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Minutes of the November 3-4, 2014 Meeting of the Ohio State Board of Pharmacy

Monday, November 3, 2014

10:00 a.m.

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

Michael A. Moné, R.Ph., *President*; Kilee S. Yarosh, R.Ph., *Vice President*; Margaret A. Huwer, R.Ph.; Richard F. Kolezynski, R.Ph.; Megan E. Marchal, R.Ph. and Fred M. Weaver, R.Ph.

Also present were Eric Griffin, Interim Executive Director; Kevin Mitchell, Assistant Executive Director; David Gallagher, Interim Compliance Supervisor; Chad Garner, Director of OARRS; Cameron McNamee, Legislative Affairs Liaison; Tracy Nave, Director of Legal Affairs; Jennifer Utterdyke, Director of Internship and Licensing and Charissa Payer, Assistant Attorney General.

Ms. Huwer provided the PAPC meeting report.

Mr. Gallagher provided the Compliance and Enforcement update.

Mr. Garner provided the OARRS/I.T. report.

R-2015-110

The Board received an application for the Continuing Education Provider Status of **Julie Drake**, **Pharm D.** (03-1-27617) Uniontown, Ohio. Mr. Kolezynski moved that the Continuing Education Provider Status be approved. The motion was seconded by Ms. Huwer and approved by the Board: Aye – 5.

R-2015-111

The Board received an application for the Continuing Education Provider Status of **Christopher Droege, R.Ph.** (03-3-28927) Cincinnati, Ohio. Ms. Huwer moved that the Continuing Education Provider Status be approved. The motion was seconded by Ms. Marchal and approved by the Board: Aye -5.

R-2015-112

The Board received an application for the Continuing Education Provider Status of **Sarah Start, R.Ph.** (03-2-19448) Granville, Ohio. Ms. Yarosh moved that the Continuing Education Provider Status be approved. The motion was seconded by Mr. Kolezynski and approved by the Board: Aye -5.

10:08 a.m.

Mr. Kolezynski moved that the Board go into Executive Session to consider the employment (dismissal, discipline, promotion, demotion, compensation, appointment) of a public employee and matters required to be confidential by law pursuant to Section 121.22(G)(1), (3) & (5) of the Ohio Revised Code. The motion was seconded by Ms.

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Marchal and a roll-call vote was conducted by President Moné as follows: Huwer – yes; Kolezynski –yes; Marchal – yes; Weaver – yes; and Yarosh – yes.

<u>11:20 a.m.</u> The executive session ended and the meeting was opened to the public.

A request for approval for the Parata Pass system was presented to the Board by **Joseph Wittrock**, **Pharm D.**, owner of *LifeLife Pharmacy*. The Board tabled the discussion and will revisit at the December meeting.

<u>12:00 p.m.</u> Ms. Utterdyke provided the Licensing update.

R-2015-113 The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that **William F. Smith**, **Pharm D**. (03-3-20174) East Liverpool, Ohio, be the responsible person for the following pharmacies:

East Liverpool City Hospital (hospital), East Liverpool (02-0630500) East Liverpool City Hospital (hospital), East Liverpool (02-0399350)

After discussion, Mr. Kolezynski moved that the Board approve the request for a period of one year. The motion was seconded by Ms. Yarosh and approved by the Board: Aye - 5.

R-2015-114 The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that **Amy Schwan, R.Ph.** (03-2-23448) Castalia, Ohio, be the responsible person for the following pharmacies:

Bellevue Home Medical Pharmacy (nursing home), Bellevue (02-0721200) The Medicine Shoppe (retail), Bellevue (02-0676450)

After discussion, Ms. Marchal moved that the Board approve the request for a period of one year. The motion was seconded by Mr. Weaver and approved by the Board: Aye – 5.

R-2015-115 The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that **William Carroll, R.Ph.** (03-3-11842) Amelia, Ohio, be the responsible person for the following pharmacies:

Mercy Hospital Anderson (hospital), Cincinnati (02-0384850) Mercy Hospital Anderson Outpatient (hospital), Cincinnati (02-1992150)

Mr. Kolezynski moved that the Board table the discussion for additional information. The motion was seconded by Ms. Yarosh and approved by the Board: Aye - 5.

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R-2015-116

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that **Monica Lavelle**, **R.Ph.** (03-3-19954) North Olmstead, Ohio, be the responsible person for the following pharmacies:

Ohliger Drug Long Term Care (nursing home), North Olmstead (02-1637400) Ohliger Drug of North Olmstead, Inc. (retail), North Olmstead (02-0122900)

After discussion, Mr. Kolezynski moved that the Board approve the request for a period of one year after an inspection by the Ohio State Board of Pharmacy. The motion was seconded by Mr. Weaver and approved by the Board:

Aye – 5.

R-2015-117

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that **Mark Scovotti**, **R.Ph.** (out of state) Hoboken, New York, be the responsible person for the following pharmacies:

Metro Drugs (nonresident), New York (02-2342300) Metro Drugs (nonresident), Hoboken (02-2134050)

After discussion, Ms. Yarosh moved that the Board approve the request for a period of one year. The motion was seconded by Mr. Weaver and approved by the Board: Aye – 5.

R-2015-118

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that **Amy Myers**, **R.Ph.** (03-1-20444) Bluffton, Ohio, be the responsible person for the following pharmacies:

Pharmacy Solutions (nursing home), Pandora (02-2023900) Riley Creek Pharmacy (retail), Pandora (02-2023650)

After discussion, Ms. Huwer moved that the Board approve the request for a period of one year. The motion was seconded by Mr. Kolezynski and approved by the Board: Aye – 5.

R-2015-119

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that **Mara Weber**, **R.Ph.** (03-1-32287) Sugar Grove, Ohio, be the responsible person for the following pharmacies:

Ohio Health Emergency Care Center (retail), Westerville (02-2218250) Ohio Health Emergency Care Center (hospital), Westerville (02-2206050)

After discussion, Ms. Yarosh moved that the Board approve the request for a period of one year. The motion was seconded by Mr. Kolezynski and approved by the Board: Aye – 4/Abstain– 1.

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R-2015-120

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that **Janice Knight-Cooper**, **Pharm D.** (out of state) Los Angeles, California, be the responsible person for the following pharmacies:

Manchester Professional Pharmacy (nonresident), Los Angeles (02-2380850) Hawthrone Professional Pharmacy (nonresident), Los Angeles (02-2405100)

After discussion, Mr. Kolezynski moved that the Board approve the request for a period of one year. The motion was seconded by Ms. Marchal and approved by the Board: Aye – 5.

12:30 p.m. The Board recessed for lunch.

<u>1:35 p.m.</u> The meeting reconvened in Room South B&C.

The Board was joined by Assistant Attorney General Charissa Payer to create a record in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of **Global Health Advocates**, Dublin, Ohio.

<u>1:44 p.m.</u> The hearing ended and the record was closed.

The Board was joined by Assistant Attorney General Charissa Payer to create a record in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of **Health Maintenance Partners, Inc.**, Lucasville, Ohio.

<u>1:52 p.m.</u> The hearing ended and the record was closed.

The Board was joined by Assistant Attorney General Charissa Payer to create a record in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of **Rockwell Compounding Associates, Inc.**, Rye, New York.

<u>2:09 p.m.</u> The hearing ended and the record was closed.

Ms. Yarosh moved that the Board recess in order to consider these quasi-judicial matters in accordance with Chapter 119. of the Revised Code and the case precedent of *Angerman v. State Medical Bd.* (1990) 70 Ohio App.3d 346 and *TBC Westlake Inc. v. Hamilton Cty Bd of Revision, et al.* (1998) 81 Ohio St.3d 58. The motion was seconded by Ms. Huwer and a roll-call vote was conducted by President Moné as follows: Huwer – yes; Kolezynski –yes; Marchal – yes; Weaver – yes; and Yarosh – yes.

<u>2:24 p.m.</u> The recess ended and the hearing was opened to the public.

R-2015-121 After votes were taken in public session, the Board adopted the following order in the matter of **Global Health Advocates**, Dublin, Ohio.

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ORDER OF THE STATE BOARD OF PHARMACY

(Case Number 2013-1662)

In The Matter Of:

Global Health Advocates

c/o Shaban Mahmoud, M.D. 5186 Blazer Parkway Dublin, OH 43017

INTRODUCTION

The Matter of Gloabal Health Advocates came for consideration on November 3, 2014, before the following members of the Board: Michael A. Moné, R.Ph.; (presiding); Margaret A. Huwer, R.Ph.; Richard F. Kolezynski, R.Ph.; Megan E. Marchal, R.Ph.; Fred M. Weaver, R.Ph. and Kilee S. Yarosh, R.Ph.

Edward T. Cain, Absent. Melinda J. Ferris, Absent.

Global Health Advocates was not present nor represented by counsel. The State of Ohio was represented by Charissa D. Payer, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witness:

1. Kevin Flaharty, Ohio State Board of Pharmacy

Respondent's Witnesses:

None

State's Exhibits:

1.	Proposal to Deny/ Notice of Opportunity for Hearing	11-19-13
1A-B.	Procedurals	
2.	Ohio State Board of Pharmacy PMC Application	06-20-11
3.	State Medical Board of Ohio Certification	07-25-13
4.	Court of Common Pleas Franklin County Ohio Judgment	05-02-13
	Shaban A.E. Mahmoud, M.D. vs State Medical Board of Ohio	
	Case No. 13CVF02-01907	

Respondent's Exhibits:

None

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:

- Records of the Board of Pharmacy indicate that on or about June 17, 2011, Shaban (1) Mahmoud, M.D. was the owner of Global Health Advocates, 5186 Blazer Parkway, Dublin, Ohio 43017, and that on June 17, 2011, Global Health Advocates applied for registration as a Terminal Distributor of Dangerous Drugs with a Pain Management Clinic Classification.
- (2) Global Health Advocates have failed to furnish satisfactory proof to the Board that they comply with the requirements for the operation of a pain management clinic established by Sections 4729.55 and 4729.552 of the Revised Code. To wit: Shaban E. Mahmoud, M.D. owner, physician and responsible person, was disciplined by the State Medical Board of Ohio as a result of his failure to maintain minimal standards applicable to the selection or administration of drugs and/or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease. As a result of this discipline, Dr. Mahmoud's license to practice medicine and surgery was permanently revoked. In the Matter of ShabanA.E. Mahmoud, M.D. Before the State Medical Board of Ohio, Case No. 12-CRF- 022.

CONCLUSION OF LAW

The State Board of Pharmacy concludes that paragraph (2) of the Findings of Fact constitutes a violation of Section 4729.552(B)(1) of the Ohio Revised Code.

DECISION OF THE BOARD

Pursuant to Sections 3719.03, 4729.55 and 4729.52 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby refuses to license or register Global Health Advocates and, therefore, denies the Application for a Terminal Distributor of Dangerous Drugs with a Pain Management Clinic Classification submitted by Global Health Advocates on June 17, 2011.

Kilee Yarosh moved for Findings of Fact; Fred Weaver seconded the motion. Motion passed (Aye-5/Nay-0).

Kilee Yarosh moved for Conclusions of Law; Fred Weaver seconded the motion. Motion passed (Aye-5/Nay-0).

Megan Marchal moved for Action of the Board; Margaret Huwer seconded the motion. Motion passed (Aye-5/Nay-0).

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R-2015-122 After votes were taken in public session, the Board adopted the following order in the matter of **Health Maintenance Partners**, **Inc.**, Lucasville, Ohio.

ORDER OF THE STATE BOARD OF PHARMACY

(Case Number 2012-1387)

In The Matter Of:

Health Maintenance Partners, Inc.

c/o N. Jeannine Billiter 2021 Sunrise Avenue Portsmouth, OH 45662

INTRODUCTION

The Matter of Health Maintenance Partners, Inc. came for consideration on November 3, 2014, before the following members of the Board: Michael A. Moné, R.Ph.; (presiding); Margaret A. Huwer, R.Ph.; Richard F. Kolezynski, R.Ph.; Megan E. Marchal, R.Ph.; Fred M. Weaver, R.Ph. and Kilee S. Yarosh, R.Ph.

Edward T. Cain, Absent. Melinda J. Ferris, Absent.

Health Maintenance Partners, Inc. was not present nor represented by Counsel. The State of Ohio was represented by Charissa D. Payer, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witness:

1. Kevin Flaharty, Ohio State Board of Pharmacy

Respondent's Witnesses:

None

State's Exhibits:

1.	Proposal to Deny/ Notice of Opportunity for Hearing	03-26-13
1A-F.	Procedurals	
2.	Ohio State Board of Pharmacy PMC Application	06-12-11

Respondent's Exhibits:

None

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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 Board of Pharmacy indicate that on or about June 12, 2011, N. Jeannine Billiter was the Owner and President of Heath Maintenance Partners, Inc. and that on said date, Health Maintenance Partners, Inc. submitted an application for registration as a Terminal Distributor of Dangerous Drugs with a Pain Management Clinic Classification.
- (2) The Owner and President of Health Maintenance Partners, Inc. has failed to furnish satisfactory proof to the Board that the facility is owned and operated solely by one or more physicians authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery. Specifically, Health Maintenance Partners, Inc. is owned by N. Jeannine Billiter. Ms. Billiter is not licensed to practice medicine and surgery or osteopathic medicine and surgery in the state of Ohio.

CONCLUSION OF LAW

The State Board of Pharmacy concludes that paragraph (2) of the Findings of Fact is a violation of Section 4729.552(B)(1) of the Ohio Revised Code.

DECISION OF THE BOARD

Pursuant to Sections 3719.03, 4729.55 and 4729.52 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby refuses to license or register Health Maintenance Partners, Inc. and, therefore, denies the Application for a Terminal Distributor of Dangerous Drugs with a Pain Management Clinic Classification submitted by Health Maintenance Partners, Inc. on June 12, 2011.

Richard Kolezynski moved for Findings of Fact; Kilee Yarosh seconded the motion. Motion passed (Aye-5/Nay-0).

Kilee Yarosh moved for Conclusions of Law; Megan Marchal seconded the motion. Motion passed (Aye-5/Nay-0).

Richard Kolezynski moved for Action of the Board; Margaret Huwer seconded the motion. Motion passed (Aye-5/Nay-0).

R-2015-123

After votes were taken in public session, the Board adopted the following order in the matter of **Rockwell Compounding Associates**, **Inc.**, Rye, New York.

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ORDER OF THE STATE BOARD OF PHARMACY

(Case Number 2014-1190)

In The Matter Of:

Rockwell Compounding Associates, Inc.

c/o Steven J. Cosentino, R.Ph. 350 Theodore Fremd Ave., 3rd Floor Rye, New York 10580 (TDDD License No. 02-1614600)

INTRODUCTION

The Matter of Rockwell Compounding Associates, Inc. came for hearing on November 3, 2014, before the following members of the Board: Michael A. Moné, R.Ph.; (presiding); Margaret A. Huwer, R.Ph.; Richard F. Kolezynski, R.Ph.; Megan E. Marchal, R.Ph.; Fred M. Weaver, R.Ph. and Kilee S. Yarosh, R.Ph.

Edward T. Cain, Absent. Melinda J. Ferris, Abesnt.

Rockwell Compounding Associates, Inc. was not present nor represented by counsel. The State of Ohio was represented by Charissa D. Payer, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witness:

1. James Amend, R.Ph., Ohio State Board of Pharmacy

Respondent's Witnesses:

None

State's Exhibits:

1.	Summary Suspension Order/ Notice of Opportunity for Hearing	04-02-14
1A-1.	Procedurals	
2.	NYSED.gov Office of the Professions Verification Search	02-20-14
	for Rockwell Compounding Associates, Inc.	
3.	NYSED.gov Office of the Professions Verification Search	02-20-14
	for Steven J. Consentino	
4.	New York Education Department Original Vote and Order	12-11-13
	Numbers 27162 and 27163	
5.	NYSED License Verification for Rockwell Compounding	02-20-14
6.	NYSED License Verification for Steven J. Cosentino	10-24-14
7.	NYSED Pharmacy Informaton for Steven J. Cosentino	10-23-14

Monday, November 3, 2014 RECORD OF THE PROCEEDINGS

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Respondent's Exhibits:

None

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 Board of Pharmacy indicate that Steven J. Cosention is the responsible pharmacist at Rockwell Compounding Associates, Inc., 350 Theodore Fremd Ave., 3rd Floor, Rye, New York 10580, terminal distributor license number 02-1614600, pursuant to Sections 4729.27 and 4729.55 of the Ohio Revised Code and Rule [4729-5-11 or 4729-17-02] of the Ohio Administrative Code.
- (2) Rockwell Compounding Associates Inc., on or before September 25, 2013, did sell, deliver, offer for sale, and/or hold for sale an illegally compounded or manufactured drug in violation of state and federal law. To wit: Avastin 1.25 mg syringes were compounded and sold to the Delaware Eye Institute without a valid patient specific prescription for the drug, nor was there any other permissible reason to legally compound and sell the drug as required by Chapter 21, Section 353a of the United States Code, Section 4729.01 of the Ohio Revised Code, and Sections 4729-9-21 and 4729-9-25 of the Ohio Administrative Code.
- (3) Rockwell Compounding Associates Inc., on or before September 25, 2013, did sell, deliver, offer for sale, and/or hold for sale an illegally compounded or manufactured drug in violation of state and federal law. To wit: Avastin 1.25 mg syringes were compounded and sold to the Delaware Eye Institute and such drugs failed a sterility test conducted by Eagle Analytical Services which was reported to Rockwell Compounding Associates, Inc. on or around October 14, 2013.
- (4) Rockwell Compounding Associates Inc., ceased to satisfy the qualifications of a terminal distributor of dangerous drugs as its license issued by the New York State Board of Regents was summarily suspended on January 14, 2014. <u>In the Matter of Rockwell Compounding Associates, Inc.</u>, Original Vote and Order No. 27163, Jan. 14, 2014.

CONCLUSIONS OF LAW

(1) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2), (3), and (4) of the Findings of Fact constitute violating a

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rule of the Board as provided in Division (A)(2) of Section 4729.57 of the Ohio Revised Code.

- (2) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2), (3), and (4) of the Findings of Fact constitute violating provisions of the this Chapter as provided in Division (A)(3) of Section 4729.57 of the Ohio Revised Code.
- (3) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2), (3), and (4) of the Findings of Fact constitute violating any provisions of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 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.
- (4) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2), (3), and (4) of the Findings of Fact constitute falsely or fraudulently promoting to the public a dangerous drug as provided in Division (A)(6) of Section 4729.57 of the Ohio Revised Code.
- (5) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2), (3), and (4) of the Findings of Fact constitute ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in Section 4729.55 of the Revised Code as provided in Division (A)(7) 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 Rockwell Compounding Associates as follows:

(A) On the basis of the Findings of Fact and paragraph (1) of the Conclusions of Law, the State Board of Pharmacy hereby revokes permanently the terminal distributor license, No. 02-1614600, held by Rockwell Compounding Associates effective as of the date of the mailing of this Order.

Rockwell Compounding Associates, pursuant to Section 4729.57(C)(1) of the Ohio Revised Code, must return the license to the office of the State Board of Pharmacy immediately after receipt of this Order. The license should be sent by certified mail, return receipt requested.

Richard Kolezynski moved for Findings of Fact; Megan Marchal seconded the motion. Motion passed (Aye-5/Nay-0).

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Kilee Yarosh moved for Conclusions of Law; Margaret Huwer seconded the motion. Motion passed (Aye-5/Nay-0).

Margaret Huwer moved for Action of the Board; Richard Kolezynski seconded the motion. Motion passed (Aye-5/Nay-0).

2:32 p.m.

Mr. Kolezynski moved that the Board go into Executive Session to consider the investigation of charges or complaints against a licensee, confer with Board counsel regarding a pending or imminent court action and to discuss matters required to be confidential by law pursuant to Section 121.22(G)(1), (3) & (5) of the Ohio Revised Code. The motion was seconded by Mr. Weaver and a roll-call vote was conducted by President Moné as follows: Huwer – yes; Kolezynski –yes; Marchal – yes; Weaver – yes; and Yarosh – yes.

3:35 p.m. The executive session ended and the meeting was opened to the public.

R-2015-124

Mr. Weaver moved that the request for settlement presented by **Affiliated Podiatrists** (02-1871600) Mentor, Ohio, be accepted allowing for sufficient time for the preparation and approval of settlement documentation. The motion was seconded by Mr. Kolezynski and approved by the Board: Aye – 5.

R-2015-125

Mr. moved to dismiss the Notice of Opportunity for Hearing issued on July 2, 2014 against Mt. Auburn Urgent Care, LLC and allow for the substitution of a new application as requested by Mt. Auburn Urgent Care, LLC, such substitute application to be processed in the ordinary course. The motion was seconded by Mr. and approved by the Board: Aye - 5.

R-2015-126

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that **Kirk Betteridge**, **R.Ph.** (03-1-19028) Hilliard, Ohio, be the responsible person for the following pharmacies:

CDI Long Term Care, LLC (nursing home), Columbus (02-2070800) Crosby's Drugs, Inc. (retail), Columbus (02-0173000)

After discussion, Mr. Kolezynski moved that the Board approve the request for a period of one year after an inspection by the Ohio State Board of Pharmacy. The motion was seconded by Mr. Weaver and approved by the Board:

Aye – 5.

R-2015-127

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that **Patrick Howell, Pharm D.** (03-2-32918) West Chester, Ohio, be the responsible person for the following pharmacies:

The Craig and Frances Lindner (hospital), Mason (02-1816700)

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Cincinnati Children's Hospital (hospital), Cincinnati (02-2136250)

After discussion, Ms. Yarosh moved that the Board approve the request for a period of one year after an inspection by the Ohio State Board of Pharmacy. The motion was seconded by Mr. Kolezynski and approved by the Board: Aye – 5.

R-2015-128

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that **Michael Hoying**, **M.S.**, **R.Ph.** (03-1-17611) Medina, Ohio, be the responsible person for the following pharmacies:

Fairview General Hospital (hospital), Cleveland (02-0030050) Moll Center Pharmacy (specialty), Cleveland (02-1069200)

After discussion, Mr. Kolezynski moved that the Board approve the request for a period of one year after an inspection by the Ohio State Board of Pharmacy. The motion was seconded by Mr. Weaver and approved by the Board: Aye – 5.

R-2015-129

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that **Shady Arafa, R.Ph.** (03-1-31648) West Chester, Ohio, be the responsible person for the following pharmacies:

Best Pharmacy (retail), Dayton (02-2301900) Econo Pharmacy (retail), Springdale (02-2441350)

After discussion, Mr. Kolezynski moved that the Board approve the request for a period of two months. The motion was seconded by Ms. Huwer and approved by the Board: Aye - 5.

R-2015-130

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that **Najib Mawad**, **R.Ph.** (03-1-20929) Sylvania, Ohio, be the responsible person for the following pharmacies:

All-Care Pharmacy (nursing home), Swanton (02-2125950) Swanton Drug, Inc. (retail), Swanton (02-1459200)

After discussion, Ms. Huwer moved that the Board approve the request for a period of one year. The motion was seconded by Ms. Yarosh and approved by the Board: Aye -5.

R-2015-131

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that **Shawn Roe**, **Pharm D**. (out of state) Coralville, Iowa, be the responsible person for the following pharmacies:

VetRX Direct (nonresident), Coralville (02-1757400)

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Nucara Pharmacy #1 (nonresident), Coralville (02-2298300)

After discussion, Ms. Marchal moved that the Board approve the request for a period of one year. The motion was seconded by Mr. Weaver and approved by the Board: Aye - 5.

R-2015-132

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that **Lisa Dimick**, **R.Ph.** (out of state) Sandy, Utah, be the responsible person for the following pharmacies:

PCM Venture I, LLC (nonresident), Sandy (02-1621200) Bella Brands, LLC (nonresident), Sandy (02-2274700)

After discussion, Ms. Marchal moved that the Board approve the request for a period of one year. The motion was seconded by Ms. Huwer and approved by the Board: Aye - 5.

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The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that **Christina Barnes**, **R.Ph**. (03-1-22591) Bucyrus, Ohio, be the responsible person for the following pharmacies:

Galion Community Hospital, Inc. (hospital), Galion (02-0029100) Retail Pharmacy (retail), Mansfield (not yet applied for)

Ms. Yarosh moved that the Board table the discussion until application for the Mansfield facility is received. The motion was seconded by Ms. Marchal and approved by the Board: Aye - 5.

R-2015-134

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that **Donald Wiley**, **R.Ph.** (03-3-14220) Marion, Ohio, be the responsible person for the following pharmacies:

Marion Prescription Institutional RX (nursing home), Marion (02-1878900) Marion Prescription (retail), Marion (02-1292200)

After discussion, Ms. Yarosh moved that the Board approve the request for a period of one year. The motion was seconded by Mr. Weaver and approved by the Board: Aye – 5.

R-2015-135

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 requesting that **Rao Kamran Ali, M.D.** (35.095398) Mansfield, Ohio, be the responsible person for the following pain management clinics:

Mansfield Pain Clinic (pain management clinic), Mansfield (02-2443400) Pain Management Clinic (pain management clinic), Marion (not yet applied for)

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Mr. Kolezynski moved that the Board table the discussion until application for the Marion facility is received. The motion was seconded by Ms. Yarosh and approved by the Board: Aye – 5.

R-2015-136

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 requesting that **Kamel Abraham**, **M.D.** (35.054847) Springfield, Ohio, be the responsible person for the following pain management clinics with specific days and times of oversight:

Associated Anesthesiology (pain management clinic), Springfield (02-2139150) Associated Pain Medicine (pain management clinic), Springfield (02-2339250) Innovative Pain Solutions (pain management clinic), Springfield (02-2225300)

After discussion, Ms. Huwer moved that the Board approve the specific request for a period of three months. The motion was seconded by Ms. Yarosh and approved by the Board: Aye - 4/Nay - 1.

R-2015-137

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 requesting that **Gulam Mukhdomi**, **M.D.** (35.083053) Dayton, Ohio, be the responsible person for the following pain management clinics with specific days and times of oversight:

Chronic Pain Resources (pain management clinic), Grove City (02-2138950) Chronic Pain Resources (pain management clinic), Columbus (02-2344200)

After discussion, Ms. Yarosh moved that the Board approve the specific request for a period of three months. The motion was seconded by Mr. Weaver and approved by the Board: Aye - 4/Nay - 1.

R-2015-138

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 requesting that **Tim Chowdhury**, **M.D.** (35.080788) Dublin, Ohio, be the responsible person for the following pain management clinics with specific dates and times of oversight:

Ortho-Spine Rehabilitation Center (pain management clinic), Dublin (02-1690700) Ortho-Spine Rehabilitation Center, Inc. (pain management clinic), Marion (02-2322800)

After discussion, Ms. Yarosh moved that the Board approve the specific request for a period of three months. The motion was seconded by Mr. Weaver and approved by the Board: Aye - 4/Nay - 1.

R-2015-139

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 requesting that **Ricardo Buenaventura**, **M.D.** (35.069740) Beavercreek, Ohio, be the

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responsible person for the following pain management clinics with specific days and times of oversight:

Pain Relief of Dayton (pain management clinic), Centerville (02-2144800) Pain Relief of Dayton (pain management clinic), Vandalia (02-2144850)

After discussion, Ms. Huwer moved that the Board approve the specific request for a period of three months. The motion was seconded by Ms. Marchal and approved by the Board: Aye - 4/Nay - 1.

R-2015-140

The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 requesting that **Tracy Neuendorf**, **D.O.** (34.003509) Warren, Ohio, be the responsible person for the following pain management clinics:

Doctors Pain Clinic (pain management clinic), Youngstown (02-1774850) Doctors Pain Clinic (pain management clinic), Youngstown (02-1800950)

Ms. Marchal moved that the Board table the discussion until such time an inspection is completed by the Ohio State Board of Pharmacy. The motion was seconded by Ms. Yarosh and approved by the Board: Aye – 4/Nay– 1.

4:30 p.m.

Ms. Marchal moved that the Board go into Executive Session to consider the employment (dismissal, discipline, promotion, demotion, compensation, appointment) of a public employee and matters required to be confidential by law pursuant to Section 121.22(G)(1), (3) & (5) of the Ohio Revised Code. The motion was seconded by Ms. Huwer and a roll-call vote was conducted by President Moné as follows: Huwer – yes; Kolezynski –yes; Marchal – yes; Weaver – yes; and Yarosh – yes..

4:55 p.m. The executive session ended and the meeting was opened to the public.

The Board recessed for the day.

Tuesday, November 4, 2014

8:30 a.m.

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

Michael A. Moné, R.Ph., *President*; Kilee S. Yarosh, R.Ph., *Vice President*; Margaret A. Huwer, R.Ph.; Richard F. Kolezynski, R.Ph.; Megan E. Marchal, R.Ph. and Fred M. Weaver, R.Ph.

R-2015-141

Mr. Kolezynski moved that the Board Minutes of October 6-8, 2014, be approved as amended. The motion was seconded by Ms. Marchal and approved by the Board:

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Aye - 4/Nay - 0/Abstain - 1.

R-2015-142 Mr. Kolezynski moved that the Board Conference Call Minutes of October 2, 2014, be approved as written. The motion was seconded by Ms. Yarosh and approved by the Board: Aye – 5.

<u>8:35 a.m.</u> Mr. McNamee provided the Legislative Report.

R-2015-143 After discussion Ms. Yarosh moved that the adoption of the Rules packet for 4729-8 be approved for CSI and JCARR. The motion was seconded by Ms. Marchal and approved by the Board: Aye – 5.

R-2015-144 After discussion Ms. Marchal moved that the adoption of the Rules packet for 4729-2 be approved as amended for JCARR. The motion was seconded by Ms. Huwer and approved by the Board: Aye - 5.

R-2015-145 Mr. Moné announced the following Settlement Agreement has been signed by all parties and is now effective.

SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY

(Case Number 2013-1061)

In the Matter of:

RX PRO MONROE CLINIC DRUGS c/o MITCHELL BARRETT, R.Ph.

1470 Barrett Road Monroe, Louisiana 71202

This Settlement Agreement is entered into by and between RX Pro Monroe Clinic Drugs c/o Mitchell Barrett, R.Ph. 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.

RX Pro Monroe Clinic Drugs enters into this Agreement being fully informed of its 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, the right to appeal. RX Pro Monroe Clinic Drugs acknowledges that by entering into this Agreement it has waived its rights under Chapter 119. of the Revised Code.

WHEREAS, the State Board of Pharmacy is empowered by Section 4729.57 of the Ohio Revised Code to suspend, revoke, refuse to renew any license issued to a terminal distributor of dangerous drugs pursuant to section 4729.54 of the Revised Code, or may

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impose a monetary penalty on the license holder, for violation of any of the enumerated grounds of Section 4729.57 of the Ohio Revised Code.

WHEREAS, RX Pro Monroe Clinic Drugs is a licensed terminal distributor of dangerous drugs in the State of Ohio.

WHEREAS, on or about October 21, 2013 November 8, 2013, pursuant to Chapter 119. of the Ohio Revised Code, RX Pro Monroe Clinic Drugs was notified of the allegations or charges against it, its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. The November 8, 2013, Amended Notice of Opportunity for Hearing contains the following pertinent allegations or charges:

- (2) On or about January 1, 2013, applicant did knowingly make a false statement with purpose to secure the issuance of a license or registration, to wit: the application shows a positive answer to the following question: "[h]as the applicant, owner(s), Responsible Person, any agent, or any employee of the location being licensed, or any officer of the corporation, ever been the subject of disciplinary action by any state or federal agency?" Documentation was provided concerning a Consent Orders for coowner, Angela Nicole Hotard, and Monroe Clinic Drugs. In the Matter of Angela Nicole Hotard, Louisiana Board of Pharmacy Case No. 11-0162; In the Matter of Monroe Clinic Pharmacy, Louisiana Board of Pharmacy Case No. 11-0161. However, co-owner, Mitchell Chad Barrett, failed to provide documentation of two (2) separate disciplinary actions against his pharmacist license in Louisiana and Mississippi. <u>In the matter of</u> Mitchell Chad Barrett, Louisiana Board of Pharmacy Case No. 10-0387; In the Matter of Mitchell C. Barrett, Before the Mississippi Board of Pharmacy. Failure to provide documentation of all disciplinary actions constitutes an omission of information. Such conduct is in violation of Section 2921.13 of the Ohio Revised Code.
- (3) Co-owner of Monroe Clinic Drugs, Angela Nicole Hotard, was the subject of discipline against her license in Louisiana. To wit: While working at Monroe Clinic Pharmacy, Ms. Hotard was responsible for numerous violations of laws and rules. As a result of these violations Ms. Hotard was issued a Letter of Reprimand, fined \$1,000 and required to reimburse the Louisiana Board of Pharmacy \$250 for administrative costs. In the Matter of Angela Nicole Hotard, Louisiana Board of Pharmacy Case No. 11-0162. Monroe Clinic Drugs was likewise reprimanded, fined \$2,500, required to reimburse the Louisiana Board of Pharmacy \$250 for administrative costs and \$3,771.02 for investigation costs. In the Matter of Monroe Clinic Pharmacy, Louisiana Board of Pharmacy Case No. 11-0161. Such conduct constitutes prior discipline by a professional licensing board pursuant within the meaning of Rule 4729-9-19 of the Ohio Administrative Code and Section 4729.57 of the Ohio Revised Code.
- (4) Co-owner of Monroe Clinic Drugs, Mitchell Chad Barrett, was the subject of discipline against his license in Louisiana and Mississippi. To wit: While acting as Pharmacist-in-Charge for Village Pharmacy, Mr. Barrett committed various violations of law and rule. As a result of these violations, Mr. Barrett was issued a Letter of

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Reprimand, fined \$5,000, required to reimburse the Louisiana Board of Pharmacy \$250 for administrative costs and \$861.80 for investigative costs. In the matter of Mitchell Chad Barrett, Louisiana Board of Pharmacy Case No. 10-0387. Further, while acting as the Pharmacist-in-Charge for Gluckstadt Specialty Care Pharmacy and Compounding, Mr. Barrett was responsible for various violations of rule and law. As a result of these violations, Mr. Barrett was fined \$500 for each violation and required to pay the costs of the investigation. In the Matter of Mitchell C. Barrett, Before the Mississippi Board of Pharmacy. Such conduct constitutes prior discipline by a professional licensing board pursuant within the meaning of Rule 4729-9-19 of the Ohio Administrative Code and Section 4729.57 of the Ohio Revised Code.

RX Pro Monroe Clinic Drugs c/o Mitchell Barrett neither admits nor denies the allegations stated in the Amended Notice of Opportunity for Hearing letter dated November 8, 2013; 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, RX Pro Monroe Clinic Drugs c/o Mitchell Barrett knowingly and voluntarily agrees with the State Board of Pharmacy to the following:

- (A) Mitchell Barrett agrees to the imposition of a monetary penalty of One Thousand Dollars (\$1,000.00) due and owing within thirty days from the effective date of this Agreement. 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) Angela Hotard agrees to the imposition of a monetary penalty of Three Hundred Dollars (\$300.00) due and owing within thirty days from the effective date of this Agreement. 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.
- (C) RX PRO-Monroe Clinic Drugs has submitted sufficient information to the Board to establish substantial compliance with the required qualifications of a TDDD and are thereby granted a license.

RX-PRO Monroe Clinic Drugs acknowledges that it 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.

RX-PRO Monroe Clinic Drugs waives any and all claims or causes of action it 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. RX-PRO

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Monroe Clinic Drugs waives any rights of appeal pursuant to Chapter 119. of the Ohio Revised Code.

R-2015-146 Mr. Moné announced the following Settlement Agreement has been signed by all parties and is now effective.

SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY VOLUNTARY SURRENDER WITH PRIOR DISCIPLINE PERMANENT SURRENDER

(Case Number 2012-1880)

In The Matter Of:

ASHLEY HUYEN DEVINE, R.Ph.

6 Delphinium St. Ladera Ranch, CA 92694 (R.Ph. No. 03-3-24059)

This Settlement Agreement is entered into by and between Ashley Huyen Devine 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.

Ashley Huyen Devine 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 and the right to a formal adjudication hearing on the issues contained herein.

Ashley Huyen Devine is knowingly and voluntarily acknowledging that, in order to settle the disciplinary charges that have been filed by the Board against her. This Agreement is entered into on the basis of the following stipulations, admissions, and understandings:

- (A) The 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.
- (B) Ashley Huyen Devine neither admits nor denies the allegations in the Board's investigation; however, the Board has initiated and conducted an investigation pursuant to the mandate of Sections 3719.18 and 4729.25 of the Ohio Revised Code.

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(C) Ashley Huyen Devine acknowledges that she has been made aware of the investigation and has not failed to cooperate in said investigation. Ashley Huyen Devine further acknowledges that she has not been promised or given anything to indicate that the State of Ohio will not proceed with criminal charges; that criminal charges may be or may have been filed pursuant to the discretion of the appropriate prosecuting attorney and/or grand jury. The execution of this agreement does not affect, and is not affected by, any such criminal proceedings.

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of the filing of formal ADMINISTRATIVE charges and/or holding a 119. hearing at this time, Ashley Huyen Devine knowingly and voluntarily **SURRENDERS PERMANENTLY TO THE STATE BOARD OF PHARMACY HER LICENSE AND REGISTRATION TO PRACTICE PHARMACY, WITH PRIOR DISCIPLINE**. Pursuant to Rule 4729-9-01(F),

Ashley Huyen Devine may not be employed by, or work in, any facility licensed by the State Board of Pharmacy to possess or distribute dangerous drugs.

Ashley Huyen Devine 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.

Ashley Huyen Devine 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. Ashley Huyen Devine waives any rights of appeal pursuant to Chapter 119. of the Ohio Revised Code.

R-2015-147 Mr. Moné announced the following Settlement Agreement has been signed by all parties and is now effective.

SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY VOLUNTARY SURRENDER WITH DISCIPLINARY ACTION PENDING PERMANENT SURRENDER

(Case Number 2012-1633)

In The Matter Of:

New England Compounding Center c/o Barry J. Cadden, R.Ph. 697 Waverly Street Framingham, MA 01702 (TDDD License No. 02-1355650)

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This Settlement Agreement is entered into by and between Paul D. Moore, as the duly appointed chapter 11 Trustee ("<u>Trustee</u>") of New England Compounding Pharmacy d/b/a New England Compounding Center ("<u>NECC</u>") 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.

The Trustee is the duly appointed chapter 11 Trustee in the case numbered and styled case no. 12-19882-HJB, *In re New England Pharmacy, Inc. d/b/a New England Compounding Pharmacy,* which is pending in the United States Bankruptcy Court for the District of Massachusetts ("Bankruptcy Court").

The Trustee enters into this Agreement being fully informed of NECC's 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.

The Trustee is knowingly and voluntarily acknowledging that, in order to settle the disciplinary charges that have been filed by the Board against NECC and in order to obviate the need to conduct an administrative hearing to consider possible disciplinary sanctions against NECC's license to practice pharmacy in the State of Ohio, this Agreement is entered into, subject to the approval of the Bankruptcy Court as required by Rule 9019 of the Federal Rules of Bankruptcy Procedure, on the basis of the following stipulations, admissions, and understandings:

- (A) The Ohio State Board of Pharmacy is empowered by Section 4729.57 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.
- (B) On October 9, 2012, The Board issued a Notice of Summary Suspension to NECC, summarily suspending NECC's Terminal Distributor of Dangerous Drugs License (02-1355650).
- (C) The Trustee neither admits nor denies the allegations pending in the Board's Notice of Summary Suspension; however, the Board has sufficient evidence to prove said charges and hereby adjudicates the same.
- (D) The Trustee acknowledges that he has been made aware of the Notice of Summary Suspension and has not failed to cooperate in said investigation. The Trustee further acknowledges that he has not been promised or given anything to indicate that the State of Ohio will not proceed with criminal charges against NECC; that criminal charges may be or may have been filed against NECC pursuant to the discretion of the appropriate prosecuting attorney and/or grand jury. The execution of this agreement does not affect, and is not affected by, any such criminal proceedings.

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of the filing of formal ADMINISTRATIVE charges and/or holding a 119 hearing at this time, subject to approval of the Bankruptcy Court as required pursuant to

Tuesday, November 4, 2014

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Rule 9019 of the Federal Rules of Bankruptcy Procedure, the Trustee hereby knowingly and voluntarily SURRENDERS PERMANENTLY TO THE STATE BOARD OF PHARMACY NECC'S LICENSE AND REGISTRATION TO SELL, DELIVER OR DISTRIBUTE DANGEROUS DRUGS, WITH DISCIPLINARY ACTION PENDING. Pursuant to Rule 4729-9-01(F),

The Trustee acknowledges that it 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; and waives any rights of appeal pursuant to Chapter 119. of the Ohio Revised Code.

8:53 a.m. The Board Recessed briefly.

<u>9:00 a.m.</u> The meeting reconvened in Room South B&C.

The Board was joined by Assistant Attorney General Charissa Payer to conduct an adjudication hearing in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of **Pain Care Specialists**, **LLC**, Dublin, Ohio.

<u>10:45 a.m.</u> The hearing ended and the record was closed.

Ms. Huwer moved that the Board recess in order to consider this quasi-judicial matter in accordance with Chapter 119. of the Revised Code and the case precedent of *Angerman v. State Medical Bd.* (1990) 70 Ohio App.3d 346 and *TBC Westlake Inc. v. Hamilton Cty Bd of Revision, et al.* (1998) 81 Ohio St.3d 58. The motion was seconded by Ms. Yarosh and a roll-call vote was conducted by President Moné as follows: Huwer – yes; Kolezynski – yes; Marchal – yes; Weaver – yes; and Yarosh – yes.

<u>11:18 a.m.</u> The recess ended and the hearing was opened to the public.

R-2015-148 After votes were taken in public session, the Board adopted the following order in the matter of **Pain Care Specialists**, **LLC**, Dublin, Ohio.

ORDER OF THE STATE BOARD OF PHARMACY

(Case Number 2012-1386)

In The Matter Of:

Pain Care Specialists c/o Panduranga Rao Lingam, M.D. 6397 Emerald Parkway, Suite 100 Dublin, Ohio 43016

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INTRODUCTION

The Matter of Pain Care Specialists came for hearing on November 4, 2014, before the following members of the Board: Michael A. Moné, R.Ph.; (presiding); Margaret A. Huwer, R.Ph.; Richard F. Kolezynski, R.Ph.; Megan E. Marchal, R.Ph.; Fred M. Weaver, R.Ph. and Kilee S. Yarosh, R.Ph.

Edward T. Cain, Absent.

Melinda J. Ferris, Abesent.

Pain Care Specialists was represented by Zachary M. Swisher. The State of Ohio was represented by Charissa D. Payer, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witnesses:

1. Panduranga Rao Lingam, M.D.

Respondent's Witnesses:

1. Panduranga Rao Lingam, M.D.

State's Exhibits:

1.	Notice of Opportunity for Hearing	11-22-13
1A-I.	Procedurals	
2.	Ohio State Board of Pharmacy Pain Management Clinic Application	06-07-11
2A.	Ohio State Board of Pharmacy Practitioner Corporation Application	04-13-12
2B.	Ohio State Board of Pharmacy Terminal Distributor of Dangerous	11-15-13
	Drugs Application	
3.	State Medical Board of Ohio Citation in the Matter of	12-03-97
	Panduranga Rao Lingam, M.D.	
4.	State Medical Board of Ohio Certification in the Matter of	09-25-12
	Panduranga Rao Lingam, M.D.	

Respondent's Exhibits:

A.	Curriculum Vitae	No Date
B.	State Medical Board of Ohio Citation in the matter of	12-03-97
	Panduranga Rao Lingam, M.D.	
C.	State Medical Board Consent Agreement	04-08-98
D.	E-License Verification	No Date
E.	Franklin County Auditor Verification	09-03-14
F.	Audit Response Letter	04-11-06
G.	Pain Care Specialists Confidentiality General Policies	No Date
H.	Pain Care Specialists Organizational Policies	No Date
I.	OARRS Draft	No Date

Onio State Board of Pharmacy	•	77 South High Street, Room 1702 ◆	Columbus, Onio 4321	5-6126
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J. Gove	rning l	Board Meeting Minutes	06-0	04-11
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J.	Governing Board Meeting Minutes	06-04-11
K.	Copy of Pain Care Specialists License Renewal	11-06-13
L.	Pain Care Specialists Mission Statement and Goals	No Date
M.	Pain Care Specialists Daily Operations	No Date
N.	Pain Care Specialists AAAHC- Standard Survey Report	05-22-12

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 Board of Pharmacy indicate that on or about June 7, 2011, Panduranga Rao Lingam, M.D. was the owner and responsible person, for Pain Care Specialists, LLC, 1245 South Sunbury Road, Suite 201, Westerville, Ohio 43081, and on June 7, 2011, Pain Care Specialists, LLC applied for registration as a Terminal Distributor of Dangerous Drugs with a Pain Management Clinic Classification. On or about April 13, 2012 Pain Care Specialists, LLC submitted an application for change of address of their business to 6397 Emerald Parkway, Suite 100, Dublin, Ohio 43016. On or about November 6, 2013 Pain Care Specialists, LLC submitted an application for a change of license category at 6397 Emerald Parkway, Suite 100, Dublin, Ohio 43016.
- (2) Dr. Panduranga Rao Lingam, owner and responsible person of Pain Care Specialists, LLC, has been disciplined by the State Medical Board of Ohio in that he entered into a consent agreement with the State Medical Board of Ohio on September 25, 2012.

CONCLUSIONS OF LAW

- (1) The State Board of Pharmacy concludes that Pain Care Specialists, LLC has substantially complied with Board Standards for the licensure of an entity as a Terminal Distributor of Dangerous Drugs with Pain Management Clinic Classification.
- (2) The State Board of Pharmacy concludes that paragraph (2) of the Findings of Fact constitutes a violation of Section 4729-9-19 of the Ohio Administrative Code.

DECISION OF THE BOARD

Pursuant to Sections 3719.03, 4729.55 and 4729.52 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby approves the application submitted by Pain Care Specialists, LLC and, therefore, grants a license for a Terminal Distributor of Dangerous Drugs with a Pain Management Clinic Classification submitted by Pain Care Specialists, LLC on June 7, 2011.

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The Board places the Terminal Distributor of Dangerous Drugs with a Pain Management Clinic Classification license of Pain Care Specialists, LLC on indefinite probation the terms of which are as follows:

- (A) Pain Care Specialists, LLC must maintain an AAAHC accreditation.
- (B) If Pain Care Specialists, LLC loses or otherwise no longer holds AAAHC accreditation, the Board must be notified within thirty (30) days of the same.

Kilee Yarosh moved for Findings of Fact; Richard Kolezynski seconded the motion. Motion passed (Aye-5/Nay-0).

Margaret Huwer moved for Conclusions of Law; Fred Weaver seconded the motion. Motion passed (Aye-5/Nay-0).

Kilee Yarosh moved for Action of the Board; Fred Weaver seconded the motion. Motion passed (Aye-5/Nay-0).

<u>11:25 a.m.</u> Mr. Moné led a discussion about Board Member Committees for Fiscal Year 2015.

R-2015-149 After discussion,. Ms. Marchal moved that the following Board Members be assigned to the following Board Member Committees for Fiscal Year 2015. The motion was seconded by Ms. Huwer and approved by the Board: Aye – 5.

The Board President shall always be appointed to the Citation Review and Issuance Committee.

Mr. Cain, Mr. Moné, and Ms. Huwer were appointed to the Budget, Finance and Personnel Committee.

Mr. Weaver, Ms. Yarosh, and Mr. Kolezynski were appointed to the Continuing Education, Examination, Internship and Licensure Committee.

Ms. Huwer and Ms. Yarosh were appointed to the Legislation and Public Relations Committee.

Mr. Weaver and Ms. Marchal were appointed to the Ohio Automated Rx Reporting System (OARRS) Committee.

Ms. Marchal and Mr. Moné were appointed to the Probation Committee.

Ms. Ferris, Ms. Yarosh, and Ms. Huwer were appointed to the Rules Review Committee.

<u>11:35 a.m.</u> The Board recessed for lunch.

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<u>1:00 p.m.</u> The meeting reconvened in Room South B&C.

Mr. Kolezynski moved that the Board go into Executive Session to consider the investigation of charges or complaints against a licensee, confer with Board counsel regarding a pending or imminent court action and to discuss matters required to be confidential by law pursuant to Section 121.22(G)(1), (3) & (5) of the Ohio Revised Code. The motion was seconded by Ms. Yarosh and a roll-call vote was conducted by President Moné as follows: Huwer – yes; Kolezynski –yes; Marchal – yes; Weaver – yes; and Yarosh – yes.

1:10 p.m. The executive session ended and the meeting was opened to the public.

Pursuant to Section 4729.16 of the Ohio Revised Code, the Ohio State Board of Pharmacy convened for the purpose of considering summary suspensions as required by Section 3719.121 of the Ohio Revised Code.

R-2015-150 After hearing Ms. Nave discuss the significant facts regarding the activities of the individual, Mr. Kolezynski moved that the Board summarily suspend the license to practice pharmacy belonging to **Dominic Pileggi, R.Ph.** (03-2-34002) Cincinnati, Ohio, pursuant to Ohio Revised Code 3719.121(B). The motion was seconded by Ms. Marchal and approved by the Board: Aye – 5.

1:30 p.m. The Board convened in Room South A, 31st Floor of the Vern Riffe Center for Government and the Arts. The following candidates for licensure by reciprocity introduced themselves to the Board, and then participated in a discussion of pharmacy laws and rules with Ms. Terri Ghitman, *OARRS Pharmacist*:

Rita B. Caskey	Pennsylvania
Wayne Clark Cheatum	Florida
Laura Ashley Fasolt	Florida
Michalle Asha Handy	Florida
Gregory Alfred Jonas	Michigan
Innocent Okafor Mabatah	Texas
Theresa J. McCarty	Illinois
Anand Prithiviraj	Indiana
Tanvi D. Shah	Florida
Seema Rajiv Shahani	Virginia
Joseph Waters	Massachusetts

<u>1:48 p.m.</u> The meeting reconvened in Room South B&C.

<u>R-2015-151</u> Ms. Yarosh moved that the Board appoint Steven Schierholt, Esq. as Executive Director effective November 17, 2014. The motion was seconded by Ms. Huwer and approved by the Board: Aye - 5.

R-2015-152 Mr. Moné announced the following Settlement Agreement has been signed by all parties and is now effective.

<u>SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY</u> (Case No.2012-1904)

In the Matter of:

MasterPharm, LLC. 115-02 Liberty Avenue Richmond Hill, NY 11419 (Terminal Distributor Number 01-1837600)

This Settlement Agreement is entered into by and between MasterPharm, LLC 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.

MasterPharm, LLC enters into this Agreement being fully informed of its 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. MasterPharm, LLC acknowledges that by entering into this Agreement it has waived its rights under Chapter 119. of the Revised Code.

WHEREAS, the State Board of Pharmacy is empowered by Section 4729.57 of the Ohio Revised Code to suspend, revoke, refuse to renew any license issued to a terminal distributor of dangerous drugs pursuant to section 4729.54 of the Revised Code, or may impose a monetary penalty on the license holder, for violation of any of the enumerated grounds of Section 4729.57 of the Ohio Revised Code.

WHEREAS, MasterPharm, LLC is a licensed terminal distributor of dangerous drugs in the State of Ohio.

WHEREAS, on or about June 6, 2014, pursuant to Chapter 119. of the Ohio Revised Code, MasterPharm, LLC was notified of the allegations or charges against it, its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. The June 6, 2014, Notice of Opportunity for Hearing contains the following allegations or charges:

(1) Records of the Board of Pharmacy indicate that MasterPharm, LLC is licensed with the State Board of Pharmacy as a Terminal Distributor of Dangerous Drugs. Records further reflect during the relevant time periods stated herein, Lin Leung, R.Ph. was 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.

Ohio State Board of Pharmacy Tuesday, November 4, 2014

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- (2) On or about August 28, 2008 MasterPharm, LLC was cited by the Missouri Board of Pharmacy for shipping drugs into Missouri without a license, and for shipping compounding products to physician offices in Missouri without a license. Order of the Missouri Board of Pharmacy Issuing Masterpharm, LLC A pharmacy permit subject to probation, Permit No. 2008024279. Such conduct constitutes failure to meet the qualifications of a terminal distributor within the meaning of Section 4729.57 of the Ohio Revised Code and prior discipline by a professional licensing board pursuant within the meaning of Rule 4729-9-19 of the Ohio Administrative Code.
- (3) On or about March 10, 2010, and May 12, 2011, MasterPharm, LLC was cited and fined by the Colorado Board of Pharmacy for failure to submit required data to Colorado's Prescription Drug Monitoring Program. In the matter of the disciplinary proceeding regarding the non-resident prescription drug outlet registration of Masterpharm, LLC, Registration No. OSP 5632, before the State Board of Pharmacy, State of Colorado, Case Nos. 2010-002017 and 2011-003981, Stipulation and Final Agency Such conduct constitutes failure to meet the qualifications of a terminal distributor within the meaning of Section 4729.57 of the Ohio Revised Code and prior discipline by a professional licensing board pursuant within the meaning of Rule 4739-9-19 of the Ohio Administrative Code.
- (4) On or about December 29, 2011, the Nebraska Department of Health and Human Services, Division of Public Health, denied MasterPharm, LLC a Nebraska Mail Service Pharmacy Permit for failure to disclose disciplinary action by the Missouri Board of Pharmacy on their Nebraska Mail Service Pharmacy Permit application. Such conduct constitutes prior discipline by a professional licensing board and or not being of good moral character within the meaning of Rule 4729-9-19 of the Ohio Administrative Code and Section 4729.57 of the Ohio Revised Code. Such conduct constitutes failure to meet the qualifications of a terminal distributor within the meaning of Section 4729.57 of the Ohio Revised Code and prior discipline by a professional licensing board pursuant within the meaning of Rule 4729-9-19 of the Ohio Administrative Code.
- On or about June 8, 2012, MasterPharm, LLR Responsible Pharmacist Lin Leung was cited by the Nebraska Department of Health and Human Services, Division of Public Health, for mailing prescriptions into Nebraska without a Mail Service Pharmacy Permit. Such conduct constitutes prior discipline by a professional licensing board and or not being of good moral character within the meaning of Rule 4729-9-19 of the Ohio Administrative Code and Section 4729.57 of the Ohio Revised Code. Such conduct constitutes failure to meet the qualifications of a terminal distributor within the meaning of Section 4729.57 of the Ohio Revised Code and prior discipline by a professional licensing board pursuant within the meaning of Rule 4729-9-19 of the Ohio Administrative Code.

MasterPharm, LLC neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated June 6, 2014; 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, MasterPharm, LLC knowingly and voluntarily agrees with the State Board of Pharmacy to the following:

The State Board of Pharmacy hereby places on probabtion for a period of three years the Terminal Distributor License, License No. 02-1837600, held by MasterPharm, LLC effective the date of the finalized agreement. The terms of probation are as follows:

- (A) MasterPharm must submit to this Board, biannually, a list of all drugs dispensed, sold or shipped into Ohio, beginning effective within 180 days from the date of this order.
- (B) MasterPharm must submit to this Board, annually, a Verified Pharmacy Practice Inspection (VPP) report for each year of probation.
- (C) MasterPharm, LLC must not violate the drug laws of Ohio, any other state, or the federal government.
- (D) MasterPharm, LLC must abide by the rules of the Ohio State Board of Pharmacy.
- (E) MasterPharm, LLC must comply with the terms of this Agreement.
- (F) MasterPharm, LLC's license is deemed to be not in good standing until successful completion of the probationary period.
- (G) 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.

MasterPharm, LLC acknowledges that it 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.

MasterPharm, LLC waives any and all claims or causes of action it 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. MasterPharm, LLC waives any rights of appeal pursuant to Chapter 119. of the Ohio Revised Code.

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<u>1:52 p.m.</u> The Board was joined by Assistant Attorney General Charissa Payer to conduct an adjudication hearing in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of **Scott Thomas Druley**, Tipp City, Ohio.

<u>2:30 p.m.</u> The hearing ended and the record was closed.

Ms. Marchal moved that the Board recess in order to consider this quasi-judicial matter in accordance with Chapter 119. of the Revised Code and the case precedent of *Angerman v. State Medical Bd.* (1990) 70 Ohio App.3d 346 and *TBC Westlake Inc. v. Hamilton Cty Bd of Revision, et al.* (1998) 81 Ohio St.3d 58. The motion was seconded by Mr. Kolezynski and a roll-call vote was conducted by President Moné as follows: Huwer – yes; Kolezynski –yes; Marchal – yes; Weaver – yes; and Yarosh – yes.

<u>2:45 p.m.</u> The recess ended and the hearing was opened to the public.

R-2015-153 After votes were taken in public session, the Board adopted the following order in the matter of **Scott Thomas Druley**, Tipp City, Ohio.

ORDER OF THE STATE BOARD OF PHARMACY

(Case Number 2013-1708)

In The Matter Of:

Scott Thomas Druley, R.Ph.

740 Chelsea Lane Tipp City, OH 45371 (R.Ph. Number 03-2-15147)

<u>INTRODUCTION</u>

The Matter of Scott Thomas Druley came for hearing on November 4, 2014, before the following members of the Board: Michael A. Moné, R.Ph.; (presiding); Margaret A. Huwer, R.Ph.; Richard F. Kolezynski, R.Ph.; Megan E. Marchal, R.Ph.; Fred M. Weaver, R.Ph. and Kilee S. Yarosh, R.Ph.

Edward T. Cain, Absent. Melinda J. Ferris, Abesnt.

Scott Thomas Druley was represented by Thomas E. Dysinger. The State of Ohio was represented by Charissa D. Payer, Assistant Attorney General.

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SUMMARY OF EVIDENCE

State's Witness:

1. Scott Thomas Druley, R.Ph.

Respondent's Witness:

1. Scott Thomas Druley, R.Ph.

State's Exhibits:

1.	Notice of Opportunity for Hearing	05-02-14
1A-C.	Procedurals	
2.	Copy of ORC 4729.41 Adult Immunizations	09-13-13
3.	Copy of ORC 4729-5-37 Protocols for the Administration	10-20-14
	of Immunizations	
4.	Kroger Immunization Protocol.2013	06-25-13
5.	Certificate of Achievement	05-11-10
6.	Copy of Kroger Immunization Consent Form	08-06-13
7.	Notarized Statement of Scott Druley	09-30-13
8.	Notarized Statement of Bradley J. Carroll	10-21-13
9.	Notarized Statement of Tanisa Wright	10-07-13

Respondent's Exhibits:

A.	Letter of Support, Dr. David M. Oinos, R.Ph.	No Date
B.	Letter of Support, Dr. David P. McFadden	10-14-14
C.	Letter of Support, Julian B. Fasano	No Date

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 you were originally licensed in the State of Ohio on August 10, 1983, pursuant to examination, and are currently licensed to practice pharmacy in the State of Ohio.
- (2) You did, on or about August 6, 2013, violate immunization protocol set forth in Section 4729.41(A)(1)(b) of the Ohio Revised Code when you administered Adacel (Tdap) to a patient under eighteen years of age, to wit: you administered Adacel (Tdap) to a three year old patient at the request of the patient's mother.
- (3) You did, on or about August 6, 2013, administer Adacel (Tdap) to a three year old patient at the request of the patient's mother. Such conduct constitutes practicing medicine without a license under Section 4731.34(A)(3)(b) of the Ohio Revised Code.

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CONCLUSION OF LAW

The State Board of Pharmacy concludes that paragraphs (2) through (3) of the Findings of Fact constitute being guilty of unprofessional conduct in the practice of pharmacy as provided in Division (A)(2) 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 hereby imposes a monetary penalty of five hundred dollars (\$500.00) on Scott Thomas Druley and payment in full 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.

Scott Thomas Druley must obtain, within 30 days from the effective date of this Order, four hours (0.4CEUs) of approved continuing pharmacy education. Two hours must be completed in immunizations and two hours must be completed in law and ethics, which may not also be used for license renewal.

Megan Marchal moved for Findings of Fact; Richard Kolezynski seconded the motion. Motion passed (Aye-5/Nay-0).

Fred Weaver moved for Conclusions of Law; Richard Kolezynski seconded the motion. Motion passed (Aye-5/Nay-0).

Richard Kolezynski moved for Action of the Board; Fred Weaver seconded the motion. Motion passed (Aye-5/Nay-0).

3:05 p.m. The Board was joined by Assistant Attorney General Charissa Payer to conduct an adjudication hearing in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of **H&H Wholesale Services**, **Inc.**, Troy, Ohio.

<u>3:35 p.m.</u> The hearing ended and the record was closed.

Ms. Yarosh moved that the Board recess in order to consider this quasi-judicial matter in accordance with Chapter 119. of the Revised Code and the case precedent of *Angerman v. State Medical Bd.* (1990) 70 Ohio App.3d 346 and *TBC Westlake Inc. v. Hamilton Cty Bd of Revision, et al.* (1998) 81 Ohio St.3d 58. The motion was seconded by Ms. Huwer and a roll-call vote was conducted by President Moné as follows: Huwer – yes; Kolezynski – yes; Marchal – yes; Weaver – yes; and Yarosh – yes.

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3:43 p.m. The recess ended and the hearing was opened to the public.

R-2015-154 After votes were taken in public session, the Board adopted the following order in the matter of **H&H Wholesale Services**, **Inc.**, Troy, Ohio.

ORDER OF THE STATE BOARD OF PHARMACY

(Case Number 2013-1988)

In The Matter Of:

H & H Wholesale Services, Inc.

c/o Andrew Sweet 1099 Rochester Rd. Troy, MI 48083

INTRODUCTION

The Matter of H & H Wholesale Services, Inc. came for hearing on November 4, 2014, before the following members of the Board: Michael A. Moné, R.Ph.; (presiding); Margaret A. Huwer, R.Ph.; Richard F. Kolezynski, R.Ph.; Megan E. Marchal, R.Ph.; Fred M. Weaver, R.Ph. and Kilee S. Yarosh, R.Ph.

Edward T. Cain, Absent. Melinda J. Ferris, Abesnt.

H & H Wholesale Services, Inc. was represented by Jason C. Yert. The State of Ohio was represented by Charissa D. Payer, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witnesses:

- 1. Homer Chapa, Ohio State Board of Pharmacy
- 2. Andrew Sweet, Responsible Person for H&H Wholesale Services

Respondent's Witness:

1. Andrew Sweet, Responsible Person for H&H Wholesale Services

State's Exhibits:

1.	Notice of Opportunity for Hearing	05-30-14
1A-1.	Procedurals	
2.	Application for License as a WDDD Instructions with attachments	08-26-13

Respondent's Exhibits:

A. Michigan Board of Pharmacy Inspection 06-21-13

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B.	2012 FDA Complaint Letter			03-27-12		
C.	2012 FDA Complaint Letter Response			05-09-12		
D.	Generic Ph	armaceutical List		No I	Oate	

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 Board of Pharmacy indicate that on or about August 26, 2013, Andrew Sweet was the Responsible Person, for H & H Wholesale Services, Inc., and that on August 26, 2013, H & H Wholesale Services, Inc. applied for registration as a Wholesale Distributor of Dangerous Drugs.
- With its WDDD application to the Board, H & H Wholesale Services, Inc., submitted documentation regarding its involvement in the case of *United States of* America v. Various blood glucose test strips (BGTS), etc., United States District Court for the Eastern District of Michigan, Southern Division, CIV. NO. 05-73407. The documentation revealed that on February 3, 2006, H & H Wholesale Services, Inc., entered into a Consent Decree of Condemnation with the United States Department of Health and Human Services, Food and Drug Administration ("FDA"), to pay a seventy-five (\$75,000) thousand dollar bond, among other things, to obtain from the United States the release of approximately 100,000 boxes of One Touch Ultra blood glucose test strips ("articles") that were seized over protest by H & H Wholesale Services, Inc., on September 2, 2005, pursuant to a Summons Warrant of Arrest of Property and Notice In Rem issued by the Court. The Consent Decree stated that the articles "are misbranded within the meaning of 21 U.S.C. § 352(o) and adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B)." Decree ordered H & H Wholesale Services, Inc., to bring the articles into compliance with the law. An inspection of H & H Wholesale Services, Inc., location in Troy, Michigan on October 25, 2011 through December 16, 2011, revealed multiple FDA violations. An FDA warning, Warning Letter, 2012-DET-09, was issued to H & H Wholesale Services, Inc. on March 27, 2012.

CONCLUSION OF LAW

The State Board of Pharmacy concludes that paragraph (2) of the Findings of Fact constitutes a violation of Section 4729-9-19 Ohio Administrative Code.

DECISION OF THE BOARD

Pursuant to Sections 3719.03 and 4729.53 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby approves the

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application submitted by H&H Wholesale Services, Inc. and, therefore, grants a license for a Wholesale Distributor of Dangerous Drugs submitted by H&H Wholesale Services, Inc. on August 26, 2013.

Further, the Board places the H&H Wholesale Services, Inc. on probation for a period of ten (10) years the terms of which are as follows:

(A) H&H Wholesale Services, Inc., must forward copies to the Board office of any State or Federal inspection, within thirty days of the inspection.

Margaret Huwer moved for Findings of Fact; Richard Kolezynski seconded the motion. Motion passed (Aye-5/Nay-0).

Megan Marchal moved for Conclusions of Law; Fred Weaver seconded the motion. Motion passed (Aye-5/Nay-0).

Kilee Yarosh moved for Action of the Board; Megan Marchal seconded the motion. Motion passed (Aye-5/Nay-0).

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Mr. Kolezynski moved that the following resolution be adopted by the Board and memorialized in the Minutes of this meeting:

RESOLUTION OF THE BOARD

WHEREAS, Eric A. Griffin, the Board's Compliance Supervisor, has shown exemplary judgment, dedication, commitment, giving of himself at great personal sacrifice to the benefit of the Board and the citizens of the State of Ohio;

WHEREAS, the Board recognizes that, the performance of the duties of Interim Executive Director has significantly contributed to the ongoing operation of this Board, enabling this Board to serve its constituents effectively and efficiently;

BE IT RESOLVED that we, the undersigned Members of the Ohio State Board of Pharmacy, in the Board's one-hundred thirtieth year, do hereby express our profound appreciation to Eric A. Griffin for his dedication and service to the Board and the citizens of Ohio; and

BE IT FURTHER RESOLVED that this resolution be spread upon the permanent minutes of the Ohio State Board of Pharmacy and a copy presented to:

Eric A. Griffin

on this 4th day of November, 2014, at the Ohio State Board of Pharmacy, Columbus, Ohio.

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Ms. Huwer seconded the motion and it was approved by the Board: Aye -5.

Mr. Kolezynski moved that the Board receive Per Diem as follows: R-2015-156

PER DIEM	11/3	11/4	Total
Cain	0	0	0
Ferris	0.	0	0
Huwer	1 .	1	2
Kolezynski	1	1	2
Marchal	1	1	2
Moné	1	1	2
Weaver	1	1	2
Yarosh	1	1	2

Ms. Yarosh seconded the motion and it was approved by the Board: Aye -5.

Mr. Weaver moved that the meeting be adjourned. The motion was seconded by Ms. Marchal and approved by the Board: Aye -5.

Date: 12/3/2014

Date: 12/3/2014

Eric A. Griffin, Interim Executiv Director