



MINUTES OF THE OCTOBER 1-2, 2018 **MEETING OF THE STATE OF OHIO BOARD OF PHARMACY**

Monday, October 1, 2018

10:05 a.m. The State of Ohio Board of Pharmacy convened in the Hearing Room, 17th Floor, of the Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio, with the following members present:

Fred M. Weaver, RPh, Presiding; Joshua M. Cox, RPh; Richard J. Newlon, *Public Member*; Megan E. Marchal, RPh; Dennis R. Miller III, RPh; Jennifer M. Rudell, RPh; and Shawn C. Wilt, RPh.

Curtis L. Passafume, RPh and Kilee S. Yarosh, RPh, Absent

Also present were Steven Schierholt, *Executive Director*; Eric Griffin, *Director of Compliance and Enforcement*; Nicole Dehner, *Chief Legal Counsel*; Joe Koltak, *Senior Legal Counsel*; Sarah Ackman, *Senior Legal Counsel* Jenni Wai, *Chief Pharmacist*; Erin Reed, *Senior Legal Counsel*; Chad Garner, *Director of OARRS*; Karrie Southard, *Director of Licensing*; Yvonne Tertel, *Assistant Attorney General*; and Ali Simon, *Public and Policy Affairs Liaison*.

10:05 a.m. Mr. Schierholt provided the Executive Director Report.

10:14 a.m. Mr. Garner provided the OARRS Report

10:24 a.m. Mr. McNamee lead a discussion on the Classification of Kratom as a Schedule 1 Controlled Substance. The Board reviewed the following information and draft rule.

Section 1: Summary

The State of Ohio Board of Pharmacy (BOP), pursuant to section 3719.44 of the Ohio Revised Code, proposes the placement of the following into Schedule I:

Mitragynine and 7-hydroxymitragynine, which are the main active constituents of the plant kratom.

Section 2: Background

Pursuant to section 3719.44 the Board may add or transfer a compound, mixture, preparation, or substance to schedule I when it appears that there is a high potential for abuse, that it has no accepted medical use in treatment in this state, or that it lacks accepted safety for use in treatment under medical supervision.



In making a determination to add an unscheduled compound, the Board is required to consider the following 8 criteria:

- (1) The actual or relative potential for abuse;
- (2) The scientific evidence of the pharmacological effect of the substance;
- (3) The state of current scientific knowledge regarding the substance;
- (4) The history and current pattern of abuse;
- (5) The scope, duration, and significance of abuse;
- (6) The risk to the public health;
- (7) The potential of the substance to produce psychic or physiological dependence liability; and
- (8) Whether the substance is an immediate precursor.

Section 3: Evaluating Kratom Under the Eight Criteria

(1) The actual or relative potential for abuse.

Scientists at the US Food and Drug Administration (FDA) first analyzed the chemical structures of the 25 most prevalent compounds in kratom. From this analysis, the agency concluded that all of the compounds share the most structural similarities with controlled opioid analgesics, such as morphine derivatives. Further analysis by the FDA determined that 22 (including mitragynine) of the 25 compounds in kratom bind to mu-opioid receptors. The FDA further notes:

The data from the PHASE model shows us that kratom compounds are predicted to affect the body just like opioids. Based on the scientific information in the literature and further supported by our computational modeling and the reports of its adverse effects in humans, we feel confident in calling compounds found in kratom, opioids.ⁱ

(2) The scientific evidence of the pharmacological effect of the substance.

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) notes that mitragynine and 7-hydroxymitragynine are selective and full agonists of the mu-opioid receptor. The receptor agonist effect of kratom alkaloids is antagonized by the opioid receptor antagonist naloxone. In addition, 5-HT_{2a} and postsynaptic α_2 -adrenergic receptors, as well as neuronal Ca²⁺ channels are also involved in the unique pharmacological and behavioral activity of mitragynine.

The EMCDDA reports the effects of kratom in humans are dose-dependent: small doses produce 'cocaine-like' stimulation while larger dosages cause 'morphine-like' sedative-narcotic effects.

After taking a few grams of dried leaves, the invigorating effects and euphoria are felt within 10 minutes and last for one to one and a half hours. Kratom users report increased work capacity, alertness, sociability and sometimes heightened sexual desire. The pupils are usually normal or very slightly contracted; blushing may be noted. In one of the few human clinical experiments, a 50 mg oral dose of mitragynine produced motor excitement, followed by giddiness, loss of motor coordination, and tremors of the extremities and face.

Kratom taken in large, sedating doses corresponding to 10–25 g of dried leaves may initially produce sweating, dizziness, nausea and dysphoria but these effects are shortly superseded with calmness, euphoria and a dreamlike state that last for up to six hours.

In animal studies, the antinociceptive and cough-suppressant effects of mitragynine were comparable to those of codeine. In mice, 7-hydroxymitragynine was several times more potent analgesic than morphine even upon oral administration.ⁱⁱ

Kratom is slightly toxic to animals. Mice chronically treated with 7-hydroxymitragynine developed tolerance, cross-tolerance to morphine and withdrawal signs that could be precipitated by naloxone administration.ⁱⁱⁱ

(3) The state of current scientific knowledge regarding the substance.

The metabolism of mitragynine in humans occurs via hydrolysis of the side-chain ester, *O*-demethylation of the methoxy groups, oxidative and/or reductive transformations, and the formation of glucuronide and sulfate conjugates. In a man who fatally overdosed propylhexedrine and kratom, the postmortem mitragynine concentrations ranged from 0.01 mg/kg to 1.20 mg/l.^{iv}

The FDA through their Public Health Assessment via Structural Evaluation (PHASE) methodology found that there is no evidence to indicate that kratom is safe or effective for any medical use. The compounds in kratom were found to bind to mu-opioid receptors similar to other opioids. The FDA also found serious side effects associated with kratom, including seizures and respiratory depression.^v

(4) The history and current pattern of abuse.

Kratom, which contains the main active alkaloids mitragynine and 7-hydroxymitragynine, has a long history of use in Southeast Asia as an opium substitute. Kratom is also known in Southeast Asia as thang, thom, krathom, kakuam, ketum, and biak. In recent years, the presence of the psychoactive plant kratom has increased significantly on the recreational market in the United States. It has been marketed in the US as a plant-based product with broad healing properties mostly sold in smoke shops, gas stations, and over the internet.

On May 22, 2018, the FDA issued three warning letters to three marketers and distributors of kratom products for illegally selling unapproved kratom-containing drug products. These products were marketed with unproven claims about treating pain, lowering blood pressure, treating cancer, and reducing neuron damage caused by strokes.^{vi}

In a 2016 publication, the Centers for Disease Control (CDC) characterized kratom exposures reported to poison centers and uploaded to the National Poison Data System (NPDS) from January 2010 through December 2015. During the stated timeframe, U.S. poison centers received 660 calls related to kratom exposure. Of the calls reported, 487 (73.8%) reported intentional exposure to kratom, and 595 (90.2%) reported ingestion of the drug. In addition to reports of isolated exposures to kratom (428 (64.8%)), reports of kratom being used with other substances (ethanol, benzodiazepines, narcotics, acetaminophen, and other botanicals) were also recorded. Additionally, forensic laboratory analyses of drug evidence have identified kratom/mitragynine, along with synthetic cannabinoids and synthetic opioids during the analyses of products seized on the illicit market. The consumption of kratom individually, or in conjunction with alcohol or other drugs, is of serious concern as it can lead to severe adverse effects and death.^{vii}

According to research conducted by the FDA, no marketer has sought to develop a drug that includes kratom in the US. Kratom is a controlled substance in 16 countries, including Thailand and Malaysia where it is found naturally. It is also banned in several states including Alabama, Arkansas, Indiana, Vermont, Rhode Island, Wisconsin and the District of Columbia have banned kratom, along with at least three cities — Denver, San Diego and Sarasota, Florida.^{viii} Currently, the Drug Enforcement Administration (DEA) has listed kratom as a Drug and Chemical of Concern.^{ix}

(5) The scope, duration, and significance of abuse.

According to the DEA, reports from law enforcement indicate that kratom is being imported for widespread distribution to the public within the United States. Between February 2014 and July 2016, over 55,000 kilograms

(kg) of kratom material were encountered by law enforcement at various ports of entry within the United States. Additionally, over 57,000 kg of kratom material offered for import at numerous ports of entry, between 2014 and 2016, are awaiting an FDA admissibility decision. The amount of kratom currently seized or awaiting an admissibility decision by law enforcement, between 2014 and 2016, is enough to produce over 12 million doses of kratom.^x

Drug reports pertaining to the trafficking, distribution, and abuse of kratom/mitragynine were analyzed by Federal, State, and local forensic laboratories. According to data from the System to Retrieve Information from Drug Evidence (STRIDE) and STARLiMS (a web-based, commercial laboratory information management system), from January 2006 through March 2016, there were 293 records for kratom and/or mitragynine. From January 2010 through May 2016, the National Forensic Laboratory Information System (NFLIS) registered 720 reports containing mitragynine. NFLIS and STRIDE/STARLiMS records/reports were reported across 43 States, thus showing the widespread abuse and trafficking of kratom/mitragynine. The presence of these substances during drug evidence analyses demonstrates the presence of these substances on the recreational drug market.^{xi}

Growing concern over the use of kratom is reflected in the increased requests for analyses of mitragynine and 7-hydroxymitragynine in human toxicology panels (blood/urine samples) to private analytical laboratories. These analyses have been requested by addiction treatment facilities/pain management doctors, drug courts, medical examiner/coroner offices, drug testing facilities, state laboratory systems, state police department, and private entities. The number of positive results from these analyses increased as follows: 31 positive results from August 2012 to July 2013 for mitragynine and/or 7-hydroxymitragynine; 274 positive results for mitragynine between July 2013 and May 2014; 555 positive results for mitragynine between December 2014 and March 2016. According to DEA, the increasing trend in the number of positive results from these analyses demonstrates the growing abuse and popularity of these substances and the concern related to the abuse of this plant material and its psychoactive constituents.^{xii}

The most recent Drug Trend Report from the Ohio Substance Abuse Monitoring Network (June 2017 - January 2018) finds that Kratom is available in the Akron-Canton and Cleveland regions. Notably, participants in the Akron-Canton region reported being able to purchase the drug from heroin dealers and through Internet purchase, while community professionals indicated that the drug can be purchased at head shops. Participants in the Cleveland region reported being able to purchase the drug in powdered form and in capsules. Participants reported that the drug looks similar to brown powdered heroin, produces similar effects as heroin, and is primarily used by individuals subject to drug screening and by people addicted to heroin who use the drug to alleviate opiate withdrawal symptoms. Participants reported that the most common route of administration for kratom is intravenous injection (aka "shooting"). Participants in the Akron-Canton region estimated that out of 10 kratom users, seven would shoot the drug and three would orally consume the drug (including drinking it as a tea).^{xiii}

(6) The risk to the public health.

Information from the scientific literature also demonstrates the health risks associated with kratom use. Reports of hepatotoxicity, psychosis, seizure, weight loss, insomnia, tachycardia, vomiting, poor concentration, hallucinations, and death associated with kratom use have been documented.^{xiv}

Numerous deaths associated with kratom, which contains the main active constituents mitragynine and 7-hydroxymitragynine, have been reported indicating that this substance is a risk to the public health. Deaths related to kratom exposure have been reported in the scientific literature beginning in 2009-2010, with a cluster of nine deaths in Sweden from use of the kratom product "Krypton". Since then, five more deaths related to

kratom exposure were reported in the scientific literature, and sixteen other deaths related to kratom exposure, have been confirmed by autopsy/medical examiner reports (mitragynine and/or 7-hydroxymitragynine were identified in biological samples). Of these deaths, 15 occurred between 2014 and 2016.^{xv}

In November 2017, the FDA published a public health advisory urging consumers not to use kratom or any compounds in the plant.^{xvi} In February 2018, the FDA was aware of 44 death associated with kratom-containing products and reports of kratom being laced with other opioids like hydrocodone. In some cases, kratom was being used in combination with other drugs, including illicit drugs, prescription opioids, benzodiazepines and over the counter medications. According to FDA, mixing kratom with other opioids is a serious concern because the activity of kratom at opioid receptors has similar risks to combining FDA-approved opioids. Additionally, the agency found that there may be serious side effects associated with kratom including seizures, liver damage, withdrawal symptoms and respiratory depression.^{xvii}

Recent data from the Ohio Department of Health found deaths specifically linked to kratom. In 2016 and 2017 Kratom was indicated as the primary cause of death for six Ohioans.^{xviii}

There are also concerns regarding the conditions under which the drug is produced. For example, there was recently a multi-state recall of kratom products that tested positive for salmonella contamination. On April 6, 2018, in response to a mandatory recall order from the FDA after several of its kratom products were found to contain *Salmonella*, Triangle Pharmedicals, LLC of Las Vegas, NV, initiated a recall of such products. As of April 17, 2018, the firm is recalling all kratom powder products it manufactured, processed, packed and/or held from April 4, 2017 to present. This recall includes at least 26 different products. As of May 24, 2018, a total of 199 people infected with the outbreak strains of *Salmonella* were reported from 41 states. According to FDA, thirty-eight percent of ill people were hospitalized, and no deaths were reported.^{xix}

(7) The potential of the substance to produce psychic or physiological dependence liability.

The FDA through their Public Health Assessment via Structural Evaluation (PHASE) methodology found that there is no evidence to indicate that kratom is safe or effective for any medical use. The compounds in kratom were found to bind to mu-opioid receptors similar to other opioids.

A 2014 study of regular Kratom users found that more than half of the regular users (>6 month of use) developed severe dependence problems, while 45 percent showed a moderate kratom dependence. Such dependence problems included physical and psychological withdrawal symptoms.^{xx} Additionally, a 2018 case report from Canada found evidence of maternal and neonatal kratom dependence and withdrawal.^{xxi}

The European Monitoring Centre for Drugs and Drug Addiction as noted that regular kratom use can produce dependence. Such dependence produces withdrawal symptoms including include craving, weakness and lethargy, anxiety, restlessness, rhinorrhea, myalgia, nausea, sweating, muscle pain, jerky movements of the limbs, tremor as well as sleep disturbances and hallucinations.^{xxii}

(8) Whether the substance is an immediate precursor.

Kratom is not known to be an immediate precursor.

Section 5: Finding of the Board

Section 3719.44 of the Ohio Revised Code authorizes that the State of Ohio Board of Pharmacy may add or transfer a compound, mixture, preparation, or substance to schedule I when it appears that there is a high

potential for abuse, that it has no accepted medical use in treatment in this state, or that it lacks accepted safety for use in treatment under medical supervision.

After a thorough review of all available data, the State of Ohio Board of Pharmacy finds that kratom:

1. Has a high potential for abuse;
2. Has no accepted medical use in treatment in this state;
3. Lacks accepted safety for use in treatment under medical supervision; and
4. Poses a risk to the public health of the citizens in this state.

Based on these findings, the Board hereby concludes that kratom be controlled in Schedule I and authorizes the filing of amended rule 4729-11-02 of the Administrative Code:

4729-11-02 Schedule I controlled substances.

(A) The state board of pharmacy hereby schedules the following synthetic cannabinoid compounds as schedule I controlled substance hallucinogens:

(1) PB-22 (chemical name: quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate);

(2) 5-Fluoro-PB-22 (chemical name: quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate).

(B) Except as otherwise provided in section [3719.41](#) of the Revised Code, any compound that meets at least three of the following pharmacophore requirements to bind at the CB1 and CB2 receptors, as identified by a report from an established forensic laboratory, is a schedule I controlled substance hallucinogen:

(1) A chemical scaffold consisting of substituted or non-substituted ring structures that facilitate binding of required elements (such as: indole compounds, indazoles, benzimidazoles or other ring types);

(2) Alkyl or aryl side chain off the chemical scaffold providing hydrophobic interaction with the CB1 and CB2 receptors;

(3) Carbonyl or ester or equivalent for hydrogen bonding;

(4) Cyclohexane, naphthalene ring, substituted butanamide or equivalent for steric requirements for CB1 and CB2 receptor binding.

(C) Except as otherwise provided in section [3719.41](#) of the Revised Code, any compound that contains the structural requirements of the cathinone pharmacophore, as identified by a report from an established forensic laboratory, is a schedule I controlled substance.

(D) Except as otherwise provided in section [3719.41](#) of the Revised Code, any compound that meets the following fentanyl pharmacophore requirements to bind at the mu receptor, as identified by a report from an established forensic laboratory, is a schedule I controlled substance opiate:

(1) A chemical scaffold consisting of:

(a) A five, six or seven member ring structure containing a nitrogen, whether or not further substituted; and

(b) An attached nitrogen to the ring, whether or not that nitrogen is enclosed in a ring structure, including an attached aromatic ring or other lipophilic group to that nitrogen;

(2) A polar functional group attached to the chemical scaffold, including but not limited to, a hydroxyl, ketone, amide or ester;

(3) An alkyl or aryl substitution off the ring nitrogen of the chemical scaffold; and

(4) The compound has not been approved for medical use by the United States food and drug administration.

(E) 6-monoacetylmorphine (6-MAM) is a schedule I controlled substance opium derivative.

(F) 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methyl-benzamide (U-47700) is a schedule I controlled substance opium derivative.

(G) Etizolam (4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine) is a schedule I controlled substance depressant.

(H) Mitragynine (to include synthetic equivalents as well as mitragynine naturally contained in the plant of the genus and species name: Mitragyna speciosa Korth, also known as kratom) its isomers, esters, ethers, salts and salts of isomers, esters and ethers.

(I) 7-Hydroxymitragynine (to include synthetic equivalents as well as 7-hydroxymitragynine naturally contained in the plant of the genus and species name: Mitragyna speciosa Korth, also known as kratom) its isomers, esters, ethers, salts and salts of isomers, esters and ethers.

R-2019-052 Mr. Wilt moved that, based upon review of the aforementioned information, the Board approve the Classification of Kratom as a Schedule 1 Controlled Substance. The motion was seconded by Ms. Marchal and approved by the Board: Aye—6.

10:49 a.m. Mr. Schierholt discussed the possibility of changing the classification of Gabapentin to a scheduled drug. The Board mutually agreed that more information would need to be gathered before this decision was made. Board staff offered to research this subject and present at a future Board Meeting.

10:56 a.m. Mr. Schierholt discussed the Ohio Department of Health death data and reviewed a synopsis of the analysis.

- 10:59 a.m.** Mr. McNamee lead a discussion on Drug Distributor Rules, 4729:6-1-01— and reviewed public hearing comments with the Board.
- R-2019-053** Mr. Wilt moved to adopt the revisions as discussed to Drug Distributor Rules, 4729:6-1-01. The motion was seconded by Ms. Marchal and approved by the Board: Aye—6.
- R-2019-054** Mr. McNamee reviewed proposed changes to OARRS Rules, being moved in Ohio Administrative Code 4729-37 to 4729:8. Ms. Rudell moved that the Board approve the changes to OARRS Rules. The motion was seconded by Mr. Miller and approved by the Board: Aye—6.
- 11:40 a.m.** Ms. Dehner led a discussion related to a licensee whose personal mental health information was included in a publicly available Board Order, the Board was in agreement with removing information in the Order specific to the licensee’s mental health condition.
- 11:44 a.m.** Mr. Wilt moved that the Board go into Executive Session to consider the investigation of charges or complaints against a licensee, confer with Board counsel regarding a pending or imminent court action and to discuss matters required to be confidential by law pursuant to Section 121.22(G)(1), (3) & (5) of the Ohio Revised Code. The motion was seconded by Ms. Rudell and a roll-call vote was conducted by President Weaver as follows: Cox-yes; Marchal-yes; Miller-yes; Newlon-yes; Passafume-yes; Rudell-yes; and Wilt-yes.
- 12:37 p.m.** Executive Session concluded, and the Board recessed for the day.

Tuesday, October 2, 2018

- 9:08 a.m.** The State of Ohio Board of Pharmacy convened in the Mershon Auditorium at The Ohio State University, 1871 N. High Street, Columbus, Ohio 43210, with the following members present:
- Fred M. Weaver, RPh, Presiding; Richard J. Newlon, *Public Member*; Megan E. Marchal, RPh; D. Rich Miller III, RPh; Curtis L. Passafume, Jr., RPh; Jennifer M. Rudell, RPh; and Shawn C. Wilt, RPh.
- Joshua M. Cox, RPh and Kilee S. Yarosh, RPh, Absent.
- The Board was joined by Assistant Attorney General Yvonne Tertel to conduct an adjudication hearing in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of **Amy Wildermuth, Oregonia, Ohio.**
- 10:49 a.m.** Mr. Wilt moved that the Board recess in order to consider the quasi-judicial matters in accordance with Chapter 119. of the Revised Code and the case precedent of *Angerman v. State Medical Bd.* (1990) 70 Ohio App.3d 346 and *TBC Westlake Inc. v. Hamilton Cty Bd of Revision, et al.* (1998) 81 Ohio St.3d 58. The motion was seconded by Mr. Newlon and a roll-call vote was conducted by President Weaver as follows: Newlon-yes; Marchal-yes; Miller-yes; Passafume-yes; Rudell-yes; and Wilt-yes.
- 11:05 a.m.** The recess ended, and the hearing was opened to the public.
- R-2019-055** After votes were taken in public session, the Board adopted the following order in the matter of **Amy Wildermuth, Oregonia, Ohio.**

ORDER OF THE STATE BOARD OF PHARMACY

(Case Number 2017-2593)

In The Matter Of:

Amy Wildermuth, R.Ph.
 6213 Oregonia Road
 Oregonia, OH 45054
 (License No. 03-1-22458)

INTRODUCTION

The Matter of Amy Wildermuth came for hearing on October 2, 2018, before the following members of the State of Ohio Board of Pharmacy (Board): Fred M. Weaver, RPh, *Presiding*; RPh; Megan E. Marchal, RPh; Dennis R. Miller, RPh; Richard J. Newlon, *Public Member*; Curtis L. Passafume, Jr., RPh; Jennifer M. Rudell, RPh; and Shawn C. Wilt, RPh.

Joshua M. Cox, RPh and Kilee S. Yarosh, RPh, Absent.

Amy Wildermuth was represented by Zachary Swisher. The State of Ohio was represented by Yvonne Tertel, Assistant Attorney General.

SUMMARY OF EVIDENCE**State's Witnesses:**

1. Gregory McGlaun—State of Ohio Board of Pharmacy

Respondent's Witnesses:

1. Amy Wildermuth—Respondent
2. Michael Wildermuth—Respondent's Husband
3. Jenn MacDonald—PRO Advocate
4. Jarrod Grossman—Executive Director, PRO

State's Exhibits:

- | | |
|--|------------|
| 1. Notice of Opportunity for Hearing | 11-01-2017 |
| 2. Request for Hearing | 12-03-2017 |
| 3.1. Scheduling Letter (05-01-2018 Hearing Date) | 12-06-2017 |
| 3.2. Scheduling Letter (10-02-2018 Hearing Date) | 04-26-2018 |
| 4. Credential View Screen | 09-13-2018 |
| 5. Walmart Report of Investigation | 11-08-2017 |
| 6.1. Digital Video Snapshot ("DVS") 10-29-2018 12:01:24 P.M. | 10-29-2017 |
| 6.2. DVS 10-29-2017 12:01:24 P.M. | 10-29-2017 |
| 6.3. DVS 10.29.2017 12:01:26 P.M. | 10-29-2017 |
| 6.4. DVS 10-29-2017 12:01:27 P.M. | 10-29-2017 |
| 6.5. DVS 10-29-2017 12:01:35 P.M. | 10-29-2017 |
| 6.6. DVS 10-29-2017 12:01:41 P.M. | 10-29-2017 |

6.7. DVS 10-29-2017	12:01:52 P.M.	10-29-2017
7.1. DVS 10-30-2017	6:56:11 A.M.	10-30-2017
7.2. DVS 10-30-2017	6:56:15 A.M.	10-30-2017
7.3. DVS 10-30-2017	6:56:17 A.M.	10-30-2017
7.4. DVS 10-30-2017	6:56:18 A.M.	10-30-2017
7.5. DVS 10-30-2017	6:56:22 A.M.	10-30-2017
7.6. DVS 10-30-2017	6:56:35 A.M.	10-30-2017
8.1. Statement of Melissa McPherson		10-30-2017
8.2. Statement of James Pennington		10-30-2017
8.3. Statement of Amy Wildermuth		10-30-2017
9.1. Tylenol 3 (photos)		10-30-2017
9.2. Fioricet (photos)		10-30-2017
9.3. Clonazepam (photos)		10-30-2017
9.4. Amber Prescription Bottles (photos)		10-30-2017
9.5. Non-controlled Drugs (photos)		10-30-2017
10.1. Greene County/Bill of Information—certified copy		03-26-2018
10.2. Greene County/Judgment Entry (ILC granted)—certified copy		06-13-2018

Respondent's Exhibits:

A.	Letter of Dr. Marc Whitsett, MD.	12-30-2017
B.	Letter of Support Michael Wildermuth, RPh.	09-02-2018
C.	Letter of Support Amanda Harrison	08-31-2018
D.	Unopposed Motion for Intervention in Lieu of Conviction, Greene County Common Pleas Court, Case No. 18 CR 217.	04-13-2018
E.	Letter of Support Debbie Klein	08-18-2018
F.	Letter of Support Donald James Mills	01-25-2018
G.	Letter of Support Katherine Gibson	03-15-2018
H.	Program Attendance Records	Various
I.	Letter of Support and Information Jarrod Grossman, PharmD.	09-16-2018
J.	Current Ohio PRO Test History Report	01-01-2017—09-26-2018

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. Amy Wildermuth was seen on video footage, on or about October 29, 2017, stealing acetaminophen/codeine while employed at Walmart Pharmacy located at 70 Hospitality Drive, Xenia, Ohio.
2. Amy Wildermuth was also seen on video footage, on or about October 30, 2017, stealing acetaminophen/codeine prior to Walmart Pharmacy opening.
3. On or about October 30, 2017, Amy Wildermuth admitted to agents from the Board the following:

- a. Amy Wildermuth had been stealing acetaminophen/codeine tablets since October 2016 and consuming them while working as a pharmacist.
 - b. Amy Wildermuth also admitted to stealing butalbital/acetaminophen/caffeine tablets since April 2017 and consuming them while working as a pharmacist.
 - c. Amy Wildermuth admitted to taking 7-10 tablets of acetaminophen/codeine and 4-5 butalbital/acetaminophen/caffeine tablets while working on October 29, 2017.
 - d. Amy Wildermuth admitted to being addicted to both acetaminophen/codeine and butalbital/acetaminophen/caffeine.
4. During a search of Amy Wildermuth's person on or about October 30, 2017, she had in her smock pocket one (1) tablet of acetaminophen/codeine. In Amy Wildermuth's purse, she had thirty-five (35) acetaminophen/codeine tablets and twenty-five (25) butalbital/acetaminophen/caffeine tablets. Also in Amy Wildermuth's purse, she had Meloxicam, promethazine hydrochloride, clonazepam and azithromycin monohydrate, for which she denied stealing and stated she had a prescription.

CONCLUSIONS OF LAW

1. Such conduct as set forth in the Findings of Fact, constitutes a violation of Section 2913.02 of the ORC, theft of a controlled substance, a felony of the fourth degree.
2. Such conduct as set forth in the Findings of Fact, constitutes a violation of the following divisions of section 4729.16 of the ORC, as effective as of April 6, 2017, each violation constituting a minor misdemeanor:
 - a. Engaged in dishonesty or unprofessional conduct in the practice of pharmacy, ORC Section 4729.16(A)(2)(b); and
 - b. Is addicted to or abusing alcohol or drugs or is impaired physically or mentally to such a degree as to render the pharmacist unfit to practice pharmacy, ORC Section 4729.16(A)(2)(c); and
 - c. Violated...any of the provisions of chapter 4729, 3715.75 to 3715.72 of the Revised Code, chapter 2925. or 3719. of the Revised Code, or any rule adopted by the board under those provisions, ORC 4729.16(A)(2)(e).
 - d. Engaged in any conduct for which the board may imposed discipline as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.16(A)(2)(l).
3. Such conduct as set forth in the Findings of Fact, constitutes a violation of each of the following divisions of Rule 4729-5-04 of the OAC as effective April 28, 2016:
 - a. Violated any state or federal law or rule regardless of the jurisdiction in which the acts were committed, OAC Rule 4729-5-04(A); and

- b. Violated...any of the provisions of Chapters 4729., 3715., 3719., and 2925. of the Revised Code, or any rule adopted by the board under those provisions, OAC Rule 4729-5-04(B); and
- c. Is addicted to or abusing alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the pharmacist or pharmacy intern unfit to practice pharmacy, OAC Rule 4729-5-04(D); and
- d. Failed to conform to prevailing standards of care of similar pharmacists under same or similar circumstances, whether or not actual injury to a patient is established, O.A.C. Rule 4729-5-04(L).

DECISION OF THE BOARD

Pursuant to Section 3719.121 of the Ohio Revised Code, the State of Ohio Board of Pharmacy hereby removes the Summary Suspension Order issued to Amy Wildermuth on November 1, 2017.

Pursuant to Section 4729.16 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby suspends indefinitely the pharmacist identification card, No. 03-122458, held by Amy Wildermuth and such suspension is effective as of the date of the mailing of this Order.

1. Amy Wildermuth, pursuant to Rule 4729-9-01(F) of the Ohio Administrative Code, may not be employed by or work in a facility licensed by the State Board of Pharmacy to possess or distribute dangerous drugs during such period of suspension.
2. Amy Wildermuth, pursuant to Section 4729.16(B) of the Ohio Revised Code, must return her identification card and license (wall certificate) to the office of the State Board of Pharmacy within ten days after receipt of this Order unless the Board office is already in possession of both. The identification card and wall certificate should be sent by certified mail, return receipt requested.

Further, after July 1, 2019, the Board will consider any petition filed by Amy Wildermuth for a hearing, pursuant to Ohio Revised Code Chapter 119., for reinstatement. The Board will only consider reinstatement of the license to practice pharmacy in Ohio if the following conditions have been met:

1. Amy Wildermuth must maintain a current address with the Board throughout the duration of the suspension.
2. Amy Wildermuth must enter into and adhere to the terms of a **new** contract, signed within thirty days after the effective date of this Order, with an Ohio Department of Mental Health and Addiction Services (ODMHAS) treatment provider or a treatment provider acceptable to the Board for a period of not less than five years and, upon signing, submit a copy of the contract to the Board office. Failure to adhere to the terms of the treatment contract will be

considered a violation of the Board's Order and subject Amy Wildermuth to potential sanctions up to and including revocation of license. The contract must provide that:

- a. Random, observed urine drug screens shall be conducted at least once each month.
 - b. The urine sample must be given within twelve hours of notification. The urine drug screen must include testing for creatinine or specific gravity of the sample as the dilutional standard.
 - c. Alcohol and Ethyl Glucuronide (ETG) must be added to the standard urine drug screen.
 - d. Results of all drug screens must be negative. Refusal of a drug screen or a diluted drug screen is equivalent to a positive result. Any positive results, including those which may have resulted from ingestion of food, but excluding false positives which resulted from medication legitimately prescribed, indicates a violation of the contract.
 - e. In the event of a negative diluted screen, a hair sample test must be completed at the cost of the [Respondent] in a timeframe consistent with the drug lab's recommended policy, but in any event no later than 12 days after the negative diluted screen.
 - f. The intervener/sponsor shall submit reports to the Board, in a format acceptable to the Board, indicating drug screens and their results in a timely fashion. Actual copies of drug screens shall be made available to the Board upon request.
 - g. Attendance is required a minimum of three times per calendar week (Sunday through Saturday) on separate days, at an Alcoholics Anonymous, Narcotics Anonymous, and/or similar support group meeting.
 - h. The program shall immediately report to the Board any violations of the contract and/or lack of cooperation.
3. Amy Wildermuth shall not refuse an employer provided drug or alcohol screen. If the Board becomes aware of any positive drug or alcohol screen results that were obtained in the course of employment or any mechanism other than via the signed contract with ODMHAS, the Board shall treat these results as a violation of the Board's Order and request [Respondent] reappear before the Board for possible additional sanctions, including and up to revocation of license.
 4. Amy Wildermuth shall not refuse a breathalyzer or other drug testing requested by law enforcement during the duration of suspension. The Board shall treat any such refusal as a violation of the Board's Order and request Amy Wildermuth reappear before the Board for possible additional sanctions, including and up to revocation of license.

5. Amy Wildermuth must immediately report any violation of the terms of this suspension to the Board by contacting legal@pharmacy.ohio.gov. Failure to self-report any violation shall be treated as a violation of this Board's Order and will subject [Respondent] to possible additional sanctions, including and up to revocation of license.
6. Amy Wildermuth must demonstrate satisfactory proof to the Board that she is no longer addicted to or abusing liquor or drugs or impaired physically or mentally to such a degree as to render her unfit to practice pharmacy.
7. Amy Wildermuth must provide, in the reinstatement petition, documentation of the following:
 - a. Compliance with the contract required above (e.g.-proof of giving the sample within twelve hours of notification and copies of all drug and alcohol screen reports, meeting attendance records, treatment program reports, etc.);
 - b. Compliance with the continuing pharmacy education requirements set forth in Chapter 4729-7 of the Ohio Administrative Code as applicable and in effect on the date of petitioning the Board for reinstatement;
 - c. Compliance with the terms of this Order;
 - d. Proof of successful completion of Treatment In Lieu of Conviction in Greene County Common Pleas Court, Case No. 18 CR 217.
8. If reinstatement is not accomplished within **three years** of the effective date of this Order, Amy Wildermuth must also show successful completion of the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Exam (MPJE), or equivalent examination(s) approved by the Board.
9. Any reinstatement shall not occur until such time as any criminal intervention in lieu of conviction has been successfully completed.
10. Violation of any term of suspension, including but not limited to any violation of the contract signed with the ODMHAS or other approved treatment provider may result in additional action before the Board up to and including revocation of your pharmacy license.
11. Any violation of Chapters 2925., 3715., 3719., 4729., of the Ohio Revised Code, any administrative code violation or a violation of any other state or federal law will be considered a violation of this Order resulting in a hearing before the Board and may also result in criminal and/or administrative charges.
12. If Amy Wildermuth's employment is related to the practice of pharmacy, Amy Wildermuth must notify employer of the terms of Amy Wildermuth's suspension and this Board's Order.

13. Failure to complete the terms set forth in this Board's Order, or to petition for reinstatement within five years of the date of this Order, will result in the Board issuing a notice of opportunity of hearing to consider additional disciplinary action, including and up to and revocation of Amy Wildermuth's license.

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

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

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

SO ORDERED.

11:09 a.m. Ms. Southard provided the Licensing Report.

11:14 a.m. Intern Extension Requests:

R-2019-056 The Board received a request for approval under Ohio Administrative Code Rule 4729:2-2-04(C) for Ucheabuchi Chudi-Nwankwor (06-015818) to receive permission to renew the intern license. Ms. Marchal moved that the Board approve the request for an additional renewal in application year 2018. The motion was seconded by Mr. Passafume and approved by the Board: Aye-6.

R-2019-057 The Board received a request for approval under Ohio Administrative Code Rule 4729:2-2-04(C) for Therese Greco (06-012642) to receive permission to renew the intern license. Mr. Passafume moved that the Board approve the extension through March of 2019. The motion was seconded by Ms. Marchal and approved by the Board: Aye-6.

R-2019-058 The Board received a request for approval under Ohio Administrative Code Rule 4729:2-2-04(C) for Angelo Palmer (06-011415) to receive permission to renew the intern license. Mr. Passafume moved that the Board approve the extension through March 28, 2019. The motion was seconded by Ms. Marchal and approved by the Board: 4-2.

11:20 a.m. Mr. Griffin provided the Compliance report.

11:28 a.m. Ms. Simon provided the Legislative report.

11:33 a.m. Ms. Dehner provided the Legal report.

11:35 p.m. The Board opened the floor to the students of Ohio State University for a question and answer session.

12:07 p.m. The Board recessed for lunch.

1:09 p.m. The Board reconvened in the Mershon Auditorium.

- 1:09 p.m.** Ms. Wai lead a discussion on Pharmacist Controlled Substance Prescribing Pursuant to Consult Agreement.
- R-2019-059** Ms. Wai and Ms. Simon proposed changes to the rules regarding drug repository programs being moved from Ohio Administrative Code Chapter 4729-35 to Division 4729:5-10. Mr. Passafume moved that the board approve these changes. The motion was seconded by Ms. Rudell and approved by the Board: Aye-6.
- R-2019-060** Ms. Wai and Ms. Simon proposed changes to the rules regarding charitable pharmacies being moved from Ohio Administrative Code Chapter 4729-36 to Division 4729:5-7. Mr. Passafume moved that the board approve these changes. The motion was seconded by Mr. Wilt and approved by the Board: Aye-6.
- R-2019-061** Ms. Wai and Ms. Simon proposed changes to the rules regarding prescription drug collection being moved from Ohio Administrative Code Chapter 4729-8 to Division 4729:10. Mr. Passafume moved that the board approve these changes. The motion was seconded by Ms. Marchal and approved by the Board: Aye-6.
- 1:48 p.m.** The Board revisited the Cleveland Clinic's comments on Drug Distributor Rules from the meeting the day prior, on October 1, 2018.
- R-2019-062** Mr. Passafume suggested outreach to the Cleveland Clinic and moved to approve the Rules as drafted. The motion was seconded by Mr. Wilt and approved by the Board: Aye-6.
- 1:49 p.m.** Ms. Dehner presented the Clinic Continuing Education Provider Request that had been submitted for the Health Partners Free Clinic.
- R-2019-063** Mr. Passafume moved to approve the Health Partners Free Clinic's request. The motion was seconded by Ms. Marchal and approved by the Board Aye-6.
- 1:50 p.m.** Mr. Newlon departed from the meeting. Ms. Dehner presented an overview of elder abuse and updates on which medical professionals are now required to report elder abuse.
- 1:58 p.m.** Ms. Ackman presented two Office Based Opioid Treatment (OBOT) waivers for Clearing Paths Therapeutic Services, LTD at two separate locations.
- R-2019-064** Mr. Wilt moved to approve Clearing Paths Therapeutic Services, LTD waiver request related to criminal convictions of its staff. The motion was seconded by Mr. Passafume and approved by the Board Aye-5.
- R-2019-065** Mr. Passafume moved to approve Clearing Paths Therapeutic Services, LTD waiver request related to non-physician ownership. The motion was seconded by Mr. Miller and approved by the Board Aye-5.
- R-2019-066** Mr. Weaver announced the following Settlement Agreement has been signed by all parties and is now effective:

**IN THE MATTER OF:
CASE NO. 2018-2065**

Kaitlin Lott
714 Lily Lane
Parkersburg, WV 26101
License No. 09-200512

SETTLEMENT AGREEMENT IN LIEU OF ADMINISTRATIVE PROCEEDINGS

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Kaitlin Lott, for the purpose of resolving all issues between the parties relating to the Board investigation of Kaitlin Lott's thefts of various dangerous drugs. Together, the Board and Kaitlin Lott are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.96 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.90 of the Ohio Revised Code to practice as a pharmacy technician in the state of Ohio.
2. Kaitlin Lott is an Ohio-licensed registered pharmacy technician under license number 09-200512.

FACTS

1. On or about July 16, 2018, the Board initiated an investigation into the theft of drugs from Rite Aid Pharmacy #1430, located at 201 Washington Street, Belpre, Ohio.
2. On or about September 12, 2018, surveillance video was reviewed and identified Registered Pharmacy Technician Kaitlin Lott, license number 09-200512, without consent or a valid prescription taking the drugs. Kaitlin Lott used a metal spatula to force open the lock to the schedule II controlled substance cabinet and withdrew a stock bottle of drugs when the pharmacist had stepped out of the pharmacy. Lott then, utilizing the same metal spatula, relocked the cabinet.
3. When interviewed by SOBP Agents on September 13, 2018, Technician Lott admitted to stealing controlled substances from Rite Aid #1430 from approximately June 2018 through September 13, 2018 and trafficking the drugs.

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. Kaitlin Lott waives an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code, including her right to receive notice of charges, request and participate in an administrative hearing, and waives any right to an appeal.
3. Kaitlin Lott admits the allegations set forth as Facts herein; the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy laws, rules, and regulations, and hereby accepts her admission in lieu of administrative proceedings.
4. **KAITLIN LOTT PERMANENTLY AND VOLUNTARILY SURRENDERS TO THE STATE OF OHIO BOARD OF PHARMACY HER REGISTRATION AS A REGISTERED PHARMACY TECHNICIAN, LICENSE NO. 09-200512, WITH DISCIPLINE PENDING.**
5. **Kaitlin Lott may never reapply for any license issued by the State of Ohio Board of Pharmacy pursuant to Chapters 3719., 3796., 4729., or 4752. of the Revised Code.**
6. **Kaitlin Lott agrees never to be employed by or otherwise work in any facility or establishment licensed by the State of Ohio Board of Pharmacy.**
7. Kaitlin Lott agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
8. Kaitlin Lott understands that she has the right to be represented by counsel for review and execution of this agreement.
9. Kaitlin Lott agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which she currently holds a professional license.
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.

R-2019-067

Mr. Weaver announced the following Settlement Agreement has been signed by all parties and is now effective:

IN THE MATTERS OF:

Case No. 2018-1031-B

Jeffrey Potter
7892 Hartman Rd.
Wadsworth, OH 44281
License No. 03-320050

AND

Case No. 2018-1031-A
Clinical Apothecaries, Inc.
c/o Jeffrey Potter
License No. 02-1146750

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 (Board) and Jeffrey Potter and Clinical Apothecaries, Inc. (Clinical Apothecaries) for the purpose of resolving all issues between the parties relating to the Board investigation of compounding and pharmacy practices of Jeffrey Potter and Clinical Apothecaries. Together, the Board and Jeffrey Potter and Clinical Apothecaries 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 Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.54 of the Ohio Revised Code.
2. Jeffrey Potter is an Ohio-licensed pharmacist, under license number 03-320050.
3. Clinical Apothecaries is a licensed Terminal Distributor of Dangerous Drugs (TDDD) under license number 02-1146750, which lists Jeffrey Potter as the Responsible Person.

FACTS

1. On or about January 5, 2018, the Board initiated an investigation of Jeffrey Potter and Clinical Apothecaries, Terminal Distributor of Dangerous Drugs license number 02-1146750, related to Jeffrey Potter and Clinical Apothecaries’ compounding and pharmacy practices of Jeffrey Potter.
2. On or about January 16, 2018, amended on May 9, 2018, the Board sent a Summary Suspension/Notice of Opportunity for Hearing to Jeffrey Potter and to Clinical Apothecaries, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.
3. On or about February 5, 2018, Jeffrey Potter and Clinical Apothecaries, by and through counsel Steven Sindell, requested a hearing in both matters.

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. Jeffrey Potter and Clinical Apothecaries neither admit nor deny the allegations stated in the Notice of Opportunity for Hearing letters dated January 16, 2018 and as amended May 9, 2018; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.
3. Clinical Apothecaries hereby permanently surrenders the TDDD license 02-1146750.
4. Jeffrey Potter agrees to undergo Board-arranged mental and physical examination(s), consistent with Section 4729.16(E) of the Ohio Revised Code, by a Board-approved physician to determine Jeffrey Potter's fitness for licensure as a pharmacist and his ability to practice with requisite judgment, skill, competence or safety. The examinations will be at the expense of Jeffrey Potter, consistent with 4729.16(E), paragraph (2).
 - a. Jeffrey Potter agrees to comply with all treatment recommendations (if any) and provide proof of compliance to the Board.
 - b. Jeffrey Potter agrees to sign a medical release to the Board for the results of the examination(s) and all follow up treatment received to demonstrate compliance with the treatment recommendations.
5. Jeffrey Potter must take and pass the Multistate Pharmacy Jurisprudence Examination (MPJE).
6. If reinstatement is not accomplished within **three years** of the effective date of the original summary suspension, January 16, 2018, Jeffrey Potter must also show successful completion of the North American Pharmacist Licensure Examination (NAPLEX) or an equivalent examination approved by the Board.
7. The Board agrees to lift the summary suspension of Jeffrey Potter's pharmacist license 03-320050 and imposes an indefinite suspension. Upon providing proof of the following to the Board, Jeffrey Potter may petition the Board for reinstatement of his pharmacist license:
 - a. Compliance with mental/physical examination results and compliance with all treatment recommendations; and
 - b. Proof of passing MPJE exam results.

8. Jeffrey Potter, pursuant to Rule 4729-9-01(F) of the Ohio Administrative Code, may not be employed by or work in a facility licensed by the State Board of Pharmacy to possess or distribute dangerous drugs during such period of suspension.
9. Jeffrey Potter, pursuant to Section 4729.16(B) of the Ohio Revised Code, must return her/his identification card and license (wall certificate) to the office of the State Board of Pharmacy within ten days after receipt of this Order unless the Board office is already in possession of both. The identification card and wall certificate should be sent by certified mail, return receipt requested.
10. Jeffrey Potter and Clinical Apothecaries agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.
11. Jeffrey Potter and Clinical Apothecaries agree to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
12. Jeffrey Potter and Clinical Apothecaries understand that each has the right to be represented by counsel for review and execution of this agreement.
13. 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 Jeffrey Potter and Clinical Apothecaries will operate.
14. Jeffrey Potter and Clinical Apothecaries withdraw the hearing requests, waive any right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waive any right to an appeal.
15. 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.
16. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.
17. 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.

R-2019-068

Mr. Weaver announced the following Settlement Agreement has been signed by all parties and is now effective:

IN THE MATTER OF:
Case No. 2017-1900

Robert Gerland, RPh
2054 Elmwood
Lakewood, OH 44107

License No. 03-01-19226**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 (Board) and Robert Gerland for the purpose of resolving all issues between the parties relating to the Board investigation of errors in dispensing prescription drugs, unauthorized use of the OARRS reporting system, and impairment at work. Together, the Board and Robert Gerland 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 Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Sections 4729.07 and 4729.08 of the Ohio Revised Code to practice pharmacy in the state of Ohio.
2. Robert Gerland is an Ohio-licensed pharmacist under license number 03-01-19226, whose license was summarily suspended by the Board on July 25, 2017.

FACTS

1. On or about July 17, 2017 the Board initiated an investigation of Robert Gerland pharmacist license number 03-01-19226 related to Robert Gerland's errors in dispensing prescription drugs, unauthorized use of the OARRS reporting system, and impairment at work.
2. On or about July 25, 2017 the Board sent a Summary Suspension/Notice of Opportunity for Hearing to Robert Gerland, 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. On or about January 25, 2018 the Board sent an amended Notice of Opportunity for Hearing to Robert Gerland.
3. On or about August 3, 2017, Robert Gerland timely requested an administrative hearing, which was subsequently scheduled for November 13, 2017.
4. On or about October 18, 2017, Robert Gerland requested a continuation of the hearing date which was subsequently scheduled for March 6, 2018.
5. On or about February 16, 2018 Robert Gerland requested a continuation of the hearing date which was subsequently scheduled for February 5, 2019.

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. Robert Gerland neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated July 25, 2017 and January 25, 2018; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.
3. Robert Gerland agrees to submit to random, observed urine drug screens to be conducted at least once each month for a period of six (6) months, to be coordinated through the Pharmacists Rehabilitation Organization (PRO):
 - a. The urine sample must be given within twelve hours of notification. The urine drug screen must include testing for creatinine or specific gravity of the sample as the dilutional standard.
 - b. Alcohol and Ethyl Glucuronide (ETG) must be added to the standard urine drug screen.
 - c. Results of all drug screens must be negative. Refusal of a drug screen or a diluted drug screen is equivalent to a positive result. Any positive results, including those which may have resulted from ingestion of food, but excluding false positives which resulted from medication legitimately prescribed, indicates a violation of the contract.
 - d. In the event of a negative diluted screen, a hair sample test must be completed at the cost of Robert Gerland in a timeframe consistent with the drug lab's recommended policy, but in any event no later than 12 days after the negative diluted screen.
 - e. PRO or the testing laboratory shall immediately report to the Board any violations of the contract and/or lack of cooperation. Actual copies of drug screens shall be made available to the Board upon request.
 - f. No controlled substance prescription medication may be ingested without prior approval of PRO and/or the Board's Probation Committee.
4. Robert Gerland shall not refuse an employer provided drug or alcohol screen. If the Board becomes aware of any refused or positive drug or alcohol screen results that were obtained in the course of employment or any mechanism other than via the signed agreement with the Board, the Board shall treat these results as a violation of the Board's Order and request Robert Gerland reappear before the Board for possible additional sanctions, including and up to revocation of license.
5. Robert Gerland shall not refuse a breathalyzer or other drug testing requested by law enforcement during the duration of suspension. The Board shall treat any such refusal as a violation of the Board's Order and request Robert Gerland reappear before the Board for possible additional sanctions, including and up to revocation of license.

6. Robert Gerland must immediately report any violation of the terms of this suspension to the Board by contacting legal@pharmacy.ohio.gov. Failure to self-report any violation shall be treated as a violation of this Board's Order and will subject Robert Gerland to possible additional sanctions, including and up to revocation of license.
7. Robert Gerland agrees to undergo Board-arranged mental and physical examination(s), consistent with Section 4729.16(E) of the Ohio Revised Code, by a Board-approved physician to determine Robert Gerland's fitness for a licensure as a pharmacist and his ability to practice with requisite judgment, skill, competence or safety. The examinations will be at the expense of Robert Gerland, consistent with 4729.16(E), paragraph (2).
 - a. Robert Gerland agrees to comply with all treatment recommendations (if any) and provide proof of compliance to the Board.
 - b. Robert Gerland agrees to sign a medical release to the Board for the results of the examination(s) and all follow up treatment received to demonstrate compliance with the treatment recommendations.
8. If reinstatement is not accomplished within **three years** of the effective date of the original summary suspension, July 25, 2017, Robert Gerland must also show successful completion of the North American Pharmacists Licensure Examination (NAPLEX) and Multistate Pharmacy Jurisprudence Examination (MPJE) or an equivalent examination approved by the Board.
9. The Board agrees to lift the summary suspension of Robert Gerland's pharmacist license 03-01-19226 and hereby imposes an indefinite suspension. Upon providing proof of the following to the Board, Robert Gerland may petition the Board for reinstatement of his pharmacist license:
 - a. Compliance with mental/physical examination results and compliance with all treatment recommendations; and
 - b. Random, observed, negative urine drug screens conducted at least once each month for a period of six (6) months.
10. Robert Gerland, pursuant to Rule 4729-9-01(F) of the Ohio Administrative Code, during the term of his suspension, may not be employed by or work in a facility licensed by the State Board of Pharmacy to possess or distribute dangerous drugs during such period of suspension.
11. Robert Gerland, pursuant to Section 4729.16(B) of the Ohio Revised Code, must return his identification card and license (wall certificate) to the office of the State Board of Pharmacy within ten days after receipt of this Order unless the Board office is already in possession of both. The identification card and wall certificate should be sent by certified mail, return receipt requested.
12. Robert Gerland agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

13. Robert Gerland agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
14. Robert Gerland understands that he has the right to be represented by counsel for review and execution of this agreement.
15. Robert Gerland withdraws the hearing request, waives any right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives 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.

R-2019-069

Mr. Weaver announced the following Settlement Agreement has been signed by all parties and is now effective:

IN THE MATTER OF:
CASE No. 2017-2036

Alex Meier
1860 Pheasant Point Ct.
Troy, Ohio 45373
License No. 06-015087

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 (Board) and Alex Meier, for the purpose of resolving all issues between the parties relating to the Board investigation of the disclosure of criminal charges on a pharmacy intern renewal application. Together, the Board and Alex Meier 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 Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.11 of the Ohio Revised Code to practice pharmacy as an intern in the state of Ohio.
2. Alex Meier is an Ohio-licensed pharmacy intern under license number 06-015087.

FACTS

1. On or about August 17, 2017, the Board initiated an investigation of Alex Meier pharmacist intern license number 06-015087 related to Alex Meier's disclosure of criminal charges on a pharmacy intern renewal application.
2. On or about June 18, 2018, the Board sent a Notice of Opportunity for Hearing to Alex Meier, 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 June 26, 2018, Alex Meier timely requested an administrative hearing, which was subsequently scheduled for October 3, 2018.

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. Alex Meier neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated June 18, 2018; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.
3. Alex Meier agrees to pay to the OSBP the amount of amount of \$250.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.
4. Alex Meier agrees to be compliant with all terms of the A.C.E. Program.
5. Alex Meier agrees to provide the Board with the Court's disposition of *State of Ohio vs. Alex Meier*, Case # 17CR-21, Athens County Court of Common Pleas.
6. The Board hereby publicly reprimands Alex Meier's pharmacist intern license, number 06-015087.
7. Alex Meier agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
8. Alex Meier understands that he has the right to be represented by counsel for review and execution of this agreement.

9. Alex Meier agrees and acknowledges that this Board 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 Board on renewal applications, if required by the wording of the question in the particular renewal application being filed, or applications for a new license.
 10. Alex Meier waives an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and specifically withdraws his request for a hearing in this matter 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.
-

R-2019-070

Mr. Weaver announced the following Settlement Agreement has been signed by all parties and is now effective:

IN THE MATTER OF:
CASE NO. 2017-1267

Mercy Medical Center
c/o Kyle Sobecki
1320 Mercy Drive NW
Canton, OH 44708
License No. 02-1143700

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 (Board) and Mercy Medical Center, for the purpose of resolving all issues between the parties relating to the Board investigation of failure to provide adequate safeguards to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs. Together, the Board and Mercy Medical Center 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 Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.54 of the Ohio Revised Code.
2. Mercy Medical Center is a licensed Terminal Distributor of Dangerous Drugs under

license number 02-1143700.

FACTS

1. On or about February 17, 2017, the Board initiated an investigation of Mercy Medical Center, Terminal Distributor of Dangerous Drugs license number 02-1143700, related to Mercy Medical Center's failure to provide adequate safeguards to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs.
2. On or about April 13, 2018 the Board sent a Notice of Opportunity for Hearing to Mercy Medical Center, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its 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. Mercy Medical Center neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated April 13, 2018; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.
3. Mercy Medical Center agrees to pay to the Board a monetary penalty the amount of \$10,000.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.
4. Mercy Medical Center agrees to perform a monthly audit of all Schedule II Controlled Substances. Mercy Medical Center shall report to the Board the results of the audit, on a monthly basis, for six (6) months from the date of this agreement.
5. Mercy Medical Center agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.
6. Mercy Medical Center 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 Mercy Medical Center 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 Mercy Medical Center by the Board and will NOT discharge Mercy Medical Center from any obligation under the terms of this Agreement.

7. Mercy Medical Center agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement. Mercy Medical Center understands that it has the right to be represented by counsel for review and execution of this agreement.

8. 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 Mercy Medical Center will operate.

9. Mercy Medical Center waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any 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.

R-2019-071

Mr. Weaver announced the following Settlement Agreement has been signed by all parties and is now effective:

IN THE MATTER OF:
CASE No. 2017-2060

Anthony Rojc, R.Ph.
7820 Cranberry Lane
Mentor, Oh 44060
License No. 03-2-15691

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 (Board) and Anthony Rojc, for the purpose of resolving all issues between the parties relating to the Board investigation of unlawful access of the OARRS database and violation of Section 4729.86(A)(3) of the ORC. Together, the Board and Anthony Rojc 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 Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Sections 4729.07 and 4729.08 of the Ohio Revised Code to practice pharmacy as a pharmacist in the state of Ohio.
2. Anthony Rojc is an Ohio-licensed pharmacist under license number 03-02-15691.

FACTS

1. On or about August 28, 2017 the Board initiated an investigation of Anthony Rojc, pharmacist license number 03-02-15691, related to Antony Rojc’s unlawful access of the OARRS database and violation of Section 4729.86(A)(3) of the ORC.
2. On or about April 24, 2018 the Board sent a Notice of Opportunity for Hearing to Anthony Rojc 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 May 16, 2018, Antony Rojc timely requested an administrative hearing, which was subsequently scheduled for December 12, 2018.

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. Anthony Rojc neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated April 24, 2018; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio’s pharmacy law as set forth in the Notice, and hereby adjudicates the same.
3. Anthony Rojc agrees to follow and comply with sentencing and all probation orders and requirements of the Mentor Municipal Court, including but not limited to the following orders from the Court: house arrest 80 days, completing all mandated community service, continuing education, fines and court costs, and an order prohibiting access to OARRS for 6 months from the date of sentencing.

4. Anthony Rojc must obtain, within 90 days from the effective date of this Agreement, 12 hours of approved continuing pharmacy education (1.2 CEUs) in customer privacy, ethics and/or HIPAA regulations, which may not also be used for license renewal. Copies of completed CEUs must be e-mailed to legal@pharmacy.ohio.gov.
5. Anthony Rojc agrees to no further violations of the Board's rules and regulations and no further improper access of protected health information of any person. Any future violation will result in further sanctions, including possible revocation of Anthony Rojc's pharmacy license.
6. Anthony Rojc agrees to a retroactive suspension on the OARRS database from October 1, 2017 through October 1, 2018.
7. Anthony Rojc agrees to not to serve as a responsible person for the first 12 months of employment.
8. Anthony Rojc agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
9. Anthony Rojc understands that he has the right to be represented by counsel for review and execution of this agreement.
10. Anthony Rojc agrees and acknowledges that this Board 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 Board on renewal applications or applications for a new license.
11. Anthony Rojc waives an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and specifically withdraws his request for a hearing in this matter 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.

R-2019-072

Mr. Weaver announced the following Settlement Agreement has been signed by all parties and is now effective:

**IN THE MATTER OF:
CASE No. 2016-1223**

Jeffrey Scott Bennett
17703 Walnut Creek Pike
Ashville, OH 43103
License No. 03-3-25466

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 (Board) and Jeffrey Scott Bennett for the purpose of resolving all issues between the parties relating to the Board investigation of misbranding at the Medicine Shoppe #1018. Together, the Board and Jeffrey Scott Bennett 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 Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Sections 4729.07 and 4729.08 of the Ohio Revised Code to practice pharmacy in the state of Ohio.
2. Jeffrey Scott Bennett is an Ohio-licensed pharmacist under license number 03-3-25466.

FACTS

1. On or about March 1, 2016 the Board initiated an investigation of Jeffrey Scott Bennett pharmacist license number 03-3-25466, related to Jeffrey Scott Bennett misbranding drugs at the Medicine Shoppe #1018.
2. On or about February 23, 2018 the Board sent a Notice of Opportunity for Hearing to Jeffrey Scott Bennett 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 March 7, 2018, Jeffrey Scott Bennett timely requested an administrative hearing, which was initially scheduled for August 7, 2018 and subsequently continued to February 6, 2019.

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. Jeffrey Scott Bennett neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated February 23, 2018; however, the Board has evidence

sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Jeffrey Scott Bennett agrees to pay to the OSBP the amount of amount of \$3,250.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.
4. Jeffrey Scott Bennett must obtain, within 90 days from the effective date of this Agreement, six hours of approved continuing pharmacy education (0.6 CEUs) in patient safety and ethics, which may not also be used for license renewal. Copies of completed CEUs must be e-mailed to legal@pharmacy.ohio.gov.
5. Jeffrey Scott Bennett agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
6. Jeffrey Scott Bennett understands that he has the right to be represented by counsel for review and execution of this agreement.
7. Jeffrey Scott Bennett agrees and acknowledges that this Board 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 Board on renewal applications or applications for a new license.
8. Jeffrey Scott Bennett waives an opportunity to be heard 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.

R-2019-073

Mr. Weaver announced the following Settlement Agreement has been signed by all parties and is now effective:

**IN THE MATTER OF:
CASE NOS. 2014-2139
2012-1507**

**Marie Mascio
License No. 03-1-12458**

1558 Clubview Blvd.
Worthington, Ohio 43235

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 (Board) and Marie Mascio, for the purpose of resolving all issues between the parties relating to the indictment in *U.S. v. Maria Mascio*, for one count of conspiracy to commit health care fraud, one count of participation in a health care fraud scheme, thirty-seven counts of making health care false statements, one count of conspiracy to commit an offense against the United States, five counts of aggravated identity theft, and one count of tampering with a witness. (S.D. Ohio 2014) Case No. 2:14-CR-272. Together, the Board and Marie Mascio 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 Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Sections 4729.07 and 4729.08 of the Ohio Revised Code to practice pharmacy in the state of Ohio.
2. Marie Mascio is an Ohio-licensed pharmacist under suspended license number 03-1-12458.

FACTS

1. On or about December 11, 2014, the Board initiated an investigation of Marie Mascio, pharmacist license number 03-1-12458, related to Marie Mascio's indictment in case No. 2:14-CR-272.
2. On or about December 17, 2014, the Board sent a Summary Suspension/Notice of Opportunity for Hearing to Marie Mascio, 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. Marie Mascio neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated December 17, 2014; however, the Board has evidence

sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. **MARIE MASCIO PERMANENTLY AND VOLUNTARILY SURRENDERS TO THE STATE OF OHIO BOARD OF PHARMACY HER LICENSE AND REGISTRATION TO PRACTICE PHARMACY, LICENSE NO. 03-1-12458, WITH DISCIPLINE PENDING.**

4. **Marie Mascio agrees to immediately return her license and wall certificate to the Board, if the Board is not already in possession of both.**

5. **Marie Mascio may never reapply for any license issued by the State of Ohio Board of Pharmacy pursuant to Chapters 3719., 3796., or 4729. of the Revised Code.**

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

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

8. Marie Mascio agrees and acknowledges that this Board 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 Board on renewal applications or applications for a new license.

9. Marie Mascio waives an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and specifically withdraws her request for a hearing in this matter and waives any 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.

R-2019-074

Mr. Weaver announced the following Settlement Agreement has been signed by all parties and is now effective:

STATE OF OHIO BOARD OF PHARMACY

In the matter of applicant:) Case Nos.
) 2018-M295
Hanging Gardens OH, LLC) 2018-M422
) 2018-M426
) 2018-M432

)
) Account Nos./Application Nos.
) 141-295
) 141-422
) 141-426
) 141-432
)
) Hearing Examiner Shantae Decarlow

SETTLEMENT AGREEMENT

THIS SETTLEMENT AGREEMENT (the "Agreement") is made and executed by and among, Hanging Gardens OH, LLC, an Ohio limited liability company ("Hanging Gardens") and the State of Ohio Board of Pharmacy ("Board") (Hanging Gardens and the Board individually each a "Party," and collectively the "Parties").

WITNESSETH:

WHEREAS, on or about November 17, 2017, Hanging Gardens submitted four (4) applications to the Board to own and operate four (4) dispensaries in Ohio which were designated with the following application numbers 141-295, 141-422, 141-426, and 141-432 (collectively, the "Applications");

WHEREAS, on or about December 20, 2017, Hanging Gardens resubmitted its Applications with updated information;

WHEREAS, on or about June 11, 2018 the Board denied all four (4) of Hanging Gardens Applications (collectively, the "Denials");

WHEREAS, on or about June 22, 2018, the Board amended its Denials to add additional reasons for its Denials;

WHEREAS, Hanging Gardens requested, pursuant to R.C. Chapter 119, administrative hearings on the Denials and the Board assigned the following docket numbers to these administrative hearings: 2018-M295, 2018-M422, 2018-M426, and 2018-M432 (collectively the "Hearings");

WHEREAS, Hanging Gardens filed a lawsuit in the Franklin County Court of Common Pleas, *Hanging Gardens, OH, LLC v. State of Ohio Board of Pharmacy*, Case Number 18CV004612, relating to the Denials and sought, among other things, injunctive and declaratory relief (the "Litigation");

WHEREAS, Hanging Gardens and the Board have agreed to resolve all of the claims related to the Applications, Denials, Hearings, and Litigation pursuant to the terms set forth herein below.

NOW, THEREFORE, in consideration of the mutual promises and undertakings herein set forth, and intending to be legally bound hereby, the Parties hereto agree as follows:

1. **Preambles.** The foregoing preambles are incorporated herein by reference.
2. **Specific Releases.**
 - a. **Hanging Gardens.** Hanging Gardens agrees to withdraw its Applications from consideration. Hanging Gardens agrees to withdraw its Hearing requests with prejudice. Hanging Gardens agrees to dismiss the Litigation, with prejudice, within seven (7) days of the last-dated signature by filing a Notice of Dismissal in substantially the form as **Exhibit A** attached hereto (the "Notice of Dismissal"). Hanging Gardens agrees not to institute or reinstitute any actions, in any jurisdictions, in any forum, tribunal, court, or administrative proceeding, for any form of relief against the Board relating to, arising from, or concerning the Applications. Concurrent with the signing of this Agreement, Hanging Gardens will sign the Notice of Dismissal and will deliver this Agreement and the Notice of Dismissal to counsel for the Board. Hanging Gardens hereby authorizes counsel for the Board to file the Notice of Dismissal with the Court as provided in this Agreement.
 - b. **The Board.** The Board agrees to accept Hanging Gardens withdrawal of its Applications. The Board agrees to withdraw its Denials and all associated claims made therein. The Board agrees to allow Hanging Gardens to submit future applications in the State of Ohio for dispensaries should the Board determine to make future application opportunities available to the public.
3. **General Release.** In consideration of the covenants and agreements contained herein, the Parties, for themselves and each of their respective administrators, trustees, accountants, parents, subsidiaries, divisions, affiliates, predecessors, successors, present or former officers, directors, employees, shareholders, owners, attorneys and assigns, hereby fully and forever release, withdraw, remise, quit-claim and fully and forever discharge the other party, and each of their respective heirs, executors, administrators, trustees, accountants, parents, subsidiaries, divisions, affiliates, predecessors, successors, present or former officers, directors, employees, shareholders, owners, attorneys, and assigns, from any and all claims, demands, damages, accounts, debts, liens, suits, actions, and rights or causes of action of every kind and description, whether known or unknown, suspected or unsuspected, which it now has, or has had, or hereafter can, shall, or may have arising out of or related to the subject matter of this Agreement. The Parties agree not to pursue litigation in this matter or for any claim related to matters described herein. This release does not affect the Parties' rights to enforce the terms of this agreement.
4. **Public Record.** All Parties to this Agreement understand that this document is a public record under R.C. §149.43, and its terms will therefore become part of the minutes of a meeting of the Pharmacy Board. Except as stated above, required by R.C. §149.43, or otherwise required by law (including but not limited to regulations, court orders, and lawful subpoenas), or to the extent necessary as a result of litigation to enforce the Agreement, neither Party shall otherwise affirmatively describe or characterize this Agreement or the reasons for entering into it with a non-Party. For purposes of this Section, discussions within the Pharmacy Board among its members, staff, and employees are not prohibited.
5. **Costs and Expenses of Administrative and Court Proceedings.** Each party shall be responsible for the costs and expenses it incurred in connection with the Applications, Hearings,

and Litigation. It is expressly understood and agreed that the Board will not reimburse Hanging Gardens its application fees or other expenses incurred in connection with its Applications

6. Entire Agreement. This Agreement supersedes any and all agreements by, between and among the Parties, and represents their entire agreement pertaining to the subject matter hereof. There is no agreement or understanding relating to the subject matter hereof, whether express, implied, written or oral, not expressly set forth herein.

7. Binding Effect. This Agreement is binding upon and shall inure to the benefit of the Parties hereto and their agents, employees, successors and assigns.

8. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Ohio.

9. Interpretation. This Agreement shall be interpreted as though mutually drafted by the Parties hereto and their respective counsel.

10. Headings. The headings preceding the paragraphs herein are intended to be for convenience only and shall have no operative force or effect.

11. Authority. The Parties hereto represent and warrant to each other that each Party possesses the full requisite authority to enter into this Agreement and that the person signing this Agreement on behalf of each Party is fully and duly authorized to do so.

12. Execution in Counterparts; Facsimile Signatures. The Parties acknowledge and agree that this Agreement may be executed (1) in one or more counterparts, which together shall constitute a single, integrated agreement, and (2) by facsimile signatures which shall have the same force and effect as original signatures.

R-2019-075

Mr. Weaver announced the following Settlement Agreement has been signed by all parties and is now effective:

**IN THE MATTER OF:
CASE No. 2017-2303**

**Arlene Pisel
License No. 03-1-25604
544 Homestead Drive
Lima, OH 45807**

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 (Board) and **Arlene Pisel**, for the purpose of resolving all issues between the parties relating to the Board investigation of her failure to meet the continuing education requirements. Together, the Board and **Arlene Pisel** 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 Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Sections 4729.07 and 4729.08 of the Ohio Revised Code to practice pharmacy in the state of Ohio.
2. Arlene Pisel is an Ohio-licensed pharmacist under license number 03-1-25604.

FACTS

1. On or about September 6, 2017, the Board initiated an investigation of Arlene Pisel, pharmacist license number 03-1-25604, related to Arlene Pisel's failure to complete continuing education requirements.
2. On or about November 27, 2017 the Board sent a Notice of Opportunity for Hearing to Arlene Pisel, 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 20, 2017, Arlene Pisel timely requested an administrative hearing, which was subsequently scheduled for June 4, 2018.

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. Arlene Pisel neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated November 27, 2017; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.
3. Arlene Pisel agrees to pay to the OSBP the amount of amount of \$500. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.
4. Arlene Pisel must obtain, within 90 days from the effective date of this Agreement, 44 hours of approved continuing pharmacy education (4.4 CEUs). Of the total required, at least 2 hours (.2 CEUs) must be obtained in law, and 4 hours must be obtained in patient or medication safety which may not also be used for license renewal. Copies of completed CEUs must be e-mailed to legal@pharmacy.ohio.gov.

5. Arlene Pisel agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
6. Arlene Pisel understands that she has the right to be represented by counsel for review and execution of this agreement.
7. Arlene Pisel agrees and acknowledges that this Board 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 Board on renewal applications or applications for a new license.
8. Arlene Pisel waives an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and specifically withdraws her request for a hearing in this matter 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.

R-2019-076

Mr. Weaver announced the following Settlement Agreement has been signed by all parties and is now effective:

**IN THE MATTER OF:
CASE NO. 2016-1909**

Aring's Compound Corner
C/O Richard Rohaley, R.Ph
6725 W. Central Avenue, Suite BB
Toledo, OH 43617
License No. 02-1339450

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 (Board) and Aring's Compound Corner for the purpose of resolving all issues between the parties relating to the Board investigation of multiple errors in dispensing and compounding. Together, the Board and Aring's Compound Corner 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 Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.54 of the Ohio Revised Code.
2. Aring's Compound Corner is a licensed Terminal Distributor of Dangerous Drugs under license number 02-1339450.

FACTS

1. On or about July 27, 2016, the Board initiated an investigation of Aring's Compound Corner Terminal Distributor of Dangerous Drugs license number 02-1339450 related to Aring's Compound Corner's multiple errors in dispensing and compounding.
2. On or about March 31, 2017 the Board sent a Notice of Opportunity for Hearing to Aring's Compound Corner which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its 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. Aring's Compound Corner neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated March 31, 2017; however, the Board believes it has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.
3. Aring's Compound Corner agrees to pay to the Board a monetary penalty the amount of \$2,000.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.
4. Aring's Compound Corner must attend a Board-sponsored "Responsible Person Roundtable, within one year of the effective date of this agreement and provide proof of completion to the Board within 30 days of attendance.
5. Richard Rohaley must obtain, within 90 days from the effective date of this Agreement, 12 hours of approved continuing pharmacy education (1.2 CEUs) in the following categories: 6 hours (0.6 CEUs) in patient/medication safety (ACPE code 05-P), 3 hours (0.3 CEUs) in general pharmacy (ACPE code 04-P), and 3 hours (0.3 CEUs) in law/ethics (ACPE code 03-P). These hours may not also be used for license renewal. Copies of completed CEUs must be e-mailed to legal@pharmacy.ohio.gov.

6. Aring's Compound Corner agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license. The Board acknowledges that the execution and filing of this Agreement satisfies any notice of discipline to the Ohio Board required by any statute or regulation, and that Aring's Compound Corner has no further notice obligation to the Ohio Board unless and until it submits renewal applications or applications for a new license.
 7. Aring's Compound Corner 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 Aring's Compound Corner 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 Aring's Compound Corner by the Board and will NOT discharge Aring's Compound Corner from any obligation under the terms of this Agreement.
 8. The settlement and resolution of this controversy shall not be construed to prevent Richard Rohaley from serving as the responsible person for Aring's Compound Corner as described in Ohio Adm. Code 4729-5-11 and other applicable law and regulations.
 9. Aring's Compound Corner agrees to pay all reasonable costs associated with the collection of any payment required by this Agreement, and of the prosecution of any violation of this Agreement.
 10. Aring's Compound Corner 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 Aring's Compound Corner will operate.
 12. Aring's Compound Corner waives its right to a hearing and an 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.
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R-2019-077 Mr. Weaver announced the following Settlement Agreement has been signed by all parties and is now effective:

**IN THE MATTER OF:
CASE No. 2017-1677**

Emmylou Melton
17536 Hogan Hill Rd.
Moores Hill, IN 47032
License No. 03-132369

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 (Board) and Emmylou Melton, for the purpose of resolving all issues between the parties relating to the Board investigation of her substance abuse issues and failure to disclose a misdemeanor offense on her renewal application. Together, the Board and Emmylou Melton 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 Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Sections 4729.07 and 4729.08 of the Ohio Revised Code to practice in the state of Ohio.
2. Emmylou Melton is an Ohio-licensed pharmacist under license number 03-132369.

FACTS

1. On or about May 17, 2017, the Board initiated an investigation of Emmylou Melton, pharmacist license number 03-132369, related to Emmylou Melton’s substance abuse issues and failure to disclose a misdemeanor offense on her renewal application.
2. On or about August 17, 2017 the Board sent a Notice of Opportunity for Hearing to Emmylou Melton, 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 September 8, 2017, Emmylou Melton timely requested an administrative hearing, which was subsequently scheduled for January 9, 2018. The administrative hearing was then continued until February 5, 2018.
4. On or about January 22, 2018, Emmylou Melton requested a continuance of the February 5, 2018 administrative hearing. The administrative hearing was then continued until August 7, 2018.

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. Emmylou Melton neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated August 17, 2017; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.
3. The Parties agree Emmylou Melton's pharmacy license no. 03-132369 will be placed on probation for a period of three years from the date of this Agreement. Conditions of Emmylou Melton's probation include:
 - i. Random, observed urine drug screens shall be conducted at least once each month through coordination with the Pharmacists Rehabilitation Organization (PRO).
 - j. The urine sample must be given within twelve hours of notification. The urine drug screen must include testing for creatinine or specific gravity of the sample as the dilutional standard.
 - k. Alcohol and Ethyl Glucuronide (ETG) must be added to the standard urine drug screen.
 - l. Results of all drug screens must be negative. Refusal of a drug screen or a diluted drug screen is equivalent to a positive result. Any positive results, including those which may have resulted from ingestion of food, but excluding false positives which resulted from medication legitimately prescribed, indicates a violation of the contract.
 - m. In the event of a negative diluted screen, a hair sample test must be completed at the cost of the Emmylou Melton in a timeframe consistent with the drug lab's recommended policy, but in any event no later than 12 days after the negative diluted screen.
 - n. PRO or the testing laboratory shall immediately report to the Board any violations of the contract and/or lack of cooperation. Actual copies of drug screens shall be made available to the Board upon request.

violation shall be treated as a violation of this Board's Order and will subject Emmylou Melton to possible additional sanctions, including and up to revocation of license.

9. Any violation of probation or this Board's Order may result in a Board hearing to consider alternative or additional sanctions under Section 4729.16 of the Ohio Revised Code, including and up to revocation of Emmylou Melton's license.

10. Any violation of R.C. 2925, 3715, 3719 or 4729 or any OAC rule or a violation of any other state or federal law will be considered a violation of the Settlement Agreement and may result in a hearing before the Board and may also result in criminal and/or administrative charges

11. Emmylou Melton must obtain, within 120 days from the effective date of this Agreement, six (6) hours of approved continuing pharmacy education (0.6 CEUs) in medication errors and/or patient safety and ethics, which may not also be used for license renewal. Copies of completed CEUs must be e-mailed to legal@pharmacy.ohio.gov.

12. Emmylou Melton agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

13. Emmylou Melton understands that she has the right to be represented by counsel for review and execution of this agreement.

14. Emmylou Melton agrees and acknowledges that this Board 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 Board on renewal applications or applications for a new license.

15. Emmylou Melton waives an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and specifically withdraws her request for a hearing in this matter and waives 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.

19. This Agreement shall become effective upon the date of the Board President's signature below.

20. At the conclusion of the probationary period, the Board will issue a notice of opportunity for hearing to Emmylou Melton regarding the status of Emmylou Melton's

probation and whether Emmylou Melton has successfully met all terms of probation and may be considered in good standing.

R-2019-077

Mr. Weaver announced the following Settlement Agreement has been signed by all parties and is now effective:

**IN THE MATTER OF:
CASE NO. 2017-1892**

**Merck Sharp & Dohme Corp.
William Halm
License No. 01-2217150 c/o**

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 (Board) and Merck Sharp & Dohme Corp., for the purpose of resolving all issues between the parties relating to the Board investigation of their failure to report sample distribution to OARRS. Together, the Board and Merck Sharp & Dohme Corp. 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 Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.54 of the Ohio Revised Code.
2. Merck Sharp & Dohme Corp. is a licensed [Distributor of Dangerous Drugs entitled to distribute dangerous drugs at wholesale](#) under license number 01-2217150.

FACTS

1. On or about July 6, 2017, in response to self-disclosure by Merck regarding inadvertent reporting violations, the Board initiated an investigation of Merck Sharp & Dohme Corp, [Distributor of Dangerous Drugs entitled to distribute dangerous drugs at wholesale](#) license number 01-2217150, related to Merck Sharp & Dohme Corp.’s shipping Schedule IV, non-opioid controlled substance samples into Ohio, without reporting to OARRS.
2. On or about April 3, 2018, the Board sent a Notice of Opportunity for Hearing to Merck Sharp & Dohme Corp., which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. On or about April 17, 2018, the Board sent a revised Notice of Opportunity for Hearing, which clarified the scope of the proposed action.

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. Merck Sharp & Dohme Corp. neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated April 3, 2018; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.
3. Merck Sharp & Dohme Corp. agrees to pay to the Board a monetary penalty in the amount of \$10,000.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.
4. Merck Sharp & Dohme Corp. agrees to conduct an internal audit of its OARRS reporting activities on or before December 31, 2018.
5. The Board agrees to release Merck from any additional penalties or disciplinary action in connection with the conduct at issue related to OARRS reporting through the date of this Agreement.
6. The Board further agrees that Merck remains fully eligible for renewal of its Ohio wholesale drug distributor license.
7. Merck Sharp & Dohme Corp. agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.
8. Merck Sharp & Dohme Corp. 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 Merck Sharp & Dohme Corp. 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 Merck Sharp & Dohme Corp. by the Board and will NOT discharge Merck Sharp & Dohme Corp. from any obligation under the terms of this Agreement.
9. Merck Sharp & Dohme Corp. agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

10. Merck Sharp & Dohme Corp. 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 Merck Sharp & Dohme Corp. will operate.

12. Merck Sharp & Dohme Corp. waives its right to a hearing and an 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.

R-2019-078

Ms. Marchal moved that the September 10-11, 2018 Meeting Minutes, be approved as amended. The motion was seconded by Mr. Wilt and approved by the Board: Aye-5.

R-2019-079

Mr. Passafume moved that the meeting be adjourned. The motion was seconded by Mr. Wilt and approved by the Board: Aye—5.

2:17 p.m.

The meeting adjourned.



Fred M. Weaver, RPh, President



Date



Steven W. Schierholt, Esq., Executive Director



Date

ⁱ Office of the Commissioner. (2018, February 6). Press Announcements - Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's scientific evidence on the presence of opioid compounds in kratom, underscoring its potential for abuse. Retrieved from <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm595622.htm>

ⁱⁱ The European Monitoring Centre for Drugs and Drug Addiction. Kratom (*Mitragyna speciosa*) drug profile. <http://www.emcdda.europa.eu/publications/drug-profiles/kratom#pharmacology>

ⁱⁱⁱ The European Monitoring Centre for Drugs and Drug Addiction. Kratom (*Mitragyna speciosa*) drug profile. <http://www.emcdda.europa.eu/publications/drug-profiles/kratom#pharmacology>

^{iv} The European Monitoring Centre for Drugs and Drug Addiction. Kratom (*Mitragyna speciosa*) drug profile. <http://www.emcdda.europa.eu/publications/drug-profiles/kratom#pharmacology>

^v Office of the Commissioner. (2017, November 14). Press Announcements - Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA advisory about deadly risks associated with kratom. Retrieved from <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm584970.htm>

^{vi} Press Announcements - FDA warns companies selling illegal, unapproved kratom products marketed for opioid cessation, pain treatment and other medical uses. Retrieved from <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm608447.htm>

^{vii} United States Drug Enforcement Administration. Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-Hydroxymitragynine Into Schedule I. https://www.federalregister.gov/documents/2016/08/31/2016-20803/schedules-of-controlled-substances-temporary-placement-of-mitragynine-and-7-hydroxymitragynine-into?utm_campaign=pi+subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov

^{viii} What's Kratom, and Why Are States Banning It? Governing Magazine. <http://www.governing.com/topics/health-human-services/sl-kratom-state-ban.html>

^{ix} DEA Drug Fact Sheets (2017). Retrieved from <https://www.dea.gov/factsheets/kratom>

^x United States Drug Enforcement Administration. Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-Hydroxymitragynine Into Schedule I. https://www.federalregister.gov/documents/2016/08/31/2016-20803/schedules-of-controlled-substances-temporary-placement-of-mitragynine-and-7-hydroxymitragynine-into?utm_campaign=pi+subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov

^{xi} United States Drug Enforcement Administration. Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-Hydroxymitragynine Into Schedule I. https://www.federalregister.gov/documents/2016/08/31/2016-20803/schedules-of-controlled-substances-temporary-placement-of-mitragynine-and-7-hydroxymitragynine-into?utm_campaign=pi+subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov

^{xii} United States Drug Enforcement Administration. Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-Hydroxymitragynine Into Schedule I. https://www.federalregister.gov/documents/2016/08/31/2016-20803/schedules-of-controlled-substances-temporary-placement-of-mitragynine-and-7-hydroxymitragynine-into?utm_campaign=pi+subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov

^{xiii} Ohio Department of Mental Health and Addiction Services [OhioMHAS] (2018). Ohio Substance Abuse Monitoring Network: Surveillance of Drug Abuse Trends in the State of Ohio: June 2017 - January 2018. Columbus, OH: State of Ohio.

^{xiv} United States Drug Enforcement Administration. Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-Hydroxymitragynine Into Schedule I. https://www.federalregister.gov/documents/2016/08/31/2016-20803/schedules-of-controlled-substances-temporary-placement-of-mitragynine-and-7-hydroxymitragynine-into?utm_campaign=pi+subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov

^{xv} United States Drug Enforcement Administration. Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-Hydroxymitragynine Into Schedule I. https://www.federalregister.gov/documents/2016/08/31/2016-20803/schedules-of-controlled-substances-temporary-placement-of-mitragynine-and-7-hydroxymitragynine-into?utm_campaign=pi+subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov

^{xvi} Office of the Commissioner. (2017, November 14). Press Announcements - Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA advisory about deadly risks associated with kratom. Retrieved from <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm584970.htm>

^{xvii} Office of the Commissioner. (2018, February 6). Press Announcements - Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's scientific evidence on the presence of opioid compounds in kratom, underscoring its potential for abuse. Retrieved from <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm595622.htm>

^{xviii} Ohio Department of Health, Violence and Injury Prevention Program. State Unintentional Drug Overdose Reporting System (SUDORS). Received August 24, 2018.

^{xix} Center for Food Safety and Applied Nutrition. (2018, April 19). Outbreaks - FDA Investigates Multistate Outbreak of Salmonella Infections Linked to Products Reported to Contain Kratom. Retrieved from <https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm597265.htm>

^{xx} Singh D, Müller CP, Vicknasingam BK. Kratom (*Mitragyna speciosa*) dependence, withdrawal symptoms and craving in regular users. *Drug Alcohol Depend.* 2014 Jun 1;139:132-7. doi: 10.1016/j.drugalcdep.2014.03.017. Epub 2014 Mar 22.

^{xxi} Lindsay Mackay and Ronald Abrahams. Novel case of maternal and neonatal kratom dependence and withdrawal. *Canadian Family Physician* February 2018, 64 (2) 121-122. <http://www.cfp.ca/content/64/2/121>.

^{xxii} The European Monitoring Centre for Drugs and Drug Addiction. Kratom (*Mitragyna speciosa*) drug profile. <http://www.emcdda.europa.eu/publications/drug-profiles/kratom#pharmacology>