

## MINUTES OF THE JANUARY 9-10, 2017 MEETING OF THE STATE OF OHIO BOARD OF PHARMACY

#### Monday, January 9, 2017

**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, RPh, *President;* Joshua M. Cox, RPh; Curtis L. Passafume, Jr., RPh; Megan E. Marchal, RPh; Jennifer M. Rudell, RPh; Fred M. Weaver, RPh; Shawn C. Wilt, RPh and Kilee S. Yarosh, RPh

Also present were Steven Schierholt, *Executive Director*; Nicole Dehner, *Chief Legal Counsel*; Chad Garner, *Director of OARRS*; Chandra Galante, *Director of Licensing*; Eric Griffin, *Director of Compliance and Enforcement*; Steven Kochheiser, *Assistant Attorney General* and Cameron McNamee, *Director of Policy and Communications*.

Mr. Moné stated there was not a CPG Committee update.

Ms. Marchal stated there was nothing new to report regarding the PAPC Committee.

Ms. Galante provided the Licensing update noting the CE audit will now be a 100% check, two licensing coordinator positions will be posted by months' end and touched base on the TDDD renewal.

Mr. Griffin provided the Compliance and Enforcement report.

Mr. Garner provided the OARRS/IT update.

Ms. Dehner and Mr. Kochheiser provided the Legal report.

- **<u>R-2017-206</u>** Ms. Marchal moved that the Board adopt the proposed Settlement presented by X-Gen Pharmaceuticals, Inc. The motion was seconded by Mr. Passafume and it was approved by the Board: Aye-7.
- **10:21 a.m.** Mr. McNamee provided the Legislative update.
- **<u>11:22 a.m.</u>** The Board recessed briefly.
- **<u>11:32 a.m.</u>** The meeting reconvened in Room South B&C.

77 South High Street, 17th Floor, Columbus, Ohio 43215



- **R-2017-207** Mr. Passafume moved that Rules 4729-9-10, 4729-9-13, 4729-5-25 and 4729-18; 01, 02, 03 and 04 be approved as amended for filing with CSI and JCARR. The motion was seconded by Ms. Yarosh and approved by the Board: Aye-7.
- **R-2017-208** Mr. Passafume moved that Rule 4729-5-10 be approved for refiling with JCARR. The motion was seconded by Ms. Marchal and approved by the Board: Aye-7.
- **R-2017-209** Mr. Passafume moved that Rules 4729-37-03, 4729-9-14, and 4729-9-22 be approved for filing with JCARR. The motion was seconded by Ms. Rudell and approved by the Board: Aye-7.
- **<u>11:53 a.m.</u>** Mr. Schierholt provided the Executive Director report.
- **<u>11:58 a.m.</u>** The Board recessed for lunch.
- **<u>1:05 p.m.</u>** The meeting reconvened in Room South B&C.
- **<u>R-2017-210</u>** Mr. Moné announced that the following Settlement Agreement has been signed by all parties and is now effective:

## IN THE MATTER OF: CASE NOs. 2015-1850-A 2015-2018-A 2015-1694-A 2015-1671-A 2015-1666-A

Kroger #014942 c/o Karen Helmes, RPh 1014 Vine Street Cincinnati, Ohio 45202 License No. 02-1044350

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

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (OSBP) and Kroger #014942, for the purpose of resolving all issues between the parties relating to the OSBP investigation of (5) errors in dispensing's by (3) staff pharmacists. Together, OSBP and Kroger #014942 are referred to hereinafter as "the parties."

#### JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the OSBP has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.55 of the Ohio Revised Code to practice pharmacy the state of Ohio.

2. Kroger #014942 is a licensed Terminal Distributor of Dangerous Drugs under license number 02-1044350.

#### FACTS

1. On or about July 31, 2015, the OSBP initiated an investigation of Kroger #014942, Terminal Distributor of Dangerous Drugs license number 02-1044350, related to Kroger #014942's five (5) errors in dispensing's by three (3) staff pharmacists.

2. On or about June 16, 2016 the OSBP sent a Notice of Opportunity for Hearing to Kroger #014942, which outlined the allegations and provided notice of their right to a hearing, their rights in such hearing, and their right to submit contentions in writing.

3. On or about July 12, 2016, Kroger #014942 timely requested an administrative hearing, which was subsequently scheduled for December 7, 2016.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

#### TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Kroger #014942 neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated June 16, 2016; however, the OSBP has evidence sufficient to sustain the allegations and hereby adjudicates the same.

3. Kroger #014942 agrees to continue education and training of its pharmacy staff in Best Practices.

4. Kroger #014942 agrees to continue quarterly education meetings.

5. Kroger #014942 agrees to pay to the OSBP the amount of \$2,500.00, by means of a cashier's check made payable to "Treasurer, State of Ohio," mailed with the enclosed form to the OSBP, 77 South High Street, 17<sup>th</sup> Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Agreement.

6. Kroger #014942 agrees that all schedule II substances will continue to be double counted by the technicians with a third count being performed by the pharmacist and back-counted before the stock is returned to the lockable safe.

7. Kroger #014942 and Karen Helmes, RPh agree and acknowledge that this OSBP disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which Kroger #014942 currently holds a professional license, including the OSBP on renewal applications or applications for a new license.

8. Kroger #014942 agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter

4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Kroger #014942 of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Kroger #014942 by the OSBP and will NOT discharge Kroger #014942 from any obligation under the terms of this Agreement.

9. Kroger #014942 agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

10. Kroger #014942 understands that it has the right to be represented by counsel for review and execution of this agreement.

11. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Kroger #014942 will operate.

12. Kroger #014942 specifically withdraws its request for a hearing in this matter, waives its opportunity to be heard pursuant to Chapter 119 of the Ohio Revised Code, and waives any right to an appeal.

13. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

14. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

15. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

**<u>R-2017-211</u>** Mr. Moné announced that the following Settlement Agreement has been signed by all parties and is now effective:

IN THE MATTER OF: CASE NOs. 2016-1107-A 2016-1021-A 2015-2024-A 2015-1708-A

Kroger #014934 c/o Warren Sizemore, RPh 1014 Vine Street Cincinnati, Ohio 45202 License No. 02-1042350

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

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (OSBP) and Kroger #014934, for the purpose of resolving all issues between the parties relating to the OSBP investigation of (4) errors in dispensing by staff pharmacist Isaac Pearson. Together, OSBP and Kroger #014934 are referred to hereinafter as "the parties."

#### JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the OSBP has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.55 of the Ohio Revised Code to practice pharmacy the state of Ohio.

2. Kroger #014934 is a licensed Terminal Distributor of Dangerous Drugs under license number 02-1042350.

#### FACTS

1. On or about February 28, 2016, the OSBP initiated an investigation of Kroger #014934, Terminal Distributor of Dangerous Drugs license number 02-1042350, related to Kroger #014934's four (4) errors in dispensing by staff pharmacist Isaac Pearson.

2. On or about June 16, 2016, the OSBP sent a Notice of Opportunity for Hearing to Kroger #014934, which outlined the allegations and provided notice of their right to a hearing, their rights in such hearing, and their right to submit contentions in writing.

3. On or about July 12, 2016, Kroger #014934 timely requested an administrative hearing, which was subsequently scheduled for December 7, 2016.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

#### TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Kroger #014934 neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated June 16, 2016; however, the OSBP has evidence sufficient to sustain the allegations and hereby adjudicates the same.

3. Kroger #014934 agrees to pay to the OSBP the amount of \$2,500.00, by means of a cashier's check made payable to "Treasurer, State of Ohio," mailed with the enclosed form to the OSBP, 77 South High Street, 17<sup>th</sup> Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Agreement.

4. Kroger #014934 agrees to continue education and training of its pharmacy staff in Best Practices.

5. Kroger #014934 agrees to continue quarterly education meetings.

6. Kroger #014934 and Warren Sizemore, RPh agree and acknowledge that this OSBP disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which Kroger #014934 currently holds a professional license, including the OSBP on renewal applications or applications for a new license.

7. Kroger #014934 agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Kroger #014934 of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Kroger #014934 by the OSBP and will NOT discharge Kroger #014934 from any obligation under the terms of this Agreement.

8. Kroger #014934 agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

9. Kroger #014934 understands that it has the right to be represented by counsel for review and execution of this agreement.

10. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Kroger #014934 will operate.

11. Kroger #014934 specifically withdraws its request for a hearing in this matter, waives its opportunity to be heard pursuant to Chapter 119 of the Ohio Revised Code, and waives any right to an appeal.

12. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

13. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

14. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

**<u>R-2017-212</u>** Mr. Moné announced that the following Settlement Agreement has been signed by all parties and is now effective:

## IN THE MATTER OF: CASE NO. 2015-2187-A

## Kroger #014915 c/o Christopher Forg, RPh 1014 Vine Street Cincinnati, Ohio 45202 License No. 02-1041950

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

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (OSBP) and Kroger #014915, for the purpose of resolving all issues between the parties relating to the OSBP investigation of dispensing expired medications. Together, OSBP and Kroger #014915 are referred to hereinafter as "the parties."

#### JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the OSBP has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.55 of the Ohio Revised Code to practice pharmacy the state of Ohio.

2. Kroger #014915 is a licensed Terminal Distributor of Dangerous Drugs under license number 02-1041950.

#### FACTS

1. On or about December 10, 2015, the OSBP initiated an investigation of Kroger #014915, Terminal Distributor of Dangerous Drugs license number 02-1041950, related to Kroger #014915's dispensing expired medications.

2. On or about June 17, 2016, the OSBP sent a Notice of Opportunity for Hearing to Kroger #014915, which outlined the allegations and provided notice of their right to a hearing, their rights in such hearing, and their right to submit contentions in writing.

3. On or about July 12, 2016, Kroger #014915 timely requested an administrative hearing, which was subsequently scheduled for December 7, 2016.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

## TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Kroger #014915 neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated June 17, 2016; however, the OSBP has evidence sufficient to sustain the allegations and hereby adjudicates the same.

3. Kroger #014915 agrees to pay to the OSBP the amount of \$2,500.00, by means of a cashier's check made payable to "Treasurer, State of Ohio," mailed with the enclosed form to the OSBP, 77 South High Street, 17<sup>th</sup> Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Agreement.

4. Kroger #014915 agrees to continue education and training of its pharmacy staff in Best Practices.

5. Kroger #014915 agrees to continue with the assignment of continual monitoring and recording of expired drugs.

6. Kroger #014915 agrees to continue education and training of all pharmacy staff on recognition and removal of expired drugs.

7. Kroger #014915 and Christopher Forg, RPh agree and acknowledge that this OSBP disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which Kroger #014915 currently holds a professional license, including the OSBP on renewal applications or applications for a new license.

8. Kroger #014915 agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Kroger #014915 of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Kroger #014915 by the OSBP and will NOT discharge Kroger #014915 from any obligation under the terms of this Agreement.

9. Kroger #014915 agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

10. Kroger #014915 understands that it has the right to be represented by counsel for review and execution of this agreement.

11. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Kroger #014915 will operate.

12. Kroger #014915 specifically withdraws its request for a hearing in this matter, waives its opportunity to be heard pursuant to Chapter 119 of the Ohio Revised Code, and waives any right to an appeal.

13. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

14. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

15. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

**<u>R-2017-213</u>** Mr. Moné announced that the following Settlement Agreement has been signed by all parties and is now effective:

IN THE MATTER OF:

CASE NOs. 2015-1527 2015-1456 2015-1181

West Jefferson Urgent Care West Jefferson Internal Medicine c/o Michael Alexander, DO 95 E. Main Street West Jefferson, Ohio 43162 License Nos. 02-1944100 WITHDRAWN 02-2515900

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

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (OSBP) and West Jefferson Urgent Care and Internal Medicine, for the purpose of resolving all issues between the parties relating to the OSBP investigation of the positive answer to the legal question on their TDDD application. Together, OSBP and West Jefferson Urgent Care and West Jefferson Internal Medicine are referred to hereinafter as "the parties."

#### JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the OSBP has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.55 of the Ohio Revised Code to practice pharmacy the state of Ohio.

2. West Jefferson Urgent Care is a licensed Terminal Distributor of Dangerous Drugs under license number 02-1944100 and West Jefferson Internal Medicine submitted a Terminal Distributor of Dangerous Drugs application on or about April 25, 2015, pending license number 02-2515900.

## FACTS

1. On or about June 4, 2014, the OSBP initiated an investigation of West Jefferson Urgent Care and West Jefferson Internal Medicine, Terminal Distributor of Dangerous Drugs license number 02-1944100 and pending license number 02-2515900, related to West Jefferson Urgent Care and West Jefferson Internal Medicine's positive answer to the legal question on their TDDD application.

2. On or about May 9, 2016, the OSBP sent a Notice of Opportunity for Hearing to West Jefferson Urgent Care and a Notice of Opportunity for Hearing to West Jefferson Internal Medicine, which outlined the allegations and provided notice of their right to a hearing, their rights in such hearing, and their right to submit contentions in writing.

3. On or about May 24, 2016, West Jefferson Urgent Care and West Jefferson Internal Medicine timely requested an administrative hearing, which was subsequently scheduled for September 12, 2016.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

#### TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. West Jefferson Urgent Care and West Jefferson Internal Medicine neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letters dated May 9, 2016; however, the OSBP has evidence sufficient to sustain the allegations and hereby adjudicates the same.

3. West Jefferson Urgent Care agrees to pay to the OSBP the amount of \$1,000.00, by means of a cashier's check made payable to "Treasurer, State of Ohio," mailed with the enclosed form to the OSBP, 77 South High Street, 17<sup>th</sup> Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Agreement.

4. West Jefferson Internal Medicine agrees to pay to the OSBP the amount of \$500.00, by means of a cashier's check made payable to "Treasurer, State of Ohio," mailed with the enclosed form to the OSBP, 77 South High Street, 17<sup>th</sup> Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Agreement.

5. Eric Yoon agrees to complete, within 90 days from the effective date of this Agreement, 6 hours of approved continuing pharmacy education (0.6 CEUs), which may not also be used for license renewal. Copies of completed CEUs must be e-mailed to <u>legal@pharmacy.ohio.gov.</u>

6. Dr. Michael Alexander agrees to complete, within 90 days from the effective date of this Agreement, 6 hours of approved continuing medical education, which may not also be used for license renewal. Copies of completed CMEs must be e-mailed to <u>legal@pharmacy.ohio.gov</u>.

7. West Jefferson Internal Medicine's request to withdraw their application submitted on or about April 25, 2015, is hereby approved.

8. West Jefferson Urgent Care's Responsible Person, Dr. Michael Alexander, must submit a notarized statement to the OSBP monthly, for a period of one year from the effective date of this Agreement. The notarized statement must include a description of the number of times Dr.

Alexander was present at West Jefferson Urgent Care and a description of his duties while present at West Jefferson Urgent Care.

9. West Jefferson Urgent Care's Responsible Person, Dr. Michael Alexander, must attend the State of Ohio Board of Pharmacy's Responsible Person Roundtable within 90 days of the effective date of this agreement.

10. West Jefferson Urgent Care and West Jefferson Internal Medicine agree and acknowledge that this OSBP disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which they currently hold a professional license, including the OSBP on renewal applications or applications for a new license.

11. West Jefferson Urgent Care and West Jefferson Internal Medicine agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by West Jefferson Urgent Care and West Jefferson Internal Medicine of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to West Jefferson Urgent Care and West Jefferson Internal Medicine by the OSBP and will NOT discharge West Jefferson Urgent Care and West Jefferson Internal Medicine from any obligation under the terms of this Agreement.

12. West Jefferson Urgent Care and West Jefferson Internal Medicine agree to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

13. West Jefferson Urgent Care and West Jefferson Internal Medicine understands that it has the right to be represented by counsel for review and execution of this agreement.

14. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom West Jefferson Urgent Care and West Jefferson Internal Medicine will operate.

15. West Jefferson Urgent Care and West Jefferson Internal Medicine specifically withdraws any request(s) for a hearing in these matter and waives opportunity to be heard pursuant to Chapter 119 of the Ohio Revised Code or any right to an appeal.

16. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

17. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

18. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

**<u>R-2017-214</u>** Mr. Moné announced that the following Settlement Agreement has been signed by all parties and is now effective:

## IN THE MATTER OF: CASE NO. 2015-1858-B

Keith Barga, RPh 2627 Kristi Lynne Lane Toledo, Ohio 43617 License No. 03-3-11907

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

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (OSBP) and Keith Barga, for the purpose of resolving all issues between the parties relating to the OSBP investigation of the error in dispensing of prescription number 2337372. Together, OSBP and Keith Barga are referred to hereinafter as "the parties."

#### JURISDICTION

1. Pursuant to Section 4729.16 of the Ohio Revised Code and the rules adopted thereunder, the OSBP has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.16 of the Ohio Revised Code to practice pharmacy as in the state of Ohio.

2. Keith Barga is a licensed pharmacist under license number 03-3-11907.

#### FACTS

1. On or about October 20, 2015, the OSBP initiated an investigation of Keith Barga, pharmacist license number 03-3-11907, related to Keith Barga's error in dispensing of prescription number 2337372.

2. On or about August 24, 2016, the OSBP sent a Notice of Opportunity for Hearing to Keith Barga, which outlined the allegations and provided notice of his right to a hearing, his rights in such hearing, and his right to submit contentions in writing.

3. On or about September 27, 2016, Keith Barga timely requested an administrative hearing, which was subsequently scheduled for February 7, 2017.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

## TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Keith Barga neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated August 24, 2016; however, the OSBP has evidence sufficient to sustain the allegations and hereby adjudicates the same.

3. Keith Barga agrees to pay to the OSBP the amount of \$500.00, by means of a cashier's check made payable to "Treasurer, State of Ohio," mailed with the enclosed form to the OSBP, 77 South High Street, 17<sup>th</sup> Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Agreement.

4. Keith Barga must obtain, within 90 days from the effective date of this Agreement, 6 hours of approved continuing pharmacy education (0.6 CEUs) in medication errors and/or patient safety, which may not also be used for license renewal. Copies of completed CEUs must be e-mailed to <u>legal@pharmacy.ohio.gov.</u>

5. Keith Barga agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

6. Keith Barga understands that he has the right to be represented by counsel for review and execution of this agreement.

7. Keith Barga agrees and acknowledges that this OSBP disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which he currently holds a professional license, including to the OSBP on renewal applications or applications for a new license.

8. Keith Barga withdraws his request for a hearing pursuant to Chapter 119 of the Ohio Revised Code and waives any right to an appeal.

9. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

10. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

11. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

**<u>R-2017-215</u>** Mr. Moné announced that the following Settlement Agreement has been signed by all parties and is now effective:

## IN THE MATTER OF: CASE NO. 2016-1114-B

Carly Campbell 3422 Mink Street Mount Vernon, Ohio 43050 License No. 03-3-26843

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

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (OSBP) and Carly Campbell, for the purpose of resolving all issues between the parties relating to the OSBP investigation of the error in dispensing of RX#1322767. Together, OSBP and Carly Campbell are referred to hereinafter as "the parties."

#### JURISDICTION

1. Pursuant to Section 4729.16 of the Ohio Revised Code and the rules adopted thereunder, the OSBP has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.16 of the Ohio Revised Code to practice pharmacy as in the state of Ohio.

2. Carly Campbell is a licensed pharmacist under license number 03-3-26843.

#### FACTS

1. On or about February 10, 2016, the OSBP initiated an investigation of Carly Campbell, pharmacist license number 03-3-26843, related to Carly Campbell's error in dispensing of prescription number 1322767.

2. On or about November 22, 2016 the OSBP sent a Notice of Opportunity for Hearing to Carly Campbell, which outlined the allegations and provided notice of her right to a hearing, her rights in such hearing, and her right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

#### TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Carly Campbell neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated November 22, 2016; however, the OSBP has evidence sufficient to sustain the allegations and hereby adjudicates the same.

3. Carly Campbell agrees to pay to the OSBP the amount of \$500.00, by means of a cashier's check made payable to "Treasurer, State of Ohio," mailed with the enclosed form to the OSBP, 77 South High Street, 17<sup>th</sup> Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Agreement.

4. Carly Campbell must obtain, within 90 days from the effective date of this Agreement, 6 hours of approved continuing pharmacy education (0.6 CEUs) in medication errors and/or patient

safety, which may not also be used for license renewal. Copies of completed CEUs must be emailed to legal@pharmacy.ohio.gov.

5. Carly Campbell agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

6. Carly Campbell understands that she has the right to be represented by counsel for review and execution of this agreement.

7. Carly Campbell agrees and acknowledges that this OSBP disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which she currently holds a professional license, including to the OSBP on renewal applications or applications for a new license.

8. Carly Campbell waives any request for a hearing in this matter and an opportunity to be heard pursuant to Chapter 119 of the Ohio Revised Code, as well as any right to appeal.

9. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

10. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

11. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

**<u>R-2017-216</u>** Mr. Moné announced that the following Settlement Agreement has been signed by all parties and is now effective:

## IN THE MATTER OF: CASE NO. 2016-1536

## South Russell Veterinary Hospital, Inc. c/o Lori Bieber 5210-C Chillicothe Road Chargin Falls, OH 44022 PENDING License No. 02-2612150

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

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (OSBP) and South Russell Veterinary Hospital, Inc., for the purpose of resolving all issues between the parties relating to the OSBP investigation of the negative answer to the legal question on their Terminal Distributor of Dangerous Drugs application. Together, OSBP and South Russell Veterinary Hospital, Inc. are referred to hereinafter as "the parties."

## JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the OSBP has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.55 of the Ohio Revised Code to practice pharmacy the state of Ohio.

2. South Russell Veterinary Hospital, Inc. is a licensed Terminal Distributor of Dangerous Drugs under license number 02-2612150.

#### FACTS

1. On or about May 18, 2016, the OSBP initiated an investigation of South Russell Veterinary Hospital, Inc., Terminal Distributor of Dangerous Drugs license number 02-2612150, related to South Russell Veterinary Hospital, Inc.'s negative answer to the legal question on their Terminal Distributor of Dangerous Drugs application.

2. On or about November 21, 2016, the OSBP sent a Notice of Opportunity for Hearing to South Russell Veterinary Hospital, Inc., which outlined the allegations and provided notice of their right to a hearing, their rights in such hearing, and their right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

#### TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. South Russell Veterinary Hospital, Inc. neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated November 21, 2016; however, the OSBP has evidence sufficient to sustain the allegations and hereby adjudicates the same.

3. South Russell Veterinary Hospital, Inc. agrees to pay to the OSBP a monetary penalty in the amount of \$500.00, by means of a cashier's check made payable to "Treasurer, State of Ohio," mailed with the enclosed form to the OSBP, 77 South High Street, 17<sup>th</sup> Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Agreement.

4. South Russell Veterinary Hospital, Inc.'s Terminal Distributor of Dangerous Drugs license will be issued upon receipt of this Agreement and payment of the monetary penalty.

5. South Russell Veterinary Hospital, Inc. and Lori Bieber agree and acknowledge that this OSBP disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which South Russell Veterinary Hospital, Inc. currently holds a professional license, including the OSBP on renewal applications or applications for a new license.

6. South Russell Veterinary Hospital, Inc. agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal

Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by South Russell Veterinary Hospital, Inc. of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to South Russell Veterinary Hospital, Inc. by the OSBP and will NOT discharge South Russell Veterinary Hospital, Inc. from any obligation under the terms of this Agreement.

7. South Russell Veterinary Hospital, Inc. agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. South Russell Veterinary Hospital, Inc. understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom South Russell Veterinary Hospital, Inc. will operate.

10. South Russell Veterinary Hospital, Inc. waives any request for a hearing in this matter and an opportunity to be heard pursuant to Chapter 119 of the Ohio Revised Code, and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

**<u>R-2017-217</u>** Mr. Moné announced that the following Settlement Agreement has been signed by all parties and is now effective:

## IN THE MATTER OF: CASE NO. 2016-1320

Summit Pain Specialists, Inc. 4302 Allen Road, #300 Stow, Ohio 44224 License No. 02-2052400

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

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (OSBP) and Summit Pain Specialists, Inc., for the purpose of resolving all issues between the parties relating to the OSBP investigation of the affirmative answers to both legal questions on

Summit Pain Specialist, Inc.'s change of ownership application. Together, OSBP and Summit Pain Specialists, Inc. are referred to hereinafter as "the parties."

#### JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the OSBP has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.55 of the Ohio Revised Code to practice pharmacy the state of Ohio.

2. Summit Pain Specialists, Inc. is a licensed Terminal Distributor of Dangerous Drugs with a Pain Management Clinic Classification under license number 02-2052400.

#### FACTS

1. On or about March 16, 2016, the OSBP initiated an investigation of Summit Pain Specialists, Inc., Terminal Distributor of Dangerous Drugs license number 02-2052400, related to Summit Pain Specialists, Inc.'s affirmative answers to both legal questions on its change of ownership application.

2. On or about August 19, 2016, the OSBP sent a Notice of Opportunity for Hearing to Summit Pain Specialists, Inc., which outlined the allegations and provided notice of their right to a hearing, their rights in such hearing, and their right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

#### TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Summit Pain Specialists, Inc. neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated August 19, 2016; however, the OSBP has evidence sufficient to sustain the allegations and hereby adjudicates the same.

# 3. SUMMIT PAIN SPECIALISTS, INC. PERMANENTLY AND VOLUNTARILY SURRENDERS, WITH DISCIPLINE PENDING, TO THE STATE OF OHIO BOARD OF PHARMACY LICENSE NO. 02-2052400 INCLUDING REGISTRATION TO SELL, DELIVER OR DISTRIBUTE DANGEROUS DRUGS.

4. Summit Pain Specialists, Inc., James Bressi, and Robert Geiger may never reapply for any license issued by the State of Ohio Board of Pharmacy pursuant to Chapters 3719., 3796., and 4729. of the Revised Code.

5. Summit Pain Specialists, Inc. agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

6. Summit Pain Specialists, Inc. understands that it has the right to be represented by counsel for review and execution of this agreement.

7. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Summit Pain Specialists, Inc. will operate.

8. Summit Pain Specialists, Inc. waives any opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code any right to an appeal.

9. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

10. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

11. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

**<u>R-2017-218</u>** Mr. Moné announced that the following Settlement Agreement has been signed by all parties and is now effective:

## IN THE MATTER OF: CASE NO. 2016-1232-B

## Andrew Longmate 8477 Churchill Downs Court Holland, Ohio 43528 License No. 03234200

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

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (OSBP) and Andrew Longmate, for the purpose of resolving all issues between the parties relating to the OSBP investigation of the error in dispensing of prescription number 235959. Together, OSBP and Andrew Longmate are referred to hereinafter as "the parties."

## JURISDICTION

1. Pursuant to Section 4729.16 of the Ohio Revised Code and the rules adopted thereunder, the OSBP has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.16 of the Ohio Revised Code to practice pharmacy as in the state of Ohio.

2. And rew Longmate is a licensed pharmacist under license number 03234200.

#### FACTS

1. On or about March 2, 2016, the OSBP initiated an investigation of Andrew Longmate, pharmacist license number 03234200, related to Andrew Longmate's error in dispensing of prescription number 235959.

2. On or about December 8, 2016, the OSBP sent a Notice of Opportunity for Hearing to Andrew Longmate, which outlined the allegations and provided notice of his right to a hearing, his rights in such hearing, and his right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

#### TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Andrew Longmate neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated December 8, 2016; however, the OSBP has evidence sufficient to sustain the allegations and hereby adjudicates the same.

3. Andrew Longmate agrees to pay to the OSBP the amount of \$500.00, by means of a cashier's check made payable to "Treasurer, State of Ohio," mailed with the enclosed form to the OSBP, 77 South High Street, 17<sup>th</sup> Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Agreement.

4. Andrew Longmate must obtain, within 90 days from the effective date of this Agreement, 6 hours of approved continuing pharmacy education (0.6 CEUs) in medication errors and/or patient safety, which may not also be used for license renewal. Copies of completed CEUs must be e-mailed to legal@pharmacy.ohio.gov.

5. And rew Longmate agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

6. And rew Longmate understands that he has the right to be represented by counsel for review and execution of this agreement.

7. Andrew Longmate agrees and acknowledges that this OSBP disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which he currently holds a professional license, including to the OSBP on renewal applications or applications for a new license.

8. And rew Longmate waives his right to a hearing under to Chapter 119 of the Ohio Revised Code and waives any right to appeal.

9. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

10. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

11. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

**<u>R-2017-219</u>** Mr. Moné announced that the following Settlement Agreement has been signed by all parties and is now effective:

## IN THE MATTER OF: CASE NO. 2013-1974

X-Gen Pharmaceuticals, Inc. 300 Daniel Zenker Drive Horseheads, NY 14845 WDDD License No. 01-2037200

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

By stipulation of the parties, the State of Ohio Board of Pharmacy (Board) and X-Gen Pharmaceuticals, Inc. (the parties) agree to the following amendments to the Board's Adjudication Order dated June 7, 2016 as part of the terms for X-Gen Pharmaceutical's dismissal of Appeal in the Court of Common Pleas in Franklin County, Ohio Case No. 16-CV-5818:

Finding of Fact #1 is modified to read as follows:

Records of the Board of Pharmacy indicated that Susan Badia was the president, and Richard Park was the responsible person at, X-Gen Pharmaceuticals, Inc., Ohio Wholesale Distributor of Dangerous Drugs License No. 01-2037200, pursuant to Sections 4729. of the Ohio Revised Code within the meaning of Section 4729.56 of the Ohio Revised Code.

Finding of Fact #2 is removed. Conclusion of Law #1 is removed.

Conclusion of Law #2 is removed.

The Board's Amended Order dated with the effective date of this agreement is attached hereto and incorporated as though fully set forth herein as Attachment A.

Additional terms of the Settlement Agreement in the dismissal of above-reference Case No. 16-CV-5818 include:

1. The Board shall report these modifications of the aforementioned Order to the National Practitioner Data Bank established by Title IV, Public Law 99-660, the Health Care Quality Improvement Act of 1986, as amended, and to all boards, agencies, authorities, and other entities, no matter the jurisdiction, to which the aforementioned Order was previously reported.

2. The parties waive any right and/or claim they might have to an award of attorney fees in this appeal.

3. X-Gen Pharmaceuticals, Inc. having deposited \$4,000 with the clerk of court as security, the clerk of court is hereby ordered to release said security insaid amount to the Board of Pharmacy in the form of a check made payable to the State of Ohio Board of Pharmacy. The check may be mailed addressed to: Steven R. Kochheiser, Assistant Attorney General, 30 East Broad Street, 26th Floor, Columbus, OH 43215.

4. The Dismissal with Prejudice and instructions to the Court shall serve for all purposes as proof of payment by X-Gen Pharmaceuticals, Inc. of the \$4,000 penalty imposed by the aforementioned Order dated of the State of Ohio Board of Pharmacy.

5. X-Gen Pharmaceuticals, Inc. waives any right to appeal the Amended Order as set forth in Section 119.12 of the Revised Code.

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

**<u>R-2017-220</u>** Mr. Moné announced that the following Settlement Agreement has been signed by all parties and is now effective:

## IN THE MATTER OF: CASE NO. 2015-1436

Matthew Erick 782 Tim Tam Avenue Gahanna, Ohio 43230 License No. 03-2-19632

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

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (OSBP) and Matthew Erick, for the purpose of resolving all issues between the parties relating to the OSBP investigation of the violation of a Settlement Agreement. Together, OSBP and Matthew Erick are referred to hereinafter as "the parties."

## JURISDICTION

1. Pursuant to Section 4729.16 of the Ohio Revised Code and the rules adopted thereunder, the OSBP has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.16 of the Ohio Revised Code to practice pharmacy as in the state of Ohio.

2. Matthew Erick is a licensed pharmacist under license number 03-2-19632.

1. On or about June 21, 2016, the OSBP initiated an investigation of Matthew Erick, pharmacist license number 03219632, related to Matthew Erick's violation of his Settlement Agreement dated February 1, 2016.

2. On or about August 19, 2016, the OSBP sent a Notice of Opportunity for Hearing to Matthew Erick, which outlined the allegations and provided notice of his right to a hearing, his rights in such hearing, and his right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

#### TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Matthew Erick neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated August 19, 2016; however, the OSBP has evidence sufficient to sustain the allegations and hereby adjudicates the same.

3. Matthew Erick agrees to pay the original \$250 fine owed from the settlement agreement dated February 2, 2016 as well as the reasonable costs associated with the collection of any payment, and of the prosecution of any violation of that Agreement as set forth in term eight (8) of that agreement. The OSBP's investigative and prosecution costs amount to \$131, for a total to be paid to the Board of \$381.

4. MATTHEW ERICK PERMANENTLY AND VOLUNTARILY SURRENDERS TO THE STATE OF OHIO BOARD OF PHARMACY HIS LICENSE AND REGISTRATION TO PRACTICE PHARMACY, LICENSE NO. 03219632, WITH DISCIPLINE PENDING.

5. Matthew Erick may never reapply for any license issued by the State of Ohio Board of Pharmacy pursuant to Chapters 3719., 3796., and 4729. of the Revised Code.

6. Matthew Erick agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. Matthew Erick understands that he has the right to be represented by counsel for review and execution of this agreement.

8. Matthew Erick agrees and acknowledges that this OSBP disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which he currently holds a professional license.

9. Matthew Erick waives his right to request a hearing in this matter pursuant to Chapter 119. of the Ohio Revised Code and waives any appeal rights.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

**<u>R-2017-221</u>** Mr. Moné announced that the following Settlement Agreement has been signed by all parties and is now effective:

## IN THE MATTER OF: CASE NO. 2015-1183

Nicolene Engelbrecht 4014 Whitham Hill Drive, Apt #95 Corvallis, OR 97330 License No. 03230721

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

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (OSBP) and Nicolene Engelbrecht, for the purpose of resolving all issues between the parties relating to the OSBP investigation of Nicolene Engelbrecht's continuing education unites. Together, OSBP and Nicolene Engelbrecht are referred to hereinafter as "the parties."

#### JURISDICTION

1. Pursuant to Section 4729.16 of the Ohio Revised Code and the rules adopted thereunder, the OSBP has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.16 of the Ohio Revised Code to practice pharmacy as in the state of Ohio.

2. Nicolene Engelbrecht is a licensed pharmacist under license number 03230721.

#### FACTS

1. On or about February 25, 2015, the OSBP initiated an investigation of Nicolene Engelbrecht, pharmacist license number 03230721, related to Nicolene Engelbrecht's continuing education units.

2. On or about December 1, 2016, the OSBP sent a Notice of Opportunity for Hearing to Nicolene Engelbrecht, which outlined the allegations and provided notice of her right to a hearing, her rights in such hearing, and her right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

#### TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Nicolene Engelbrecht neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated December 1, 2016; however, the OSBP has evidence sufficient to sustain the allegations and hereby adjudicates the same.

3. Nicolene Engelbrecht agrees to pay to the OSBP the amount of \$500.00, by means of a cashier's check made payable to "Treasurer, State of Ohio," mailed with the enclosed form to the OSBP, 77 South High Street, 17<sup>th</sup> Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Agreement.

4. Nicolene Engelbrecht must obtain, within 90 days from the effective date of this Agreement, 3 hours of approved continuing pharmacy education (0.3 CEUs) which may not also be used for license renewal. Copies of completed CEUs must be e-mailed to <a href="mailto:legal@pharmacy.ohio.gov">legal@pharmacy.ohio.gov</a>.

5. Nicolene Engelbrecht agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

6. Nicolene Engelbrecht understands that she has the right to be represented by counsel for review and execution of this agreement.

7. Nicolene Engelbrecht agrees and acknowledges that this OSBP disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which she currently holds a professional license, including to the OSBP on renewal applications or applications for a new license.

8. Nicolene Engelbrecht waives her right to a hearing under Chapter 119. of the Ohio Revised Code and waives any right to appeal this matter.

9. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

10. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

11. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

**<u>R-2017-222</u>** Mr. Moné announced that the following Settlement Agreement has been signed by all parties and is now effective:

## IN THE MATTER OF: CASE NO. 2015-2231

## OhioHealth Cancer Physicians c/o Dr. Robert Exten, Jr. 475 Lexington Avenue Mansfield, Ohio 44907 PENDING License No. 02-2573400

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

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (OSBP) and OhioHealth Cancer Physicians, for the purpose of resolving all issues between the parties relating to the OSBP investigation of the negative answer to the legal question on their Terminal Distributor of Dangerous Drugs Application. Together, OSBP and OhioHealth Cancer Physicians are referred to hereinafter as "the parties."

#### JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the OSBP has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.55 of the Ohio Revised Code to practice pharmacy the state of Ohio.

2. OhioHealth Cancer Physicians applied for a Terminal Distributor of Dangerous Drugs on November 18, 2015.

#### FACTS

1. On or about December 14, 2015, the OSBP initiated an investigation of OhioHealth Cancer Physicians, Terminal Distributor of Dangerous Drugs pending license number 02-2573400, related to OhioHealth Cancer Physicians' negative answer to the legal question on their Terminal Distributor of Dangerous Drugs Application

2. On or about November 23, 2016, the OSBP sent a Notice of Opportunity for Hearing to OhioHealth Cancer Physicians, which outlined the allegations and provided notice of their right to a hearing, their rights in such hearing, and their right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

#### TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. OhioHealth Cancer Physicians neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated November 23, 2016; however, the OSBP has evidence sufficient to sustain the allegations and hereby adjudicates the same.

3. OhioHealth Cancer Physicians agrees to pay to the OSBP the amount of \$1,000.00, by means of a cashier's check made payable to "Treasurer, State of Ohio," mailed with the enclosed form to the OSBP, 77 South High Street, 17<sup>th</sup> Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Agreement.

4. OhioHealth Cancer Physicians Terminal Distributor of Dangerous Drugs license will be issued upon receipt of a corrected application, application fee, and fine payment.

5. OhioHealth Cancer Physicians and Dr. Robert Exten, Jr. agree and acknowledge that this OSBP disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which OhioHealth Cancer Physicians currently holds a professional license, including the OSBP on renewal applications or applications for a new license.

6. OhioHealth Cancer Physicians agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by OhioHealth Cancer Physicians of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to OhioHealth Cancer Physicians by the OSBP and will NOT discharge OhioHealth Cancer Physicians from any obligation under the terms of this Agreement.

7. OhioHealth Cancer Physicians agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. OhioHealth Cancer Physicians understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom OhioHealth Cancer Physicians will operate.

10. OhioHealth Cancer Physicians waives any request for a hearing in this matter and an opportunity to be heard pursuant to Chapter 119 of the Ohio Revised Code, and specifically waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

**<u>R-2017-223</u>** Mr. Moné announced that the following Settlement Agreement has been signed by all parties and is now effective:

## IN THE MATTER OF: CASE NO. 2015-1977

Jacklyn Cropper 562 49<sup>th</sup> Street SW Canton, Ohio 44706 License No. 03-3-24131

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

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (OSBP) and Jacklyn Cropper, for the purpose of resolving all issues between the parties relating to the OSBP investigation of Ms. Cropper covertly smuggling controlled substances into Trumbull Correctional Institution. Together, OSBP and Jacklyn Cropper are referred to hereinafter as "the parties."

#### JURISDICTION

1. Pursuant to Section 4729.16 of the Ohio Revised Code and the rules adopted thereunder, the OSBP has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.16 of the Ohio Revised Code to practice pharmacy as in intern in the state of Ohio.

2. Jacklyn Cropper is a licensed pharmacist under license number 03-3-24131.

#### FACTS

1. On or about November 24, 2015, the OSBP initiated an investigation of Jacklyn Cropper, pharmacist license number 03-3-24131, related to Jacklyn Cropper covertly smuggling controlled substances into Trumbull Correctional Institution.

2. On or about December 11, 2015, the OSBP sent a Notice of Opportunity for Hearing to Jacklyn Cropper, which outlined the allegations and provided notice of her right to a hearing, her rights in such hearing, and her right to submit contentions in writing.

3. On or about December 18, 2015, Jacklyn Cropper timely requested an administrative hearing, which was subsequently scheduled for January 10, 2017.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

#### TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Jacklyn Cropper neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated December 11, 2015; however, the OSBP has evidence sufficient to sustain the allegations and hereby adjudicates the same. Further, the Board finds Violations of Law as set forth in 1(a), 1(b), 1(c), and (2)(c) of the Notice dated December 11, 2015; the Board hereby dismisses Violations of Law (2)(a), (2)(b), (2)(d), and (2)(e).

## 3. JACKLYN CROPPER PERMANENTLY AND VOLUNTARILY SURRENDERS TO THE STATE BOARD OF PHARMACY HER LICENSE AND REGISTRATION TO PRACTICE PHARMACY, LICENSE NO. 03-3-24131, WITH DISCIPLINE PENDING.

4. Jacklyn Cropper agrees to immediately return her license and wall certificate to the OSBP, if OSBP is not already in possession of both.

5. Jacklyn Cropper may never reapply for any license issued by the State of Ohio Board of Pharmacy pursuant to Chapters 3719., 3796., and 4729. of the Revised Code.

6. Jacklyn Cropper agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. Jacklyn Cropper understands that she has the right to be represented by counsel for review and execution of this agreement.

8. Jacklyn Cropper agrees and acknowledges that this OSBP disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which she currently holds a professional license.

9. Jacklyn Cropper specifically withdraws her request for a hearing in this matter and an opportunity to be heard pursuant to Chapter 119 of the Ohio Revised Code and waives her right to an appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

- **<u>R-2017-224</u>** The Board received an application for the Continuing Education Provider Status of **Weston Bush**, **RPh** (03-1-22232) Sagamore Hills, Ohio. Ms. Yarosh moved that the Continuing Education Provider Status be approved. The motion was seconded by Mr. Weaver and approved by the Board: Aye-7.
- **<u>R-2017-225</u>** The Board received an application for the Continuing Education Provider Status of **Melissa Parson**, **RPh** (03-2-34305) Centerville, Ohio. Mr. Weaver moved that the Continuing Education Provider Status be approved. The motion was seconded by Ms. Rudell and approved by the Board: Aye-7.

- **R-2017-226** The Board received an application for the Continuing Education Provider Status of **Christine Pfaff**, **RPh** (03-3-25380) Lewis Center, Ohio. Mr. Cox moved that the Continuing Education Provider Status be approved. The motion was seconded by Mr. Wilt and approved by the Board: Aye-7.
- **<u>R-2017-227</u>** Mr. Passafume moved that the Board adopt the following resolution:

Pursuant to rule 4729-5-11, the Board of Pharmacy is required to adopt a resolution providing the credential types or qualifications required for the responsible person of each classification of terminal and wholesale distributor of dangerous drugs license. Only individuals that meet the credentials specified may be the responsible person for that classification type.

Effective, September 1, 2016, the Board hereby adopts the following responsible person requirements:

	CLINIC AND SPECIALTY TREATMENT PROGRAMS						
CL - CREDENTI AL CLASS	BUSINE SS TYPE	BUSINESS TYPE DEFINITION	LIMITED OR UNLIMITED	RESP. PERSON	SPECIAL REQUIREMEN TS		
CL	AS	Ambulatory Surgery	Unlimited	DO, MD, RPH, DDS, DPM			
CL	CI	Correctional Institution - clinic or med room that is located within a correctional facility or jail.	Unlimited	DO, MD, RPh, APRN			
CL	CL	Clinic - Health Dept., Free Clinic, Specialty Clinic	Unlimited	DO, MD, RPH, APRN			
CL	СТВ	Chemical Treatment - METHADONE AND /OR BUPRENORPHINE	Unlimited	DO, MD			
CL	ED	Free Standing Emergency Department	Unlimited	DO, MD, RPH			
CL	FA	First Aid Room/Departmen t	Limited	DO, MD, APRN	Provide a notarized, signed Drug List, Personnel List & Protocols.		

CL	MC	Mobile Clinic - Drugs stored on truck, aircraft, bus, etc.; includes non- emergent helicopters and aircraft	Unlimited	DO, MD, DVM, APRN, DDS	
CL	МН	Mental Health	Unlimited	DO, MD	
CL	ONC	Oncology Clinic	Unlimited	DO, MD, RPh	
CL	PC	Prescriber Practice- general medical provider	Unlimited	DO, MD, APRN, DDS, OD, RPH	
CL	POC	Point of Care - Pyxis located in another Hospital	Unlimited	RPH	
CL	RT	Clinical Trials	Unlimited	DO, MD, DVM, OD, DDS	Provide an APRN Statement (if applicable)
CL	SC	Sports Training Facility	Unlimited	DO, MD, APRN	
CL	UR	Urgent Care + Convenience Care Clinic	Unlimited	DO, MD, APRN	
STP - CREDENTI AL CLASS	BUSINE SS TYPE	BUSINESS TYPE DEFINITION	LIMITED OR UNLIMITED	RESP. PERSON	SPECIAL REQUIREMEN TS
STP	OTP	Opioid Treatment Facility	Unlimited	DO, MD	Special certification for Classification *Cat. III ONLY. PERSONALLY FURNISING BUPRENORPHI NE ONLY. MUST HAVE YEARLY INSPECTIONS
STP	РМС	Pain Management Clinic & GPMC **GPMC was approved by the Medical and	Unlimited	DO, MD	Pain Management Checklist Requirements - Background check on

		Pharmacy Board in 2011			Owners, RP, and employees.			
	FACILITY							
FCY- CREDENTI AL CLASS	BUSINE SS TYPE	BUSINESS TYPE DEFINITION	LIMITED OR UNLIMITED	RESP. PERSON	SPECIAL REQUIRMENT S			
FCY	AC	Animal Control, Dog Pound, Dog Warden, Humane Society	Unlimited	DVM				
FCY	AE	Animal Euthanasia	Limited	CET, DVM, DOG WARDEN	Provide a notarized, signed Drug List, Personnel List & Protocols. Must have completed euthanasia certification course			
FCY	BB	Blood Bank	Unlimited	DO, MD				
FCY	СС	Custodial Care, Pediatric Respite, Group Home	Unlimited	DO, MD				
FCY	DG	Dog Trainer	Limited	MANAGEME NT + LENA	Provide signed, notarized Drug List and Personnel List. Must have Law Enforcement Agent signed Drug List			
FCY	DU	Dialysis	Unlimited	DO, MD, APRN, RPH				
FCY	EM	EMS Headquarters	Limited	DO, MD, RPH	Provide a notarized, signed Drug List, Personnel List &			

					Protocols. Complete EMS Contact Addendum
FCY	EMSS	EMS Satellite	Limited	DO, MD, RPH	Provide a notarized, signed Drug List, Personnel List & Protocols. Complete EMS Contact Addendum
FCY	HC	Hospice - Patient is under comfort care only with 6 months or less to live.	Unlimited	DO, MD	
FCY	HH	Home Health Care - providing services to the patient's homes or vaccination off- site	Limited	DO, MD	Provide a notarized, signed Drug List, Personnel List & Protocols.
FCY	IC	Infusion Center	Unlimited	DO, MD, RPH	
FCY	IM	Imaging	Limited	DO, MD	Provide a notarized, signed Drug List, Personnel List & Protocols.
FCY	LA	Laboratory/Resear ch	Unlimited	DO, MD, PHD, CHEMIST, MANAGEME NT, RPH, DVM	Provide a proof of a degree in one of the following: chemistry, biochemistry, forensic science, biology, microbiology, or related pure applied

					science. Proof of certified training in the field of expertise.
FCY	ND	Nursing Home Drug Stock	Limited	DO, MD, APRN	Provide a notarized, signed Drug List, Personnel List & Protocols.
FCY	PD	Peritoneal Dialysis Center - ships directly to the patient's home, no RPH performs the final verification	Limited	MANAGEME NT	Provide a notarized, signed Drug List, Personnel List & Protocols.
FCY	PT	Physical Therapy	Limited	DO, MD	Provide a notarized, signed Drug List, Personnel List & Protocols.
FCY	TE	Teaching Institution	Limited	DDS, DO, MD, HEAD OF PROGRAM (RN), RPh, APRN, PA, OD, DVM	Provide a notarized, signed Drug List, Personnel List & Protocols. **INJECTING INTO HUMANS RESP MUST BE A DDS, DO, MD, DPM, DDS, OD, RPH, or APRN
FCY	VP	Veterinary Hospital or Zoo	Unlimited	DVM	
FCY	VT	Veterinary Practice	Unlimited	DVM	*FEE: \$40.00, Cat. III ONLY
		MEDIC	AL GASES		

MG - CREDENTI AL CLASS	BUSINE SS TYPE	BUSINESS TYPE DEFINITION	LIMITED OR UNLIMITED	RESP. PERSON	SPECIAL REQUIREMEN TS		
MG	СМ	Compressed Medical Gases (OXYGEN & NITROUS OXIDE)	LIMITED	MD, DO, RN, APRN, LNHA, RRT, OD, DDS, DVM, RPH, MANAGEME NT	Provide a notarized, signed Drug List/Medical Gas Statement and an Authorized Personnel List. *Category II - ONLY		
MG	СХ	Contingency Stock (formerly ORCS)	LIMITED	RN, LNHA, MANAGEME NT, RRT	Provide a notarized, signed Drug List/Medical Gas Statement and an Authorized Personnel List. *Category II - ONLY		
MG	GM	Manufacturer- Process Use + Food Processor	LIMITED	MANAGEME NT	Provide a notarized, signed Drug List/Medical Gas Statement and an Authorized Personnel List. *Category II - ONLY		
MG	OX	Retail Seller or Biller of Oxygen (formerly RSOX and RBOX)	LIMITED	MD, DO, RN, APRN, LNHA, RRT, OD, DDS, DVM, RPH, MANAGEME NT	Provide a notarized, signed Drug List/Medical Gas Statement and an Authorized Personnel List. *Category II - ONLY		
	PHARMACY						

PMY - CREDENTI AL CLASS	BUSINE SS TYPE	BUSINESS TYPE DEFINITION	LIMITED OR UNLIMITED	RESP. PERSON	SPECIAL REQUIREMEN TS
PMY	CF	Central Fill Pharmacy	UNLIMITED	RPH	
ΡΜΥ	СН	Charitable Pharmacy	UNLIMITED	RPH	Must provide Tax Exempt Paperwork
PMY	CI	Correctional Institution	Unlimited	RPH	
PMY	СР	Clinic Pharmacy	UNLIMITED	RPH	
РМҮ	CR	Consulting Pharmacy-NO DRUGS ON SITE	LIMITED	RPH	*ONLY CAT II LICENSE
ΡΜΥ	CRP	Consulting Pharmacy/Remote Order Entry ONLY - NO DRUGS ON SITE	LIMITED	RPH	*Only Cat II License
PMY	DM	Durable Medical Equipment	UNLIMITED	RPH	
PMY	DR	Drug Repository	UNLIMITED	RPH	Must provide Tax Exempt Paperwork
PMY	FL	Fluid Therapy	UNLIMITED	RPH	
РМҮ	HS	Hospital	UNLIMITED	RPH	
РМҮ	II	Independent Community Retail Pharmacy - 1 Outlet	UNLIMITED	RPH	
ΡΜΥ	IL	Large Chain Retail Pharmacy - 12 or more Outlets	UNLIMITED	RPH	
ΡΜΥ	IP	Pharmacy Servicing Institutions	UNLIMITED	RPH	*May included Mental Health Pharmacies & Nursing Home Inpatient Pharmacies
РМҮ	IS	Small Chain Retail Pharmacy - 2 to 11 Outlets	UNLIMITED	RPH	

РМҮ	KIOSK	Kiosk	UNLIMITED	RPH	*Must have Board approval
ΡΜΥ	MD	Multi-Disciplinary	UNLIMITED	RPH	**MAY INCLUDE COMPOUNDIN G
PMY	MO	Mail Order	UNLIMITED	RPH	
ΡΜΥ	MTM	Medication Therapy Management - NO DRUGS ON SITE	LIMITED	RPH	
ΡΜΥ	NU	Nuclear Pharmacy	UNLIMITED	RPH	
ΡΜΥ	ONC	Oncology Pharmacy	UNLIMITED	RPH	
ΡΜΥ	SP	Specialty Pharmacy - High \$ Drugs	UNLIMITED	RPH	**MAY INCLUDE COMPOUNDIN G
	PHAF	RMACY SUPPLI	ED CONTIG	ENCY STO	СК
PSCS - CREDENTI AL CLASS	BUSINE SS TYPE	BUSINESS TYPE DEFINITION	LIMITED OR UNLIMITED	RESP. PERSON	SPECIAL REQUIREMEN TS
PSCS	CC	Contingency stock within custodial care	Unlimited	RPH	
PSCS	CI	Contingency stock within a Correctional Institution	UNLIMITED	RPH	
PSCS	CS	Contingency stock within a Community Pharmacy	UNLIMITED	RPH	
PSCS	HC	Contingency stock within a Hospice Facility	UNLIMITED	RPH	
PSCS	HS	Contingency stock within a Hospital	UNLIMITED	RPH	
PSCS	МН	Contingency stock within a Mental Health Institution	UNLIMITED	RPH	

PSCS	NH	Contingency sto within a Nursing Home		UNLIMITED	RPH	
		NON-RESI	DE	INT PHAR	MACY	
NRP - CREDENTI AL CLASS	BUSINE SS TYPE	BUSINESS TYPE DEFINITION		LIMITED OR UNLIMITED	RESP. PERSON	SPECIAL REQUIREMEN TS
NRP	CF	Non-Resident Central Fill Pharmacy		UNLIMITED	RPH	
NRP	CR	Non-Resident Consulting Pharmacy- no drugs onsite		LIMITED	RPH	
NRP	CRP	Remote Order Entry ONLY - NC DRUGS ON SITE		LIMITED	RPH	*Only Cat II License
NRP	IP	Non-Resident Pharmacy Servicing an Institution		UNLIMITED	RPH	
NRP	MO	Non-Resident M Order Pharmacy		UNLIMITED	RPH	
NRP	MTM	Non-Resident Medication Therapy Management - I DRUGS ON SITE		LIMITED	RPH	*Only Cat II License
NRP	NU	Non-Resident Nuclear Pharma	су	UNLIMITED	RPH	
NRP	SP	Non-Resident Specialty Pharmacy - High Drugs	<b>ו</b> \$	UNLIMITED	RPH	**MAY INCLUDE COMPOUNDIN G
	•	W	HO	LESALER		
WHS - WHOLESALER / MANUFACTURER CREDENTIAL CLASS		BUSINESS TYPE		USINESS TYPE ESCRIPTION	RESP. PERSON	SPECIAL REQUIREMENT S
WHS		BC	Pł	ulk narmaceutical nemical Seller	MANAGEME NT	
WHS		BG	Bı gr	uying Group - A oup of /holesalers/Sto	MANAGEME NT	

		res that leverage		
		for better pricing		
WHS	CM	Compressed Medical Gases	MANAGEME NT	
WHS	CN	Clinic Wholesaler: Blood Banks, Health Departments	MANAGEME NT	
WHS	DM	Durable Medical Equipment	MANAGEME NT	Respiratory Care Board license if applicable (ORC 4752)
WHS	FS	Full Service	MANAGEME NT	
WHS	IE	Import/Export - importing drugs from in/out of the country	MANAGEME NT	
WHS	IR	In-State Rx Disposal	MANAGEME NT	Must provide DEA & EPA registration
WHS	LA	Lab	MANAGEME NT	
WHS	MF	Full Service Manufacturer	MANAGEME NT	If manufacturing Kits- need FDA registration
WHS	OD	Out-of-State Rx Disposal	MANAGEME NT	Must provide DEA & EPA registration
WHS	PM	Pre-Packaged Meds	MANAGEME NT	FDA repackaging registration
WHS	PU	Public Health Preparedness	MANAGEME NT	-
WHS	RE	Re-packed Meds	MANAGEME NT	FDA repackaging registration
WHS	WD	Waste Disposal	MANAGEME NT	

WHS	WCSM	Controlled Substance Manufacturer	MANAGEME NT	
WHS	WCSW	Controlled Substance Wholesaler	MANAGEME NT	
WHS	WI	Within own Corporation	MANAGEME NT	
WDIS - THIRD PARTY LOGISTICS CREDENTIAL CLASS	BUSINESS TYPE	BUSINESS TYPE DESCRIPTION	RESP. PERSON	SPECIAL REQUIREMENT S
WDIS	3PL	3PL'S- Stores drug onsite but does not have ownership of the drug	MANAGEME NT	MANAGEMENT
WDIS	WCSW	Controlled Substance Wholesaler	MANAGEME NT	
WVMF - VIRTUAL MANUFACTURER CREDENTIAL CLASS	BUSINESS TYPE	BUSINESS TYPE DESCRIPTION	RESP. PERSON	SPECIAL REQUIREMENT S
WVMF	VM	Virtual Manufacturer - NO DRUGS ON SITE	MANAGEME NT	Must provide a state license or VAWD accreditation
WVMF	WCSV	Controlled Substance Manufacturer	MANAGEME NT	
WMOF - OUTSOURCER CREDENTIAL CLASS	BUSINESS TYPE	BUSINESS TYPE DESCRIPTION	RESP. PERSON	SPECIAL REQUIREMENT S
WMOF	FS	Full Service	Pharmacist	Must provide the FDA inspection report (including any 483A) and a State Inspection less than 2 years' old
WMOF	SCY	Sterile Compounding	Pharmacist	

V	VMOF	WCWO	Controlled	Pharmacist	
			Substance		
			Outsourcer		

The motion was seconded by Ms. Yarosh and approved by the Board: Aye-7.

- **<u>R-2017-228</u>** Ms. Yarosh moved that the Board's Responsible Person Committee handle all future Multiple RP Requests and will only come before the full Board if the committee cannot make a determination. The motion was seconded by Mr. Passafume and approved by the Board: Aye-7.
- **<u>R-2017-229</u>** Ms. Yarosh moved to adopt the following Multiple RP Request decisions presented by the Responsible Person Committee:

# • Amy Myers, RPh (03-1-20444)-Denied

- o Riley Creek Pharmacy: Pandora, Ohio (02-2023650)
- Pharmacy Solutions: Pandora, Ohio (02-2023900)

# • Nicolas Beatty, RPh (03-1-35569)-Approved

- Fayette Pharmacy: Washington Courthouse, Ohio (02-1877800)
- Fayette County Health Department: Washington Courthouse, Ohio (02-1444800)

# • Helen Betizel, RPh (03-2-18049)-Approved

- Eden Springs Pharmacy: Green Springs, Ohio (02-2653250)
- o Eden Springs Pharmacy: Green Springs, Ohio (02-2653300)

## • Emily Hoskins, RPh (03-3-34818)-Approved

- Arrow Springs Outpatient: Lebanon, Ohio (02-2091050)
- Arrow Springs Pharmacy: Lebanon, Ohio (02-2667050)

## • Michael Schumate, RPh (03-1-12280)-Approved

- Grace Hospital Pharmacy: Cleveland, Ohio (02-1337950)
- Access RX Pharmacy, LLC: Dayton, Ohio (02-2667050)

## • Robert Castro, RPh (Out of State)-Approved

- o Zo Skin Health, Inc.: Irvine, California (01-2274100)
- o Zo Skin Health, Inc.: Irvine, California (01-2647500)

## • Michael Turnamian, RPh (Out of State)-Approved

- Gemini Labratories, LLC: Bridgewater, New Jersey (01-2402350)
- Solis Generic Pharmaceuticals, LLC: Bridgewater, New Jersey (01-2647300)

# • Harold Deas, RPh (Out of State)-Approved

- Acella Pharmaceuticals, LLC: Alpharetta, Georgia (01-1847900)
- Avion Pharmaceuticals, LLC: Alpharetta, Georgia (01-2181900)

# • Vincent Durante, RPh (Out of State)-Approved

• Pharma-C, Inc.: Paramus, New Jersey (01-2157400)

- World Gen, LLC: Paramus, New Jersey (01-1406600)
- WG Critical Care, LLC: Paramus, New Jersey (01-1958750)
- o Interchem Corporation: Paramus, New Jersey (01-1715550)

## • Jacob Beck, RPh (Out of State)-Approved

- AnovoRX Distributions, LLC: Memphis, Tennessee (01-2348100)
- AnovoRX Distributions, LLC: Memphis, Tennessee (01-2617500)

## • Robert Justman (Out of State)-Approved

- Galderma Laboratories: Fort Worth, Texas (01-1217800)
- Owen Laboratory: Fort Worth, Texas (01-2498350)

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

**<u>R-2017-230</u>** The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A)(1) requesting that **Jon Myers, RPh** (03-1-22750) Hicksville, Ohio be the Responsible Person for the following pharmacies:

Hicksville Pharmacy: Hicksville, Ohio (02-2091020) Community Memorial Hospital: Hicksville, Ohio (02-2023900)

After discussion, Ms. Yarosh moved that the Board approve the request for a period of 6 months and must petition for an extension if one is required. The motion was seconded by Ms. Marchal and approved by the Board: Aye-7.

**<u>R-2017-231</u>** The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A)(1) requesting that **Dwight Mosley, MD** (35.092811) New Albany, Ohio, be the Responsible Person for the following Pain Management Clinics:

Comprehensive Pain Specialists: Columbus, Ohio (02-2450800) Comprehensive Pain Specialists: Cincinnati, Ohio (02-2450750)

After discussion, Mr. Passafume moved that the Board approve the request for a period of 90 days. The motion was seconded by Mr. Cox and approved by the Board: Aye-7.

- **<u>R-2017-232</u>** The Board received an extension request for storage of records of **Meijer Pharmacy, Walgreens Pharmacy, and CVS Pharmacy** pursuant to Rule 4729-9-11. Mr. Weaver moved that the specific requests be approved. The motion was seconded by Ms. Marchal and approved by the Board: Aye-7.
- **<u>R-2017-233</u>** The Board received a CQE request of Camela Walker. Ms. Yarosh moved that the CQE request be approved. The motion was seconded by Mr. Weaver and approved by the Board: Aye-5/Deny-2.
- **<u>1:47 p.m.</u>** Ms. Witt, *Human Resources Manager*, introduced new Board employees Lori Klopp and Paula Economus.
- **<u>1:50 p.m.</u>** Mark Pilkington and Tony Matessa, *Cardinal Health,* gave a presentation to the Board regarding the InPower Personal Medication Assistant.

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**<u>2:50 p.m.</u>** The presentation ended.

The Board recessed briefly

**<u>3:00 p.m.</u>** The meeting reconvened in Room South B&C.

The Board was joined by Assistant Attorney General Steven Kochheiser to create a record in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of **Inverness Vet Hospital**, Toledo, Ohio.

**<u>3:12 p.m.</u>** The hearing ended and the record was closed.

Ms. Marchal moved that the Board recess in order to consider the 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. Rudell and a roll-call vote was conducted by President Moné as follows: Cox-yes; Marchal-yes; Passafume-yes; Rudell-yes; Weaver-yes; Wilt-yes and Yarosh-yes.

- **<u>4:06 p.m.</u>** The recess ended and the hearing was opened to the public.
- **<u>R-2017-234</u>** After votes were taken in public session, the Board adopted the following order in the matter of **Inverness Vet Hospital,** Toledo, Ohio.

**ORDER OF THE STATE BOARD OF PHARMACY** 

(Case Number 2015-2234)

In The Matter Of:

Inverness Veterinary Hospital c/o Jack Niggemyer, DVM 4425 Hill Ave Toledo, Ohio 43615 (TDDD License No. 02-2563200)

## **INTRODUCTION**

The Matter of Inverness Veterinary Hospital came for consideration on January 9, 2017, before the following members of the State of Ohio Board of Pharmacy (Board): Michael A. Moné, R.Ph., *Presiding;* Joshua M. Cox, R.Ph; Megan E. Marchal, R.Ph.; Curtis L. Passafume, Jr., R.Ph.; Jennifer M. Rudell, R.Ph.; Fred M. Weaver, R.Ph.; Shawn C. Wilt, R.Ph. and Kilee S. Yarosh, R.Ph.

Inverness Veterinary Hospital was not present nor represented by Counsel. The State of Ohio was represented by Steven Kochheiser, Assistant Attorney General.

## SUMMARY OF EVIDENCE

## State's Witnesses:

1. Homer Chapa—State of Ohio Board of Pharmacy

## Respondent's Witnesses:

None

## State's Exhibits:

olication 07-05-2016
11-21-2016
10-28-2015
03-19-2007
No Date
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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 Board finds the following to be fact:

1. On or about October 28, 2015, the Board received an application for a Terminal Distributor of Dangerous Drugs license from Inverness Veterinary Hospital by and through Jack Niggemyer who did sign and submit the document with an answer of "No" to the question inquiring whether 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 (or pending action) by any state or federal agency; even if subsequently dismissed or resolved without formal discipline. Upon further investigation, it was determined that answer was false.

2. During an investigation, an Agent of the Board discovered that Jack Niggemyer, Responsible Person for Inverness Veterinary Hospital, was disciplined by the State of Ohio Veterinary Board.

a. On or about March 14, 2007, Jack Niggemyer entered into a settlement agreement with the Ohio Veterinary Board for failing to keep medical records in accordance with Ohio veterinary practice act as set forth in Section 4741 of the ORC and Chapter 4741 of the Ohio Administrative Code (OAC). Pursuant to the settlement agreement, Jack Niggemyer received a letter of reprimand, was required to pay a \$500 fine, and submit ten (10) patient records each quarter to the Ohio Veterinary Board office.

## CONCLUSIONS OF LAW

1. Such conduct as set forth in the Findings of Fact Section also constitutes a violation of the following division of Section 4729.57 of the ORC:

a. Making any false material statements in an application for a license as a TDDD, ORC Section 4729.57(A)(1).

2. Finally, such conduct as set forth in paragraphs (1) and (2) of the Findings of Fact Section constitutes the following violation of the OAC, each punishable by a maximum fine of \$1,000:

a. Has been disciplined by any professional licensing board, OAC Rule 4729-9-19(A)(7).

## DECISION OF THE BOARD

1. Pursuant to Section 4729.57 of the Ohio Revised Code, the State of Ohio Board of Pharmacy hereby imposes a monetary penalty in the amount of \$1,150.00, by means of a cashier's check made payable to "Treasurer, State of Ohio," mailed with the enclosed form to the OSBP, 77 South High Street, 17<sup>th</sup> Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Order.

2. Pursuant to Sections 4729.57, 4729.54 and 4729.55 of the Ohio Revised Code, and after consideration of the record as a whole, upon receipt of payment of the monetary penalty the State of Ohio Board of Pharmacy approves the Application for Registration as a Terminal Distributor of Dangerous Drugs submitted by Inverness Veterinary Hospital on or about October 28, 2015.

Mr. Wilt moved for Findings of Fact; Mr. Weaver seconded the motion. Motion passed (Aye-7/Nay-0).

Ms. Marchal moved for Conclusions of Law; Mr. Wilt seconded the motion. Motion passed (Aye-7/Nay-0).

Ms. Marchal moved for Action of the Board; Mr. Weaver seconded the motion. Motion passed (Aye-7/Nay-0).

#### SO ORDERED.

- <u>**R-2017-235</u>** Mr. Moné announced that the citation issued to **LoneStar Pharmaceuticals,** Argyle, Texas is hereby dismissed.</u>
- **<u>R-2017-236</u>** Mr. Moné announced that the citation issued to **Turing Pharmaceuticals**, New York, New York is hereby dismissed.
- **<u>4:10 p.m.</u>** The Board was joined by Assistant Attorney General Steven Kochheiser to create a record in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of **AlexRon Pharmaceuticals, LLC,** Willoughby, Ohio.

**<u>5:02 p.m.</u>** The hearing ended and the record was closed.

Mr. Weaver moved that the Board recess in order to consider the 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: Marchal-yes; Passafume-yes; Rudell-yes; Weaver-yes; Wilt-yes and Yarosh-yes.

- **<u>5:26 p.m.</u>** The recess ended and the hearing was opened to the public.
- **<u>R-2017-237</u>** After votes were taken in public session, the Board adopted the following order in the matter of **AlexRon Pharmaceuticals, LLC,** Willoughby, Ohio.

### **ORDER OF THE STATE BOARD OF PHARMACY**

(Case Number 2016-1849)

In The Matter Of:

# AlexRon Pharmaceuticals, LLC c/o Ronald Russo 4834 Wood Street Willoughby, Ohio 44094 (DENIED License No. 01-2636800)

### **INTRODUCTION**

The Matter of AlexRon Pharmaceuticals, LLC came for consideration on January 9, 2017, before the following members of the State of Ohio Board of Pharmacy (Board): Michael A. Moné, R.Ph., *Presiding;* Megan E. Marchal, R.Ph.; Curtis L. Passafume, Jr., R.Ph.; Jennifer M. Rudell, R.Ph.; Fred M. Weaver, R.Ph.; Shawn C. Wilt, R.Ph. and Kilee S. Yarosh, R.Ph.

Joshua M. Cox, R.Ph.; Absent.

AlexRon Pharmaceuticals, LLC was not present nor represented by Counsel. The State of Ohio was represented by Steven Kochheiser, Assistant Attorney General.

## SUMMARY OF EVIDENCE

State's Witnesses:

1. Trey Edwards—State of Ohio Board of Pharmacy

Respondent's Witnesses:

None

State's Exhibits:

1.	Notice of Opportunity for Hearing/Proposal to Deny Application	10-11-2016
2.	Request for Hearing	11-02-2016
3.	Notice of Hearing Date for December Board Meeting	11-04-2016
4.	Credential View Screen	11-15-2016
5.	Wholesale Distributor of Dangerous Drugs Application	12-03-2015
6.	Wholesale Distributor of Dangerous Drugs Application	03-10-2016

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7.	Request to Withdraw Application(s)	04-14-2016
8.	Wholesale Distributor of Dangerous Drugs Application	06-30-2016
9.	Email Correspondence regarding Counsel Status	07-28-2016
10.	Certificate from Ohio Supreme Court	11-21-2016
11.	Investigative Photos	No Date
12.	Notice of Hearing Date for January Board Meeting	12-07-2016

Respondent's Exhibits:

None

## FINDINGS OF FACT & CONCLUSIONS OF LAW

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

1. The Board received an application for a Wholesale Distributor of Dangerous Drugs license from Alexron Pharmaceuticals, Inc. dated on or about June 30, 2016 signed by Ronald Russo. In its review of the application, the Board determined that you do not meet the minimum qualifications for registration as a wholesaler distributor of dangerous drugs.

2. During an investigation by an agent of the Board, it was also discovered that Responsible Person, Ronald Russo, is not a licensed attorney authorized to practice law in the state of Ohio. On the application and related documents submitted to the board, Ronald Russo held himself out as being authorized and capable of practicing law in this state by signing as General Counsel for Alexron Pharmaceutical, LLC and by indicating he is "a business attorney with twenty (20) years experience." The Lake County Bar Association has opened an unauthorized practice of law investigation on Mr. Russo as a result of his representations that he is a licensed attorney.

3. The applicant's past experience in the manufacture or distribution of dangerous drugs, including controlled substances, is not acceptable to the board, in violation of Section 4729.53(A)(2) of the Revised Code and Rule 4729-9-28(H) of the Administrative Code; and

4. The applicant is not equipped as to land, buildings, equipment, and personnel to properly carry on the business of a wholesale distributor of dangerous drugs, including providing adequate security for and proper storage conditions and handling for dangerous drugs, and is not complying with the requirements under this chapter and the rules adopted pursuant thereto for maintaining and making available records to properly identified board officials and federal, state, and local law enforcement agencies, in violation of Sections 3719.03(B) and 4729.53(A)(3) of the Revised Code; and

5. The applicant has not furnished satisfactory proof that personnel employed by the applicant have the appropriate education or experience, as determined by the board, to assume responsibility for positions related to compliance with this chapter and the rules adopted pursuant thereto, in violation of Section 4729.53(A)(4) of the Revised Code; and

6. Adequate safeguards are not assured to prevent the sale of dangerous drugs to any person other than those named in division (B) of Section 4729.51 of the Revised Code, in violation of Section 4729.53(A)(6) of the Revised Code.

7. Kathleen Russo is named as an authorized member, manager, or representative of AlexRon Pharmaceutical, LLC in the Articles of Organization dated on or about July 24, 2012 with the Ohio Secretary of State's office; however, Kathleen Russo is not listed on the application materials nor has she provided fingerprints for a criminal background check in violation of Rule 4729-9-16 of the Ohio Administrative Code.

8. The granting of the registration certificate is not in the public interest, in accordance with Sections 4729.53(B) and 3719.03(E) of the Revised Code.

9. The applicant's policies and procedures fail to meet minimum standards, in violation of Rules 4729-9-28(F) and 4729-9-28(G)

10. Additionally, Ronald Russo made material misrepresentations as to his status as a licensed attorney and the Board finds he is not of good moral character in violation of Section 3719.03(A) of the Revised Code and Rule 4729-9-19(A)(4) of the Ohio Administrative Code.

## DECISION OF THE BOARD

1. Pursuant to Section 4729.56 of the Ohio Revised Code, Rule 4729-9-19 of the Ohio Administrative Code, and after consideration of the record as a whole, the State of Ohio Board of Pharmacy hereby denies the Application for Registration as a Wholesale Distributor of Dangerous Drugs submitted by AlexRon Pharmaceuticals, LLC on or about June 30, 2016.

2. Pursuant to Chapter 4729-9-01(I) of the Ohio Administrative Code, AlexRon Pharmaceuticals, LLC may not reapply for any State of Ohio Board of Pharmacy license for a minimum of three years.

3. Pursuant to Section 4729.56 of the Ohio Revised Code, the State of Ohio Board of Pharmacy imposes a monetary penalty in the amount of \$1,000.00, by means of a cashier's check made payable to "Treasurer, State of Ohio," mailed with the enclosed form to the OSBP, 77 South High Street, 17<sup>th</sup> Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Order.

Mr. Passafume moved for Findings of Fact; Mr. Weaver seconded the motion. Motion passed (Aye-6/Nay-0).

Ms. Yarosh moved for Action of the Board; Mr. Wilt seconded the motion. Motion passed (Aye-6/Nay-0).

## SO ORDERED.

**5:31 p.m.** Mr. McNamee led a discussion regarding Rule 4729-5-14.

- **<u>R-2017-238</u>** Mr. Passafume moved that Rule 4729-5-14 be approved for filing with CSI and JCARR. The motion was seconded by Mr. Wilt and approved by the Board: Aye-6.
- 5:49 p.m. Mr. McNamee led a discussion regarding Rules 4729-29-03, 4729-29-02, and 4729-29-01.
- **R-2017-239** Mr. Passafume moved that Rules 4729-29-03, 4729-29-02, and 4729-29-01 be approved for filing with JCARR. The motion was seconded by Ms. Rudell and approved by the Board: Aye-6.
- **<u>6:37 p.m.</u>** The Board recessed for the day.

### Tuesday, January 10, 2017

**8:36 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, RPh, *President;* Megan E. Marchal, RPh; Curtis L. Passafume, Jr., RPh; Jennifer M. Rudell, RPh; Fred M. Weaver, RPh; Shawn C. Wilt, RPh and Kilee S. Yarosh, RPh

Ms. Marchal 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. Passafume and a roll-call vote was conducted by President Moné as follows: Marchal-yes; Rudell-yes; Weaver-yes; Wilt-yes and Yarosh-yes.

**<u>9:17 a.m.</u>** The meeting reconvened in Room South B&C.

The Board was joined by Assistant Attorney General Steven Kochheiser to create a record in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of **Toxicology Associates, Inc.,** Columbus, Ohio.

**10:15 a.m.** The hearing ended and the record was closed.

Ms. Marchal moved that the Board recess in order to consider the 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. Rudell and a roll-call vote was conducted by President Moné as follows: Marchal-yes; Passafume-yes; Rudell-yes; Weaver-yes; Wilt-yes and Yarosh-yes.

- **10:30 a.m.** The recess ended and the hearing was opened to the public.
- **<u>R-2017-240</u>** After votes were taken in public session, the Board adopted the following order in the matter of **Toxicology Associates, Inc.,** Columbus, Ohio.

## **ORDER OF THE STATE OF OHIO BOARD OF PHARMACY**

(Case Number 2016-1519)

In The Matter Of:

# Toxicology Associates, Inc. 999 Bethel Road Columbus, Ohio 43214 TDDD No. 02-0076050

### **INTRODUCTION**

The Matter of Toxicology Associates, Inc. came for consideration on January 10, 2017, before the following members of the State of Ohio Board of Pharmacy (Board): Michael A. Moné, R.Ph., *Presiding;* Megan E. Marchal, R.Ph.; Curtis L. Passafume, Jr., R.Ph.; Jennifer M. Rudell, R.Ph.; Fred M. Weaver, R.Ph.; Shawn C. Wilt, R.Ph. and Kilee S. Yarosh, R.Ph.

Joshua M. Cox, R.Ph; Absent.

Toxicology Associates, Inc. was not present nor represented by Counsel. The State of Ohio was represented by Steven Kochheiser, Assistant Attorney General.

### SUMMARY OF EVIDENCE

State's Witnesses:

- 1. Paul Schad, RPh—State of Ohio Board of Pharmacy
- 2. Erin Reed, Esq.—State of Ohio Board of Pharmacy

Respondent's Witnesses:

None

State's Exhibits:

1.	Notice of Opportunity for Hearing	11-29-2016
2.	Credential View Screen	01-03-2017
3.	Complaint from Margaret A. Walter MD FACS	05-15-2016
5.	Inspection Report	06-17-2014
6.	Response to June 17, 2014 Inspection Report	06-17-2014
7.	Inspection Report	10-03-2016
8.	Photos from October 3, 2016 Inspection	10-03-2016
9.	October 25, 2016 Inspection Report	10-25-2016
10.	Photos from October 25, 2016 Inspection	10-25-2016
11.	Statement dated November 8, 2016	11-08-2016

**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 Board finds the following to be fact:

1. On or about May 16, 2016, the Board received a complaint concerning Toxicology Associates, Inc.'s practices as a laboratory with a terminal distributor of dangerous drugs license.

2. The State of Ohio Board of Pharmacy staff conducted inspections at your facility in October of 2016 and observed the following; similar observations were also noted during an inspection conducted in June of 2014:

a. The poor condition of the facility, its equipment, and cleanliness. Specifically, filthy counter-tops, floors and ceiling tiles. The filthy counter-tops stored unmarked containers and beakers with various chemicals. The noxious fumes emanating from the containers and beakers were not properly ventilated out of the facility because the three fume hoods, covered in dirt or rust, were not in working order and/or were not operational. Several chemicals on the work benches were expired. In addition, old food contained in a freezer without a thermometer as well as expired chemicals were found within the facility.

b. Employees have unsupervised access to controlled substances, which are stored in an unlocked refrigerator and not in a substantially constructed cabinet.

- c. No records of controlled substances inventory.
- d. Expired controlled substances used for analysis.

3. The Compliance and Enforcement Staff that conducted the inspection ended the inspection early due to health and safety concerns of the noxious fumes and lack of ventilation within the facility.

## CONCLUSIONS OF LAW

1. Such conduct as set forth in paragraphs (2)(a) through (d) of the Findings of Fact Section constitutes a violation of Section 4729.55(B) of the Ohio Revised Code (ORC), a laboratory as defined in section 3719.01 of the Revised Code will maintain supervision and control over the possession and custody of dangerous drugs that may be acquired by or on behalf of the applicant.

2. Such conduct as set forth in paragraphs (2)(a) through (d) of the Findings of Fact Section constitutes a violation of each of the following divisions of Section 4729.57 of the ORC:

a. Violating any provision of this chapter, ORC Section 4729.57(A)(3); and

b. Ceasing to satisfy the qualifications of a TDDD set forth in 4729.55 of the Revised Code, ORC Section 4729.57(A)(7).

3. Such conduct as set forth in paragraphs (2)(a), (2)(d) and (3) of the Findings of Fact Section constitutes a violation of each of the following divisions of Section 3715.63 of the ORC:

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b. It is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health, ORC Section 3715.63(A)(3).

4. Such conduct as set forth in paragraphs (2)(a) through (d) of the Findings of Fact Section constitutes the following violations of Ohio Administrative Code Rule (OAC) 4729-13, approved laboratories:

a. The applicant is not qualified to conduct the business of an approved laboratory; OAC Rule 4729-13-03(A); and

b. Adequate safeguards are not assured to prevent the illegal acquisition, distribution, or utilization of dangerous drugs or their diversion into illicit channels, OAC Rule 4729-13-03(C); and

c. Records are not being kept in accordance with OAC Rule 4729-13-04; and

d. Controlled substances are not being stored in a securely locked, substantially constructed cabinet, OAC Rule 4729-13-05(B).

5. Such conduct as set forth in paragraph (2)(c) of the Findings of Fact Section constitutes a violation of Ohio Administrative Code Rule 4729-5-11(C)(6), Record keeping.

6. Such conduct as set forth in paragraphs (2)(a) and (2)(c) of the Findings of Fact Section constitutes a violation of Ohio Administrative Code Rule 4729-9-06, failure to conduct proper disposal of dangerous drugs which are controlled substances.

7. Such conduct as set forth in paragraphs (2)(a) through (d) the Findings of Fact Section constitutes a violation of Ohio Administrative Code Rule 4729-9-11, failure to maintain security and control of dangerous drugs.

8. Such conduct as set forth in paragraph (2)(c) of the Findings of Fact Section constitutes a violation of Ohio Administrative Code Rule 4729-9-14(B), failure to maintain proper records of controlled substances.

9. Such conduct as set forth in paragraphs (2)(a) through (d) the Findings of Fact Section constitutes a violation of Ohio Administrative Code Rule 4729-9-19(A)(4), failure to be of good moral character and habit.

10. Such conduct as set forth in paragraphs (2)(a) through (d) the Findings of Fact Section constitutes a violation of Ohio Administrative Code Rule 4729-9-22, failure to maintain proper Records of Dangerous Drugs.

#### **DECISION OF THE BOARD**

Pursuant to Section 4729.57 of the Ohio Revised Code, and pursuant to Section 4729-9-01(E) of the Ohio Administrative Code, and after consideration of the record as a whole, the State of Ohio Board of Pharmacy adjudicates the matter of Toxicology Associates, Inc. as follows:

On the basis of the Findings of Fact and section (1) of the Conclusions of Law, the State of Ohio Board of Pharmacy hereby revokes permanently the Terminal Distributor of Dangerous Drugs License, No. 02-0076050, held by Toxicology Associates, Inc. effective as of the Board's findings on January 10, 2017.

On the basis of the Findings of Fact and section (2) of the Conclusions of Law, the State of Ohio Board of Pharmacy hereby revokes permanently the Terminal Distributor of Dangerous Drugs License, No. 02-0076050, held by Toxicology Associates, Inc. effective as of the Board's findings on January 10, 2017.

On the basis of the Findings of Fact and section (3) of the Conclusions of Law, the State of Ohio Board of Pharmacy hereby revokes permanently the Terminal Distributor of Dangerous Drugs License, No. 02-0076050, held by Toxicology Associates, Inc. effective as of the Board's findings on January 10, 2017.

On the basis of the Findings of Fact and section (4) of the Conclusions of Law, the State of Ohio Board of Pharmacy hereby revokes permanently the Terminal Distributor of Dangerous Drugs License, No. 02-0076050, held by Toxicology Associates, Inc. effective as of the Board's findings on January 10, 2017.

On the basis of the Findings of Fact and section (5) of the Conclusions of Law, the State of Ohio Board of Pharmacy hereby revokes permanently the Terminal Distributor of Dangerous Drugs License, No. 02-0076050, held by Toxicology Associates, Inc. effective as of the Board's findings on January 10, 2017.

On the basis of the Findings of Fact and section (6) of the Conclusions of Law, the State of Ohio Board of Pharmacy hereby revokes permanently the Terminal Distributor of Dangerous Drugs License, No. 02-0076050, held by Toxicology Associates, Inc. effective as of the Board's findings on January 10, 2017.

On the basis of the Findings of Fact and section (7) of the Conclusions of Law, the State of Ohio Board of Pharmacy hereby revokes permanently the Terminal Distributor of Dangerous Drugs License, No. 02-0076050, held by Toxicology Associates, Inc. effective as of the Board's findings on January 10, 2017.

On the basis of the Findings of Fact and section (8) of the Conclusions of Law, the State of Ohio Board of Pharmacy hereby revokes permanently the Terminal Distributor of Dangerous Drugs License, No. 02-0076050, held by Toxicology Associates, Inc. effective as of the Board's findings on January 10, 2017.

On the basis of the Findings of Fact and section (9) of the Conclusions of Law, the State of Ohio Board of Pharmacy hereby revokes permanently the Terminal

Distributor of Dangerous Drugs License, No. 02-0076050, held by Toxicology Associates, Inc. effective as of the Board's findings on January 10, 2017.

On the basis of the Findings of Fact and section (10) of the Conclusions of Law, the State of Ohio Board of Pharmacy hereby revokes permanently the Terminal Distributor of Dangerous Drugs License, No. 02-0076050, held by Toxicology Associates, Inc. effective as of the Board's findings on January 10, 2017.

The Board further orders Toxicology Associates, Inc. to pay to a monetary penalty in the amount of \$10,000.00, by means of a cashier's check made payable to "Treasurer, State of Ohio," mailed with the enclosed form to the OSBP, 77 South High Street, 17<sup>th</sup> Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Order.

Ms. Yarosh moved for Findings of Fact; Ms. Marchal seconded the motion. Motion passed (Aye-6/Nay-0).

Mr. Wilt moved for Conclusions of Law; Ms. Yarosh seconded the motion. Motion passed (Aye-/6Nay-0).

Ms. Yarosh moved for Action of the Board; Mr. Passafume seconded the motion. Motion passed (Aye-6/Nay-0).

#### SO ORDERED.

## ORDER VACATING THE JANUARY 12, 2017 ORDER OF THE STATE OF OHIO BOARD OF PHARMACY AND SETTING THE MATTER FOR HEARING (Case Number 2016-1519)

In The Matter Of:

Toxicology Associates, Inc. 999 Bethel Road Columbus, Ohio 43214 TDDD No. 02-0076050

On November 29, 2016, the State of Ohio Board of Pharmacy (Board) issued a Notice of Opportunity for Hearing of Proposed Disciplinary Action (Notice) in the matter of Toxicology Associates, Inc., License Number 02-0076050. As of the thirtieth day after mailing pursuant to Section 119.07 of the Revised Code, the Board had not received a request for a hearing from Toxicology Associates, Inc. Accordingly, the matter was set before the Board pursuant to *Goldman v. State Med. Bd.* and heard on January 10, 2017. On January 12, 2017, the Board issued its Order in the matter and served Toxicology Associates, Inc., with its Order. Upon receipt of the January 12, 2017 Order, the Board received communication from Benjamin Corpus, the owner/operator of Toxicology Associates, Inc. indicating he had requested a hearing on December 27, 2016 as instructed in the Notice letter via email.

After consultation with the Board's Information Technology Department, Toxicology Associates, Inc.'s request for a hearing dated December 27, 2016 was located in a spam e-mail folder. As such, this Board hereby vacates its Order dated January 12, 2017 and grants Toxicology Associates, Inc. a hearing in this matter as to the allegations set forth in the Notice letter dated November 29, 2016. A scheduling letter with a new hearing date will be sent to Toxicology Associates, Inc.

- **<u>R-2017-241</u>** Ms. Marchal moved that the Board Meeting Minutes of December 5-6, 2016 are approved as written. The motion was seconded by Ms. Yarosh and approved by the Board: Aye-6.
- **10:36 a.m.** The Board discussed the InPower Personal Medication Assistant presented by Cardinal Health at yesterday's meeting.
- **<u>R-2017-242</u>** Mr. Weaver moved that the meeting be adjourned. The motion was seconded by Mr. Passafume and approved by the Board: Aye-6.
- **<u>10:43 a.m.</u>** The meeting was adjourned.
- **<u>1:30 p.m.</u>** The following candidates for licensure by reciprocity participated in a discussion of pharmacy laws and rules with Ms. Terri Ghittman, *OARRS Pharmacist*, in Room South A, 31<sup>st</sup> Floor of the Vern Riffe Center for the Government and the Arts:

**KRISTEN LEIGH AMMAY** JEFF A. BATES DAVID JOSEPH BLANZY SHELLEY ANNETTE BROWN JESSICA SHU-SHUAN CHEN **KELLI ANN CONNER** DANIELLE E. DUNLAP JORDAN SHEA GOETZKE **KYLE RYAN GRIMSLID** LAUREN HOVAN **BRIAN ANDREW KUEHNE** HONG T. LAM **BONI-SUE LANINFA** PIO JUAN DAVID LANSANGAN ANDREA M. LINDERS JON THEODORE MCCLYMONT CARLA MCFADDEN RYUN SCHOEFIELD MCKENZIE SATENDRA H. PATEL TALLIE LENORE PEDERSON CHELSEA REGINA PEKNY JEREMY JAMES PRUNTY NATHANAEL RYAN REPINE NICHOLAS AARON ROBINSON SHARMEEN Y. ROY

CALIFORNIA MICHIGAN **FLORIDA** INDIANA TEXAS **ILLINOIS** ARIZONA TENNESSEE TEXAS MASSACHUSETTS **KENTUCKY ILLINOIS** MASSACHUSETTS CALIFORNIA ILLINOIS NEBRASKA INDIANA **FLORIDA** MICHIGAN NEVADA INDIANA WEST VIRGINIA INDIANA WEST VIRGINIA TEXAS

JASON WILLIAM SCHLIEPER ROWENA NANNETTE SCHWARTZ LEAH CHRISTINE SHEFFER ROBERT E. SWEENEY JENNIFER KATHERINE WARD ALEXANDRA CAITLIN WILLIAMS KATIE ANN WILSON

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NEVADA ILLINOIS MISSOURI PENNYLVANIA TEXAS ARKANSAS WEST VIRGINIA

Michael A. Moné, RPh, President

Steven W. Schierholt, Esq., Executive Director

2 Date

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