDonald

FINDINGS OF FACT

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

(1) Records of the State Board of Pharmacy indicate that Anita R. McDonald was originally licensed by the State of Ohio as a pharmacist on June 15, 1999, pursuant to reciprocity, and is currently licensed to practice pharmacy in Ohio.

(2) Anita R. McDonald did, on or about October 3, 2003, while not a pharmacist, dispense or sell dangerous drugs or otherwise engage in the practice of pharmacy, to wit: after allowing her license to practice pharmacy to lapse, and after having been warned against practicing pharmacy without a license by a Board agent, Anita R. McDonald dispensed Rx #4427309 and Rx #4427312. Such conduct violates Section 4729.28 of the Ohio Revised Code.

(3) Anita R. McDonald did, on or about October 16, 2003, while not a pharmacist, dispense or sell dangerous drugs or otherwise engage in the practice of pharmacy, to wit: after allowing her license to practice pharmacy to lapse, and after having been warned against practicing pharmacy without a license by a Board agent, Anita R. McDonald dispensed Rx #4429345, Rx #4429346, Rx #2207705, Rx #2207706, and Rx #2207707. Such conduct violates Section 4729.28 of the Ohio Revised Code.

CONCLUSION OF LAW

The State Board of Pharmacy concludes that paragraphs (2) and (3) of the Findings of Fact constitute being guilty of willfully violating, conspiring to violate, attempting to violate, or aiding and abetting the violation of provisions of Chapter 4729. of the Revised Code as provided in Division (A)(5) of Section 4729.16 of the Ohio Revised Code.

DECISION OF THE BOARD

Pursuant to Section 4729.16 and 4729.25(B) of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby reprimands Anita R. McDonald for her conduct in this matter.

THIS ORDER WAS APPROVED BY A VOTE OF THE STATE BOARD OF PHARMACY.

MOTION CARRIED.

SO ORDERED.

The motion was seconded by Mrs. Gregg and approved by the Board (Aye-7/Nay-0).

**R-2004-197** Mr. McMillen presented a letter from the Ohio Pharmacists Association requesting approval of a new home study continuing pharmacy education (CPE) course on Adult Immunizations. After discussion, Mrs. Gregg moved that the Board approve this course as meeting the criteria set for CPE programs on immunization. The motion was seconded by Mr. Lipsyc and approved by the Board (Aye-7/Nay-0).

**R-2004-198** Mr. McMillen next presented a request for approval of the MedicWare Electronic Prescription Transmission System. After discussion, Mrs. Gregg moved that the Board find this system to be approvable subject to final inspection after implementation. The motion was seconded by Mrs. Adelman and approved by the Board (Aye-7/Nay-0).

**R-2004-199** The Board then discussed the appointment of members to the Ad Hoc Committees for rules regarding HB 64 (Scuba Divers and Oxygen) and Nuclear Pharmacy. Mrs. Gregg moved that the following members be appointed to each committee. The motion was seconded by Mr. Braylock and approved by the Board (Aye-7/Nay-0).

Committee for new rules regarding Oxygen and Scuba Diver sales pursuant to H.B. 64:

1. Martin Bailey
2. Patrix Heschel
3. Ken Karst
4. Rich Lauer
5. Twink Miller
6. Linda Pansing
7. Scott Pansing
8. Dave Rauch
9. Dorothy Teater, Board Member (Chair)

A sub-committee of individuals involved in Nuclear Pharmacy to review the effects of the USP Chapter 797 Sterile Compounding Guidelines and the potential Sterile Compounding rules drafted by the Ad Hoc Committee on Rule Review for 2004 on the Nuclear Pharmacy rules in OAC Chapter 4729-15:

1. George Hinkle
2. Lisa Koss
3. Terry Malone
4. Steve Mattmuller
5. Janet Robertson
6. Jim Weil
7. Robert Giacalone, Board Member (Chair)

**R-2004-200** The Board next discussed a letter received from Prasanna L. Soni, M.D. proposing mechanisms for the preparation and distribution of a compounded product to patients. After discussion, Mrs. Gregg moved that Board staff inform Dr. Soni that the preparation and distribution methods discussed in his letter were not in accordance with state and federal law and were, therefore, not acceptable. The motion was seconded by Mr. Braylock and approved by the Board (Aye-7/Nay-0).

**R-2004-201** Mr. McMillen next presented a request for an exemption to OAC Rule 4729-5-11 (Responsible pharmacist) received from Joseph R. Moss, Jr., Pharm.D. for the following Terminal Distributor of Dangerous Drugs licenses:

UHHS Bedford Medical Center (02-0774350)  
UHHS Richmond Heights Hospital (02-1214650)

After discussion, Mrs. Gregg moved that the Board approve this request for a 60 day period. The motion was seconded by Mr. Braylock and approved by the Board (Aye-7/Nay-0).

11:44 a.m.

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

PER DIEM	<u>5/3</u>	<u>5/4</u>	<u>5/5</u>	<u>Total</u>
Adelman	1	1	1	3
Braylock	1	1	1	3
Eastman	1	1	1	3
Giacalone	1	1	1	3
Gregg	1	1	1	3
Kost	1	1	1	3
Lipsyc	1	1	1	3
Teater	1	1	1	3
Turner	-	1	-	1

The motion was seconded by Mrs. Gregg and approved by the Board (Aye-7/Nay-0).

11:45 a.m.

Mrs. Gregg moved that the meeting be adjourned. The motion was seconded by Mrs. Adelman and approved by the Board (Aye-7/Nay-0).

<p><b>THE BOARD APPROVED THESE MINUTES JUNE 22, 2004</b></p>
--