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Minutes of the April 12 & 13, 2005
Meeting of the Ohio State Board of Pharmacy

TUESDAY, APRIL 12, 2005

10:05 a.m. The Ohio State Board of Pharmacy convened in Room East B, 31st Floor, of the Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, OH. Present were:

Lawrence J. Kost, R.Ph., *President*; Gregory Braylock, R.Ph.; Robert P. Giacalone, R.Ph.; Elizabeth Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; Kevin J. Mitchell, R.Ph.; Dorothy Teater, Public Member; and James Turner, R.Ph.

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*.

Mr. Winsley announced that the following settlement agreement had been signed by all parties and was now effective:

R-2005-159

SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY

Docket Number D-050311-050

in the matter of:

JASON MATTHEW CLARK, R.PH.
224 Lanford Road
Spartanburg, South Carolina 29301

R.Ph. Number 03-2-21133

This Settlement Agreement is entered into by and between Jason Matthew Clark 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.

Jason Matthew Clark 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 and the right to a formal adjudication hearing on the issues contained herein.

Jason Matthew Clark is knowingly and voluntarily acknowledging that, in order to settle possible disciplinary charges and in order to obviate the need to conduct an administrative hearing to consider possible disciplinary sanctions against Jason Matthew Clark's license to practice pharmacy in the State of Ohio, this Agreement is entered into on the basis of the following stipulations, admissions, and understandings:

Whereas, Ohio State Board of Pharmacy 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 impose a monetary penalty on the license holder for violation of any of the enumerated grounds therein.

- (1) Records of the Board of Pharmacy indicate that Jason Matthew Clark was originally licensed in the State of Ohio on July 27, 1995, pursuant to examination, and is currently licensed to practice pharmacy in the State of Ohio.
- (2) Jason Matthew Clark became addicted to opioid drugs, to wit: Jason Matthew Clark has entered into a recovery program due to addiction; has had his license to practice pharmacy suspended, and subsequently reinstated under conditions, by the South Carolina State Board of Pharmacy; and was granted pre-trial intervention in South Carolina criminal court, which he subsequently completed successfully. Jason Matthew Clark is in an after-care program while practicing pharmacy in South Carolina under a term of probation. Such conduct indicates that Jason Matthew Clark falls within the ambit of Sections 3719.121 and 4729.16(A) (3) of the Ohio Revised Code.
- (3) Jason Matthew Clark's probation with the South Carolina Board of Pharmacy runs through July of 2008, requiring terms for completing his recovery in the South Carolina Recovering Professionals Program (R.Ph.).

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of a formal hearing at this time, Jason Matthew Clark knowingly and voluntarily agrees with the State Board of Pharmacy to the following:(A) Jason Matthew Clark must maintain compliance with his South Carolina sanctioned recovery and his fitness to continue his practice of pharmacy.

- (4) Jason Matthew Clark must inform the Ohio State Board of Pharmacy if he plans to return to Ohio to practice pharmacy in Ohio, and must appear before the Board to show compliance with his recovery program as mandated by the South Carolina State Board of Pharmacy.

If, in the judgment of the Board, Jason Matthew Clark 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.

Jason Matthew Clark 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.

Jason Matthew Clark 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. Jason Matthew Clark 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.

/s/
Jason M. Clark, R.Ph., Respondent

/d/ 08/07/05
Date Signed

/s/
Suzanne R. Eastman, President,
Ohio State Board of Pharmacy

/d/ 09/13/05
Date Signed

/s/
Sally Ann Steuk,
Ohio Assistant Attorney General

/d/ 09/13/05
Date Signed

10:10 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 and for the purpose of conferring with an attorney for the Board regarding pending or imminent court action pursuant to Section 121.22(G)(3) of the Revised Code. The motion was seconded by Mr. Braylock and a roll-call vote was conducted by President Kost as follows: Braylock – yes; Giacalone – yes; Gregg – yes; Lipsyc – yes; Mitchell – yes; Teater – yes; and Turner – yes.

10:35 a.m. Board member Suzanne R. Eastman, R.Ph., arrived and joined the Executive Session in progress.

11:45 a.m. The Executive Session ended and the meeting was opened to the public.

R-2005-160 Mrs. Gregg moved that the Board deny the settlement offer presented in the matter of **Neil Frasca**, R.Ph. The motion was seconded by Mr. Braylock and approved by the Board: *Aye – 7/Abstain – 1* (Eastman).

R-2005-161 Mrs. Gregg moved that the Board deny the settlement offer presented in the matter of **John Harrington**, R.Ph. The motion was seconded by Mr. Braylock and approved by the Board: *Aye – 7/Abstain – 1* (Eastman).

R-2005-162 Mrs. Gregg next moved that the Board deny the settlement offer presented in the matter of **Warren Hone**, R.Ph. The motion was seconded by Mrs. Eastman and approved by the Board: *Aye – 7/Abstain – 1* (Eastman).

R-2005-163 Mr. Braylock moved that the Board deny the continuance request received in the matter of **David James**, R.Ph., and that the hearing be held as scheduled. The motion was seconded by Mrs. Eastman and approved by the Board: *Aye – 7*.

11:51 a.m. The Board recessed for lunch.

1:01 p.m. The State Board of Pharmacy reconvened in Room East B, 31st Floor, of the Vern Riffe Center with all members present.

The Board was joined by representatives of **Medco** to discuss plans for a central fill operation agreement between Medco and other pharmacies.

1:30 p.m. The discussion with the representatives of Medco was suspended to allow the Board to adjourn to Room South A, 31st Floor, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio, for the purpose of meeting with the candidates for licensure by reciprocity.

Following presentations by Board members, the candidates for licensure by reciprocity introduced themselves, and participated in a discussion of pharmacy laws and rules with Mr. McMillen. They were then presented with their pharmacist identification cards.

Brandon Cowell Baker	03-2-26632	Pennsylvania
Leomard G. Bennett, Jr.	03-2-26638	Georgia
Shahrzad M. Bozorg	03-2-26645	Pennsylvania
Randi Conard	03-2-26619	New Jersey
Rebecca Lynn Corey	03-2-26612	Pennsylvania
Darryl David Ivanson	03-2-26607	Indiana
Kathryn Thompson Mitchell	03-2-26624	Texas
Christan Uwabenkonye O'Haeri	03-2-26623	North Carolina
Carrie Anne Rea	03-2-26621	Pennsylvania

- 1:55 p.m. The Board reconvened in Room East B to complete the discussion with Medco.
- 2:11 p.m. The meeting with the representatives of Medco ended. Mr. Mitchell left the meeting to participate in the ACPE Accreditation visit to Toledo University College of Pharmacy.
- 2:20 p.m. The Board was joined by Assistant Attorney General Sally Ann Steuk to conduct an adjudication hearing in accordance with Ohio Revised Code Chapters 119. and 4729. in the matter of Douglas Birkhimer, R.Ph., Columbus.
- 4:17 p.m. The hearing ended and the record was closed. The Board took a brief recess.
- 4:29 p.m. The Board was joined by Assistant Attorney General Sally Ann Steuk for the purpose of creating a record in accordance with Ohio Revised Code Chapters 119. and 4729. in the matter of Saks Distributing, TDDD Applicant, Sylvania.
- 5:02 p.m. The record was closed.
- 5:05 p.m. Mr. Lipsyc 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. Turner and a roll-call vote was conducted by President Kost as follows: Braylock – yes; Giacalone – yes; Gregg – yes; Lipsyc – yes; Mitchell – yes; Teater – yes; and Turner – yes.
- 5:20 p.m. The Executive Session ended and the meeting was opened to the public. Mr. Braylock moved that the Board adopt the following order in the matter of SAKS Distributing, TDDD Applicant:

R-2005-164

ORDER OF THE STATE BOARD OF PHARMACY

Docket Number. D-050113043

in the matter of:

SAKS DISTRIBUTING

7665 Clark Street
Holland, Ohio 43528

INTRODUCTION

The matter of Saks Distributing came for consideration on April 12, 2005, before the following members of the Board: Lawrence Kost, R.Ph., (*presiding*); Gregory Braylock, R.Ph.; Suzanne Eastman, R.Ph.; Robert Giacalone; R.Ph.; Elizabeth Gregg, R.Ph.; Nathan Lipsyc; R.Ph.; Dorothy Teater, Public Member, and James Turner, R.Ph.

Syed Rahman was not present, nor was Saks Distributing represented by counsel.

The State of Ohio was represented by Assistant Attorney General Sally Ann Steuk.

SUMMARY OF EVIDENCE

State's Witnesses: Dale Fritz, Jr., Ohio State Board of Pharmacy
Jesse Wimberly, Ohio State Board of Pharmacy

Respondent's Witnesses: None

State's Exhibits:

1. Proposal to Deny/Notice of Opportunity for Hearing letter [01/13/05].
2. Copy of Application for Registration as a Wholesale Distributor of Dangerous Drugs, with Syed Rahman signing as President, and dated November 9, 2004.
3. Three photographs of an office building.
4. Copy of Application for Registration as a Wholesale Distributor of Dangerous Drugs with Syed Rahman signing as President, and dated Sept. 4, 2003.

Respondent's Exhibits: None

FINDINGS OF FACT

After having heard the testimony, and 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) On January 13, 2005, Saks Distributing was notified by letter of its right to a hearing, its rights in such hearing, and its right to submit any contentions in writing.
- (2) As demonstrated by undated return receipt, signed by Khalida Rahman, Syed Rahman received the letter of January 13, 2005, informing him of the allegations and the proposal to deny his application for registration as a Wholesale Distributor of Dangerous Drugs license, and his rights.
- (3) Saks Distributing has not responded in any manner to the letter of January 13, 2005, and has not requested a hearing in this matter; therefore the matter was referred to the Board for consideration.
- (4) Records of the Board of Pharmacy indicate that on or about November 16, 2004, Syed Rahman was the owner and president of Saks Distributing, and that on said date Syed Rahman applied for registration as a Wholesale Distributor of Dangerous Drugs. Records further reflect that on April 5, 2004, the Board permitted the withdrawal of Saks Distributing's application, dated September 10, 2003, for Registration as a Wholesale Distributor of Dangerous Drugs.

CONCLUSIONS OF LAW

- (1) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (5) through (7), (9) and (10) of the Findings of Fact constitute failure to meet the qualifications set forth in Section 4729.53(A) of the Ohio Revised Code.
- (2) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2) through (7) of the Findings of Fact constitute failure to furnish satisfactory proof to the Board that granting a registration certificate to Saks Distributing is in the public interest as provided in Section 4729.53(B) of the Ohio Revised Code.

DECISION OF THE BOARD

Pursuant to Section 4729.52(A) of the Ohio Revised Code, the State Board of Pharmacy hereby refuses to register Saks Distributing and, therefore, denies the Application for Registration as a Wholesale Distributor of Dangerous Drugs submitted November 16, 2004.

The motion was seconded by Mrs. Teater and approved by the Board: *Aye* – 7.

Mr. Giacalone then moved that the Board adopt the following order in the matter of Douglas Birkhimer, R.Ph.:

R-2005-165

ORDER OF THE STATE BOARD OF PHARMACY

Docket Number D-040719-004

in the matter of:

DOUGLAS EDWARD BIRKHIMER, R.PH.

3774 Adell Road
Columbus, Ohio 43228

R.Ph. Number 03-1-24341

INTRODUCTION

The matter of Douglas Edward Birkhimer came for hearing on April 12, 2005, before the following members of the Board: Lawrence J. Kost, R.Ph. (*presiding*); Gregory Braylock, R.Ph.; Suzanne R. Eastman, R.Ph., Robert P. Giacalone, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; Dorothy S. Teater, Public Member; and James E. Turner, R.Ph.

Douglas Edward Birkhimer was represented by Daniel D. Connor and the State of Ohio was represented by Sally Ann Steuk, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witnesses None

Respondent's Witnesses: Douglas Edward Birkhimer, R.Ph., Respondent
Amy Birkhimer
Nick Kallis, R.Ph.
Michael Quigley, R.Ph.
Bill Ringle

State's Exhibits

1. Reinstatement Hearing Request letter from Daniel D. Connor [07-07-04]
- 1A-1D. Procedurals
2. State Board of Pharmacy Order in re Douglas Edward Birkhimer, R.Ph. [12-10-03]
- 3.
4. Notarized Statement of Douglas E. Birkhimer [03-21-03]
- 5.

Respondent's Exhibits

- A1. PRO Pharmacist's Recovery Contract for Doug Birkhimer [12-17-03]

- A2. The Woods at Parkside Treatment Compliance letter from Kerry Kennedy, MSW, LISW, CCDCIII [11-22-04]; Authorization to Disclose Information Form [03-24-05]; Continuing Care Attendance Log and Progress Notes [11-10-03 to 02-07-05]
 - A3. PRO Licensee Summary Report [07-08-03 to 03-21-05]; PRO Drug Panel [not dated]
 - A4. Support Group Attendance Records [10-28-03 to 03-06-05]
 - A5.
 - A6. Affidavit of Restitution for Douglas E. Birkhimer [04-05-05]
 - A7. Seven letters of Support [-3-07-05 to 03-30-05]
 - A8. Summary Reports of Continuing Pharmacy Education Exam History from U.S. Pharmacist [02-19-03 to 06-14-03] and from Pharmacist's Letter [02-21-03 to 08-29-04]; twenty-one Continuing Pharmaceutical Education Credits and Certificates [04-25-04 to 03-13-05]
- B.

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 Douglas Edward Birkhimer has complied with the terms set forth in the Order of the State Board of Pharmacy, Docket No. D-030409-064, 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. 03-1-24341, held by Douglas Edward Birkhimer to practice pharmacy in Ohio conditioned upon the placement of Douglas Edward Birkhimer on probation for five years beginning on the effective date of this Order, with the following conditions:

- (A) Douglas Edward Birkhimer 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) Zolpidem, hydrocodone, and tramadol must be added to the standard urine drug screen.
 - (c) Results of all drug screens must be negative. Refusals of urine screens or diluted urine screens are equivalent to a positive result. 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.
 - (2) The intervener/sponsor shall provide copies of all drug and alcohol 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) Douglas Edward Birkhimer 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 Douglas Edward Birkhimer's progress towards recovery and what Douglas Edward Birkhimer 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 Douglas Edward Birkhimer'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) Douglas Edward Birkhimer may not serve as a responsible pharmacist.
 - (3) Douglas Edward Birkhimer may not destroy, assist in, or witness the destruction of controlled substances.
 - (4) Douglas Edward Birkhimer must abide by the contract with his treatment provider and must immediately report any violation of the contract to the Board.
 - (5) Douglas Edward Birkhimer must not violate the drug laws of Ohio, any other state, or the federal government.
 - (6) Douglas Edward Birkhimer must abide by the rules of the State Board of Pharmacy.
 - (7) Douglas Edward Birkhimer must comply with the terms of this Order.
- (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.

Douglas Edward Birkhimer 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.

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

5:30 p.m. The meeting was recessed until Wednesday, April 13, 2005.

WEDNESDAY, APRIL 13, 2005

8:07 a.m. The State Board of Pharmacy convened in Room East B, 31st Floor, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio with the following members present:

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

The Board discussed the FY06-07 Budget as it had passed the House and was about to begin hearings in the Senate. There were no items requiring official action by the Board.

After a discussion of the draft minutes from the March 7-8, 2005 meeting, Mrs. Gregg moved that the minutes be approved as amended. The motion was seconded by Mr. Lipsyc and approved unanimously by the Board: *Aye – 7.*

R-2005-166 Mr. McMillen then presented a request for an exemption from Rule 4729-5-10 (Prescription pick-up station) received from the following sites:

Medicine Shoppe (02-0450000)
Doctor's Urgent Care (02-0367250)

After discussion, Mrs. Eastman moved that the Board deny the request as it did not meet the criteria for exemption specified in the rule. The motion was seconded by Mrs. Gregg and approved by the Board: *Aye – 7.*

R-2005-167 Mr. McMillen then presented a request for approval of a remote access order processing pharmacy received from **Medistar Healthcare Connections Corporation** of Phoenix, AZ (TDDD Pending). After discussion, Mr. Braylock moved that the Board find this to be approvable pending final inspection after the first Ohio site is added. The motion was seconded by Mrs. Eastman and approved by the Board: *Aye – 7.*

Mr. Rowland then discussed a proposed new Board policy on granting continuances of hearings and on proposed settlement agreements to be considered by the Board. After discussion, Mr. Turner moved that the Board rescind all previous policies on this subject and adopt the following policy:

R-2005-168 **BOARD POLICY ON HEARING CONTINUANCES AND SETTLEMENT AGREEMENTS**

1. Continuance requests must be requested 45 days prior to the scheduled hearing (absent an emergency or special circumstances), or they will be presented to the Board for consideration at the next scheduled meeting. Absent special circumstances, continuances will not be granted for the sole purpose of facilitating settlement negotiations.
2. A request for settlement without a hearing must be presented to the Board at least 60 days prior to the week of the hearing.

The motion was seconded by Mrs. Teater and approved by the Board: *Aye – 7.*

Mr. Benedict and Mr. Lipsyc presented the Probation Report. There were no issues requiring official action by the Board.

R-2005-169 Mr. Benedict then presented a request for an exemption to Rule 4729-5-11 (Responsible person) requesting that **Nick Femia**, R.Ph., be permitted to be the Responsible Pharmacist for the following Terminal Distributor of Dangerous Drugs licenses:

Mahoning Valley Hospital/Youngstown (02-1390500)
Mahoning Valley Hospital/Trumbull (02-1390450)

After discussion, Mrs. Eastman moved that the Board approve this request for 90 days. The motion was seconded by Mrs. Gregg and approved by the Board: *Aye – 7.*

R-2005-170 The Board next considered a request for an exemption from Rule 4729-5-10 (Prescription pick-up station) received from the following sites:

Teregen Laboratories (02-1235150)
Various Physician Office contained in the letter of request

After discussion, Mr. Giacalone moved that the Board approve the request as long as the parties to the request comply with the requirements in the rule for such an exemption. The motion was seconded by Mr. Braylock and approved by the Board: *Aye – 7.*

Mr. Braylock reported on the recent meeting of the Nursing Board's Committee on Prescriptive Governance (CPG). There were no items requiring official action by the Board.

8:57 a.m. The Board took a brief recess.

9:12 a.m. The meeting resumed. Mr. Keeley discussed his Budget Report with the Board.

R-2005-171 Mr. Keeley then discussed the fact that a Board approved electronic prescribing system, **RXMadeSimple**, had changed its name to **MedPlus**. He asked that the Board approve the name change so that the Board records and approvals could be adjusted. After discussion, Mrs. Gregg moved that the Board approve the name change to MedPlus and that the list of Board approved electronic prescribing systems be adjusted accordingly. The motion was seconded by Mr. Lipsyc and approved by the Board: *Aye – 7.*

R-2005-172 Mr. Keeley then discussed a new electronic prescribing system, **Epic Electronic Prescribing System**, which requested Board approval for its installation at the Cleveland Clinic. After discussion, Mr. Braylock moved that the Board find the Epic Electronic Prescribing System at the Cleveland Clinic to be approvable, pending final inspection of the installed product. The motion was seconded by Mr. Turner and approved by the Board: *Aye – 7.*

9:41 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 David R. James, R.Ph., Hamilton.

11:42 a.m. The hearing was recessed for lunch.

1:21 p.m. The hearing resumed.

6:45 p.m. The hearing ended and the record was closed. The Board took a brief recess.

6:54 p.m. The meeting resumed. Mr. Keeley presented a request from the **ddn Corporation** for Board approval of their Automated Product Machine (APM) system. After discussion, the consensus of the Board was that this subject should be tabled until representatives of the company could be present to answer the Board's questions.

Mr. Keeley distributed his Legislative Report to the Board.

The Board next considered a request for an exemption from Rule 4729-5-10 (Prescription pick-up station) received from **Home Care Solutions Pharmacy** so that antibiotics to be administered by the patient through a peripherally inserted central catheter (PICC) could be delivered to the patient's physician for distribution to the patient. After discussion, the Board tabled this request pending further discussion with the pharmacy by Board staff.

R-2005-173 Mr. Winsley presented a request for an exemption to Rule 4729-5-11 (Responsible person) requesting that **Amy Youst**, R.Ph., be permitted to be the Responsible Pharmacist for the following Terminal Distributor of Dangerous Drugs licenses, both located at the same address:

Olde Town Medicine & Sundries (02-1477400)
Continuum Care Pharmacy (Pending)

After discussion, Mr. Braylock moved that the Board approve this request for one year. The motion was seconded by Mrs. Gregg and approved by the Board: Aye – 7.

7:06 p.m. Mrs. Gregg moved that the Board go into Executive Session to investigate complaints regarding licensees and registrants pursuant to Section 121.22(G)(1) of the Revised Code. The motion was seconded by Mr. Turner and a roll-call vote was conducted by President Kost as follows: Braylock – yes; Giacalone – yes; Gregg – yes; Lipsyc – yes; Mitchell – yes; Teater – yes; and Turner – yes.

7:30 p.m. 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 David R. James, R.Ph.:

R-2005-174

ORDER OF THE STATE BOARD OF PHARMACY

Docket Number: D-040805-008

in the matter of:

DAVID R. JAMES, R.PH.
6897 Southampton Lane
Hamilton, Ohio 45011

R.Ph. Number 03-1-20960

INTRODUCTION

The matter of David R. James came for hearing on April 13, 2005, before the following members of the Board: Lawrence Kost, R.Ph., (*presiding*); Gregory Braylock R.Ph.; Suzanne Eastman, R.Ph.; Robert. Giacalone; R.Ph.; Elizabeth Gregg; R.Ph.; Nathan Lipsyc; R.Ph.; Dorothy Teater; Public Member; and James Turner, R.Ph.

David R. James was represented by Mark. W. Napier and the State of Ohio was represented by Sally Ann Steuk, Assistant Attorney General

SUMMARY OF EVIDENCE

State's Witnesses: David R. James, R.Ph., Respondent
Richard Haun, Ohio State Board of Pharmacy
Rod MacGregor, M.D.
Kevin Murphy
Joanne Morgan, R.Ph.
Jeanne Getter, R.Ph.

Respondent's Witnesses: Jill James
David R. James, R.Ph., Respondent

State's Exhibits:

1. Notice of Opportunity For Hearing letter [08-05-04]
- 1A-1B. Procedurals
- 1C. Addendum Notice letter [12-16-04]
- 1D-1J. Procedurals
2. LabCorp Chain of Custody Form [05-30-03]; LabCorp Drug Screen Report [05-30-03]; Excel Corporate Care MRO Flowsheet [06-10-03]
3. Dangerous Drug Distributor Inspection Report of Middcare, Inc. [05-28-03]

4. Three Accountability Statements completed at Middcare Pharmacy for the following drugs: Hydrocodone 10/500; Hydrocodone 10/650; and Hydrocodone 10/660 [07-22-03]
5. Notarized Statement of Carol LeRoy [01-25-05]
6. Notarized Statement of Kevin M. Murphy [01-18-05]
7. Notarized Statement of Dan Weiss [01-18-05]
8. Notarized Statement of Jeanne Getter [01-18-05]
9. Notarized Statement of Fay Smillie [02-15-05]
10. Notarized Statement of Rod McGregor, M.D. [02-17-05]
11. Two DEA Reports of Theft or Loss of Controlled Substances of Middcare Pharmacy [06- 03-03]
12. Three letters of resignation from David R. James [06-02-03 to 06-04-03]; Letter to the Ohio State Board of Pharmacy from David R. James [not dated]

Respondent's Exhibits

- A. Resume of David R. James, R.Ph. [not dated].
- B. The Children's Hospital Discharge Summary for David R. James [04-20-69].
- C-E. Four page Indiana University Medical Center Medical Record for David R. James [07-27-94].
- F. Letter from Daniel H. Walters, M.D. and Mina H. Lutts, M.D. [02-22-05]
- G. Seven-page Middletown Regional Health System Annual Review of David R. James [08-27-02].
- H. Five page Middletown Regional Hospital Performance/Competency Assessment of David R. James [12-14-98].
- I. Three page E-mail letter between David R. James and Joanne Morgan [09-28-01 to 10-01-01].
- J. E-mail letter from David R. James to Kevin Murphy [12-17-02].
- K. Two-page Middcare Pharmacy 2003 Strategic Business Plan [not dated].
- L. Four-page Middletown Regional Hospital Project Justification form [02-13-03].
- M. Medical Report of David R. James [10-11-95].
- N. Two-page Middcare Inc. Financial Review, December 2001.
- O. Two-page MRH Owes Middcare Report [03-01-03 to 03-31-03].
- P. E-mail letter from Jenny Stoops to David R. James [02-05-03].
- Q. Letter from Robin N. Piper, Butler County Prosecuting Attorney to Mark W. Napier [09-03-04].
- R. Public Records request letter from Mark W. Napier [08-30-04]; reply to public records request letter from Sally Ann Steuk, Ohio State Board of Pharmacy [09-08-04]; Reply letter from Mark Napier [09-15-04].
- S. Six-page facsimile for Subpoena Requests from Mark W. Napier [02-17-05].
- T. Middcare Pharmacy Policy and Procedure for "After Hours Access into Middcare Pharmacy" [Revised May 29, 2003].
- U. Middletown Regional Hospital Security Report [05-22-03].
- V. Two-page Medco Health Solutions Performance Review of David James [11-16-04].
- W. Letter from Lisa A. Martinex, RN/JD to Mark W. Napier [04-06-05]; two Subpoenas for Middletown Regional Hospital Custodian of Records and Middcare Pharmacy Custodian of Records [03-07-05].
- X. Two-page Middcare, Inc. Policy and Procedure for "Drug Inventory" [Revised March, 2002].
- Y. Two-page Middcare, Inc. Policy and Procedure for "Middcare Pharmacy Quality Assessment and Improvement Plan" [Revised March, 2002].
- Z. Middcare, Inc. Policy and Procedure for "The Administration of Drugs in Accordance with Licensure, Laws and Regulations" [Revised March, 2002].
- AA. Middcare, Inc. Policy and Procedure for "Cash and Controlled Drug Storage and Security" [Revised March, 2002].
- BB. Middcare, Inc. Policy and Procedure, with attachment for "After Hours Access into Middcare Pharmacy" [Revised March, 2002].
- CC. Middletown Regional Hospital Purchase Order Listing [03-02-05].

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 the following to be fact:

- (1) Records of the State Board of Pharmacy indicate that David R. James was originally licensed in the State of Ohio on March 7, 1995, pursuant to reciprocity, and is currently licensed to practice pharmacy in the State of Ohio.
- (2) David R. James, as Responsible Pharmacist did, on or about May 31, 2001 to May 31, 2003, fail to provide "supervision and control" of dangerous drugs as required in Section 4729.55(B) of the Revised Code, and "adequate safeguards" to assure that dangerous drugs are being distributed in accordance with all state and federal laws as required in Section 4729.55(C) of the Revised Code, to wit: David R. James worked in the pharmacy approximately 10 hours per week; and, when drugs were missing, David R. James did not fill out appropriate forms. The Board specifically finds that David R. James' testimony was contrived and not credible. David R. James' performance or lack thereof, fell far short of the necessary functioning of a responsible pharmacist. Such conduct is in violation of Rule 4729-9-11 of the Ohio Administrative Code.
- (3) David R. James, as Responsible Pharmacist did, on or about May 31, 2001 to May 31, 2003, fail to provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs, to wit: the following drugs were diverted from the pharmacy without adequate detection and/or prevention:

Drug	Strength	Amount
Hydrocodone	10/500 mg	1834
Hydrocodone	10/650 mg	8653
Hydrocodone	10/660 mg	2497

The Board specifically finds that David R. James' testimony was contrived and not credible. David R. James' recordkeeping, especially the use of white-out on pharmacy records, was unacceptable. Further, David R. James' testimony regarding drug returns defies industry standards, and was rejected by the Board as not credible. Such conduct is in violation of Rule 4729-9-05 of the Ohio Administrative Code and is not in accordance with Section 4729.55 of the Ohio Revised Code and, constitutes willfully violating a rule of the Board a provision of Chapter 4729. of the Ohio Revised Code and/or within the meaning of Section 4729. of the Ohio Revised Code.

CONCLUSIONS OF LAW

- (1) The State Board of Pharmacy concludes that paragraphs (2) and (3) 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.
- (2) 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 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 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 David R. James 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 on David R. James a monetary penalty of one thousand dollars (\$1,000.00) due and owing on or before June 5, 2005. 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.
- (B) On the basis of the Findings of Fact and Conclusions of Law set forth above, the State Board of Pharmacy hereby places David R. James on probation for two years from the effective date of this Order with the following conditions:
- (1) David R. James must obtain, within one hundred-eighty days from the effective date of this Order, two hours (0.2 CEUs) of Board approved continuing pharmacy education in jurisprudence, which may not also be used for license renewal. If proof of successful completion is not submitted to the Board office before the end of the probation period, David R. James will remain on probation until this condition is achieved.
 - (2) The State Board of Pharmacy hereby declares that David R. James'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) David R. James may not serve as a responsible pharmacist.
 - (4) David R. James must not violate the drug laws of Ohio, any other state, or the federal government.
 - (5) David R. James must abide by the rules of the State Board of Pharmacy.
 - (6) David R. James must comply with the terms of this Order.
- (C) 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.

David R. James 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.

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

After a discussion about the central fill program proposed by Medco, the consensus of the Board was that a decision on the issue should be tabled until the Medco representatives and Board staff meet to resolve some identified issues.

7:38 p.m.

Mr. Turner moved that the Board receive Per Diem as follows:

<u>PER DIEM</u>	<u>4/11</u>	<u>4/12</u>	<u>4/13</u>	<u>4/14</u>	<u>Total</u>
Braylock	1	1	1		3
Eastman		1	1		2
Giacalone		1	1		2
Gregg		1	1		2
Kost		1	1		2
Lipsyc		1	1		2
Mitchell		1	1	1	3
Teater		1	1		2
Turner		1	1		2

The motion was seconded by Mrs. Teater and approved by the Board: *Aye* – 7.

7:39 p.m. Mr. Lipsyc moved that the meeting be adjourned. The motion was seconded by Mrs. Gregg and approved by the Board: *Aye* – 7.

<p>THE OHIO STATE BOARD OF PHARMACY APPROVED THESE MINUTES MAY 3, 2005</p>
