



OHIO STATE BOARD OF PHARMACY

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ORDER OF THE STATE BOARD OF PHARMACY

(Docket Number D-100310-100)

In The Matter Of:

B. ELISE MILLER, R.Ph.

P.O. Box 176

2171 Forest Hill

Coshocton, Ohio 43812

(R.Ph. No. 03-1-12257)

INTRODUCTION

The Matter of B. Elise Miller came for hearing on December 8, 2010, before the following members of the Board: Richard F. Kolezynski, R.Ph. (presiding); Edward T. Cain, Public Member; Donald M. Casar, R.Ph.; Troy A. Gahm, R.Ph.; Brian M. Joyce, R.Ph.; Deborah A. Lange, R.Ph.; Jerome J. Wiesenbahn, R.Ph. and Lori L. Woodson, R. Ph.

Michael A. Moné, R.Ph., Absent.

B. Elise Miller was represented by Michael L. Close. The State of Ohio was represented by Tracy M. Greuel, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witnesses:

1. B. Elise Miller, R.Ph., Respondent
2. David Gallagher, Ohio State Board of Pharmacy
3. Louis R. Mandi, R.Ph.
4. Avril Sutherland Wagner

Respondent's Witness:

1. B. Elise Miller, R.Ph., Respondent

State's Exhibits:

1. Copy of Notice of Opportunity for Hearing letter [03-10-10]
1A-1F. Procedurals
2. State Board of Pharmacy Settlement Agreement in re B. Elise Miller, R.Ph., Miller Pharmacy and Three Rivers O.P.T.I.O.N Care, Inc. [04-05-04]
3. Notarized statement of Douglas A. Bolden [05-20-09]
4. Notarized statement of Janet Myers [05-19-09]
5. Dangerous Drug Distributor Inspection Report at Three Rivers Infusion & Pharmacy with attachments [04-29-09]

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6. Dangerous Drug Distributor Inspection Report at Three Rivers Infusion & Pharmacy [05-19-09]
7. Dangerous Drug Distributor Inspection Report evidence receipt and attachment at Mt. Vernon Developmental Center [not dated]
- 7a. One 20 ml plastic syringe with prescription label [04-13-09]
8. Chain of Custody form with attached receipts for physical evidence [05-18-09]
- 8a. Two Wolf-Pak unlabeled containers containing approximately 2,000 ml of clear fluid [not dated]
One Hospira unlabeled container containing approximately 250 ml of clear fluid [not dated]
60 ml B-D syringe with attached needle and approximately 3 ml of clear fluid [not dated]
9. Miller Pharmacy Rx Compounding Form for RX #6525289 [04-23-09]
10. Miller Pharmacy Rx Compounding Form for RX #6525291 [04-23-09]
11. Miller Pharmacy Rx Compounding Form for RX #6525290 [04-23-09]
12. Miller Pharmacy Rx Compounding Form for RX #6525292 [04-17-09]
13. Spectrum Invoice [12-08-08]
14. HD Smith response to request for information [05-20-09]
15. Medtronic Lioresal Intrathecal refill kit label [not dated]
16. Medtronic Lioresal Intrathecal baclofen injection paperwork [not dated]
17. Dangerous Drug Distributor Inspection Report at Miller Pharmacy [04-29-09]
18. Dangerous Drug Distributor Inspection Report at Miller Pharmacy [04-30-09]
19. Dangerous Drug Distributor Inspection Report at Miller Pharmacy [05-19-09]
20. Dangerous Drug Distributor Inspection Report at Miller Pharmacy [07-23-09]
21. DEA Form 222 forms obtained from Miller Pharmacy [various dates]
22. Copy of RX #4015463 [12-30-08]
23. Copy of RX #4015496 [03-09-09]
24. Copy of RX #4015569 [04-15-09]
25. Copy of RX #4015572 [04-20-09]
26. Copy of RX #4015577 [04-22-09]
27. Copy of RX #4015578 [04-23-09]
28. Miller Pharmacy RX documentation packet for patient 1 [various dates]
29. Miller Pharmacy RX documentation packet for patient 2 [various dates]
30. Miller Pharmacy RX documentation packet for patient 3 [various dates]
31. Miller Pharmacy RX documentation packet for patient 4 [various dates]
32. Three Rivers Infusion & Pharmacy Specialists RX documentation packet for patient 5 [various dates]
33. Three Rivers Infusion & Pharmacy Specialists RX documentation packet for patient 6 [various dates]
34. Three Rivers Infusion Pharmacy purchase/dispensing comparison for 2008
35. Three Rivers Infusion Pharmacy purchase/dispensing comparison for 2009
36. Three Rivers Infusion & Pharmacy Specialists delivery receipts for Kineret [08-30-06 to 03-25-09]

Respondent's Exhibits:

- A. Prescription for lower dose of Kineret with attachments [01-26-09]
- B. Controlled substance inventory with attachments [07-29-08]
- C. Serially labeled prescriptions [04-14-09 to 04-28-09]
- D. Synchronized pump prescription [05-11-09]
- E. Maintenance schedule flow hood [not dated]

FINDINGS OF FACT

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

(1) Records of the State Board of Pharmacy indicate that B. Elise Miller was originally licensed in the State of Ohio on March 6, 1979, pursuant to examination, and is currently licensed to practice pharmacy in the State of Ohio. Records further reflect that B. Elise Miller was previously disciplined by the Board on April 5, 2004.

(2) B. Elise Miller did, on or about May 26, 2009, while practicing pharmacy at Three Rivers Infusion Pharmacy, manufacture, sell, deliver or hold or offer for sale an adulterated drug, to wit: when dispensing RX #6525420, B. Elise Miller used a Kineret™ 100 mg/0.67 ml single-use product and placed it into four different syringe dosages, thereby reducing the effectiveness of the drug. Such conduct is in violation of Section 3715.52(A)(2) of the Ohio Revised Code.

(3) B. Elise Miller did, on or about April 23, 2009, while practicing pharmacy at Three Rivers Infusion Pharmacy, misbrand a drug, to wit: when B. Elise Miller received a refill for RX #6525289, B. Elise Miller dispensed a compounded 20 ml product of baclofen 2 mg/ml and labeled the product as Lioresal™, a commercially available product. Such conduct is in violation of Section 3715.52(A)(2) of the Ohio Revised Code.

(4) B. Elise Miller did, on or about April 29, 2009, while practicing pharmacy at Three Rivers Infusion Pharmacy, manufacture, hold or offer for sale a drug that was misbranded, to wit: B. Elise Miller held for sale a Hospira™ container with approximately 250 ml of an unknown clear liquid that did not have a label. Such conduct is in violation of Section 3715.52(A)(2) of the Ohio Revised Code.

(5) B. Elise Miller did, on or about April 29, 2009, while practicing pharmacy at Three Rivers Infusion Pharmacy, manufacture, hold or offer for sale a drug that was misbranded, to wit: B. Elise Miller held for sale two WolfPak™ containers with approximately 2000 ml of an unknown clear liquid that did not have a label. Such conduct is in violation of Section 3715.52(A)(2) of the Ohio Revised Code.

(6) B. Elise Miller did, on or about April 29, 2009, while practicing pharmacy at Three Rivers Infusion Pharmacy, manufacture, hold or offer for sale a drug that was misbranded, to wit: B. Elise Miller held for sale a 60 ml B-D™ syringe with approximately 3 ml of an unknown clear liquid that did not have a label. Such conduct is in violation of Section 3715.52(A)(2) of the Ohio Revised Code.

(7) B. Elise Miller did, on or about April 29, 2009, while practicing pharmacy at Three Rivers Infusion Pharmacy, manufacture, sell, deliver or hold or offer for sale an adulterated drug, to wit: B. Elise Miller prepared parental or sterile product prescriptions in a laminar and vertical flow hood which was not properly certified. Such conduct is in violation of Section 3715.52(A)(2) of the Ohio Revised Code.

(8) B. Elise Miller did, on or about April 23, 2009, while practicing pharmacy at Three Rivers Infusion Pharmacy, misbrand a drug, to wit: when B. Elise Miller received RX

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#6525291, B. Elise Miller dispensed a compounded 20 ml product of baclofen 2 mg/ml and labeled the product as Lioresal™, a commercially available product. Such conduct is in violation of Section 3715.52(A)(2) of the Ohio Revised Code.

(9) B. Elise Miller did, on or about April 23, 2009, while practicing pharmacy at Three Rivers Infusion Pharmacy, misbrand a drug, to wit: when B. Elise Miller received RX #6525290, B. Elise Miller dispensed a compounded 20 ml product of baclofen 2 mg/ml and labeled the product as Lioresal™, a commercially available product. Such conduct is in violation of Section 3715.52(A)(2) of the Ohio Revised Code.

(10) B. Elise Miller did, on or about April 17, 2009, while practicing pharmacy at Three Rivers Infusion Pharmacy, misbrand a drug, to wit: when B. Elise Miller received RX #6525292, B. Elise Miller dispensed a compounded 20 ml product of baclofen 2 mg/ml and labeled the product as Lioresal™, a commercially available product. Such conduct is in violation of Section 3715.52(A)(2) of the Ohio Revised Code.

(11) B. Elise Miller did, from August 2, 2006, through April 30, 2009, while practicing pharmacy at Three Rivers Infusion Pharmacy, manufacture, sell, deliver or hold or offer for sale an adulterated drug, to wit: when dispensing RX #6525420, B. Elise Miller used a Kineret™ 100 mg/0.67 ml single-use product and placed it into four different syringe dosages, thereby reducing the effectiveness of the drug. Such conduct is in violation of Section 3715.52(A)(2) of the Ohio Revised Code.

(12) B. Elise Miller did, approximately 427 times from 2008 through 2009, while practicing pharmacy at Three Rivers Infusion Pharmacy, misbrand a drug, to wit: when B. Elise Miller received prescriptions for baclofen 2 mg/ml liquid, B. Elise Miller labeled and dispensed the product as Lioresal™ 40 mg/20 ml (NDC 58281-0563-01) Intrathecal Refill Kit. Such conduct is in violation of Section 3715.52(A)(2) of the Ohio Revised Code.

(13) B. Elise Miller did, on or about April 29, 2009, while practicing pharmacy at Miller's Pharmacy, fail to carry her pharmacist's identification card or renewal identification card while engaged in the practice of pharmacy. Such conduct is in violation of Section 4729.12 of the Ohio Revised Code.

(14) B. Elise Miller did, on or about April 29, 2009, while practicing pharmacy at Miller's Pharmacy, work in a pharmacy without being able to access all current federal and state laws, regulations, and rules governing the legal distribution of drugs in Ohio, to wit: B. Elise Miller did not have a "Drug Laws of Ohio" book and was unable to access the information otherwise. Such conduct is in violation of Rule 4729-9-02(A)(1) of the Ohio Administrative Code.

(15) B. Elise Miller as the Responsible Pharmacist did, between September 4, 2008, and April 29, 2009, while practicing pharmacy at Miller's Pharmacy, fail to properly execute DEA 222 Forms, to wit: B. Elise Miller or pharmacists under her control failed to record, on "copy 3" of Form number 072282225, the date the pharmacy received fentanyl citrate USP 1 gm, a Schedule II Controlled Substance. As well, B. Elise Miller or pharmacists under her control failed to record, on "copy 3" of Form number 072282226, the number of packages or date received Kadian™ 10 mg, a Schedule II Controlled Substance. Additionally, B. Elise Miller or pharmacists under her control failed to record, on "copy 3" of Form number 072282227, the date received fentanyl 12 mcg/hr patches,

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meperidine 50 mg/ml, and Kadian SR™ 10 mg capsules, each a Schedule II Controlled Substance. Such conduct is in violation of Section 1305.13(e) of the Code of Federal Regulations.

(16) B. Elise Miller as the Responsible Pharmacist did, on or about April 29, 2009, while practicing pharmacy at Miller's Pharmacy, and dates preceding, fail to provide security and control for DEA 222 order forms by limiting availability only to authorized persons, to wit: B. Elise Miller stored DEA 222 order forms at her residence where they were available to unauthorized persons. Such conduct is in violation of Rule 4729-9-09 of the Ohio Administrative Code.

(17) B. Elise Miller as the Responsible Pharmacist did, on or about April 29, 2009, and for two years preceding, while practicing pharmacy at Miller's Pharmacy, fail to take and maintain a complete controlled substance inventory. Such conduct is in violation of Section 1304.11(c) of the Code of Federal Regulations.

(18) B. Elise Miller did, on or about the following dates, while practicing pharmacy at Miller's Pharmacy, fail to record on the record of dispensing the drug name, the name of the manufacturer or distributor, or the NCD number of the generic drug dispensed:

<u>Date</u>	<u>Rx No.</u>
12-30-08	4015463
02-23-09	4015463
02-07-09	4015496
04-08-09	4015496
04-15-09	4015569
04-20-09	4015572
04-22-09	4015577
04-23-09	4015578

Such conduct is in violation of Rule 4729-5-21(l) of the Ohio Administrative Code.

(19) B. Elise Miller did, on or about the following dates, while practicing pharmacy at Miller's Pharmacy, fail to record on the record of dispensing the full name of the prescriber's agent when filling oral prescriptions:

<u>Date</u>	<u>Rx No.</u>
12-30-08	4015463
04-15-09	4015569
04-20-09	4015572
04-22-09	4015577
04-23-09	4015578

Such conduct is in violation of Rule 4729-5-21(D)(1) of the Ohio Administrative Code.

(20) B. Elise Miller did, on or about the following dates, while practicing pharmacy at Miller's Pharmacy, fail to create and maintain records of controlled substances sold, to wit: B. Elise Miller admittedly sold the following drugs, failed to keep a manual or electronic record, and indicated to a Board agent that she did not know how to enter the dispensing data into the pharmacy's computer.

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<u>Delivered</u>	<u>Patient (Code)</u>	<u>Drug</u>
04-15-09	#3	fentanyl 10 mg/ml & clonidine 450 mcg/ml
04-15-09	#4	morphine 5 mg/ml & bupivacaine 15 mg/ml
04-22-09	#5	Dilaudid™ 10 mg/ml & bupivacaine 5 mg/ml
04-27-09	#2	morphine 2.5 mg/ml & bupivacaine 7 mg/ml
04-28-09	#6	Dilaudid™ 8 mg/ml

Such conduct is in violation of Sections 3719.07(B)(3) and (C)(3)(a) and (b) of the Ohio Revised Code.

(21) B. Elise Miller did, from April 15, 2009, through April 28, 2009, while practicing pharmacy at Miller's Pharmacy, fail to create and maintain a patient profile having requisite information for the following patients (as coded): #2, #3, #4, #5, #6. Such conduct is in violation of Rule 4729-5-18 of the Ohio Administrative Code.

(22) B. Elise Miller did, on or about the following dates, while practicing pharmacy at Miller's Pharmacy, fail to manually record her name or initials on the record of dispensing:

<u>Delivered</u>	<u>Patient (Code)</u>	<u>Drug</u>
04-15-09	#3	fentanyl 10 mg/ml & clonidine 450 mcg/ml
04-15-09	#4	morphine 5 mg/ml & bupivacaine 15 mg/ml
04-22-09	#5	Dilaudid™ 10 mg/ml & bupivacaine 5 mg/ml
04-27-09	#2	morphine 2.5 mg/ml & bupivacaine 7 mg/ml
04-28-09	#6	Dilaudid™ 8 mg/ml
05-11-09	#1	Lioresal™ 200 mcg/ml & morphine 6 mg/ml

Such conduct is in violation of Rule 4729-5-21(C)(2) of the Ohio Administrative Code.

(23) B. Elise Miller did, on or about the following dates, while practicing pharmacy at Miller's Pharmacy, fail to serially number the following prescriptions:

<u>Delivered</u>	<u>Patient (Code)</u>	<u>Drug</u>
04-15-09	#3	fentanyl 10 mg/ml & clonidine 450 mcg/ml
04-15-09	#4	morphine 5 mg/ml & bupivacaine 15 mg/ml
04-22-09	#5	Dilaudid™ 10 mg/ml & bupivacaine 5 mg/ml
04-27-09	#2	morphine 2.5 mg/ml & bupivacaine 7 mg/ml
04-28-09	#6	Dilaudid™ 8 mg/ml

Such conduct is in violation of Rule 4729-5-19(A) of the Ohio Administrative Code.

(24) B. Elise Miller as the Responsible Pharmacist did, on or about May 19, 2009, while practicing pharmacy at Miller's Pharmacy, fail to maintain the following prescriptions in a separate file for Schedule II Controlled Substance prescriptions:

<u>Delivered</u>	<u>Patient (Code)</u>	<u>Drug</u>
04-15-09	#3	fentanyl 10 mg/ml & clonidine 450 mcg/ml
04-15-09	#4	morphine 5 mg/ml & bupivacaine 15 mg/ml
04-22-09	#5	Dilaudid™ 10 mg/ml & bupivacaine 5 mg/ml

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04-27-09	#2	morphine 2.5 mg/ml & bupivacaine 7 mg/ml
04-28-09	#6	Dilaudid™ 8 mg/ml
05-11-09	#1	Lioresal™ 200 mcg/ml & morphine 6 mg/ml

These prescriptions were found in multiple piles of papers that included billing information, patient information, and other drug orders (both controlled and non-controlled). Such conduct is in violation of Rule 4729-5-09(A) of the Ohio Administrative Code.

CONCLUSIONS OF LAW

(1) The State Board of Pharmacy concludes that paragraphs (2) through (24) of the Findings of Fact constitute being guilty of dishonesty and unprofessional conduct in the practice of pharmacy as provided in Division (A)(2) of Section 4729.16 of the Ohio Revised Code.

(2) The State Board of Pharmacy concludes that paragraphs (2, 7, 11, 13, 14, 16) and (18) through (24) of the Findings of Fact constitute being guilty of willfully violating, conspiring to violate, attempting to violate, or aiding and abetting the violation of provisions of Chapter 3715 of the Revised Code as provided in Division (A)(5) of Section 4729.16 of the Ohio Revised Code.

DECISION OF THE BOARD

The Board finds that the testimony of the Respondent was not believable.

B. Elise Miller's testimony clearly indicates that her practice of pharmacy does not comport to the standard of practice recognized as appropriate and required by this Board. Such standard of practice, at a minimum, requires compliance with state and federal laws regarding the practice of pharmacy.

B. Elise Miller refused to recognize or fails to understand, that her practice presents a danger to her patients.

B. Elise Miller dispensed Kineret but did not know the manufacturer's directions. This is improper.

It is axiomatic to the practice of pharmacy that sterile products, without preservatives, lose their effectiveness and efficacy once removed from the manufacturer's original container. Respondent did this when she knew or should have known that her actions created a danger to her patients.

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

(A) On the basis of the Findings of Fact and paragraph (1) of the Conclusions of Law, the State Board of Pharmacy hereby revokes permanently the pharmacist identification card, No. 03-1-12257, held by B. Elise Miller effective as of the date of the mailing of this Order.

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(B) On the basis of the Findings of Fact and paragraph (2) of the Conclusions of Law, the State Board of Pharmacy hereby revokes permanently the pharmacist identification card, No. 03-1-12257, held by B. Elise Miller effective as of the date of the mailing of this Order.

B. Elise Miller, pursuant to Section 4729.16(B) of the Ohio Revised Code, must return her license to practice (pocket ID card) and registration (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.

Deborah Lange moved for Findings of Fact; Jerome Wiesenhahn seconded the motion. Motion passed (Aye-7/Nay-0).

Troy Gahm moved for Conclusions of Law; Deborah Lange seconded the motion. Motion passed (Aye-6/Nay-1).

Jerome Wiesenhahn moved for Action of the Board; Donald Casar seconded the motion. Motion passed (Aye-5/Nay-2).

SO ORDERED.

It is hereby certified by this Board that the above language is a copy of the Order entered upon its journal in this case.

Section 119.12 of the Ohio Revised Code authorizes an appeal from this Order. An order that denied admission to an examination, or denied the issuance or renewal of a license or registration, or revoked or suspended a license, may be appealed to the court of common pleas in the Ohio county of your place of business or in your Ohio county of residence. Any other order may be appealed to the Court of Common Pleas of Franklin County, Ohio.

Such an appeal, setting forth the order appealed from and the grounds of the appeal, must be commenced by the filing of the ORIGINAL Notice of Appeal with the State Board of Pharmacy and a copy with the appropriate court within fifteen (15) days after the mailing of this Order and in accordance with the requirements of Section 119.12 of the Ohio Revised Code.

BY ORDER OF THE STATE BOARD OF PHARMACY

ORDER MAILED & EFFECTIVE: JANUARY 14, 2011

By: _____
William T. Winsley, M.S., R.Ph., Executive Director



OHIO STATE BOARD OF PHARMACY

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SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY

(Docket No. D-030917-013, D-030917-014 and D-030917-015)

In The Matter Of:

B. ELISE MILLER, R.Ph.

MILLER PHARMACY

and

THREE RIVERS O.P.T.I.O.N. CARE, INC.

2171 Forest Hill

Coshocton, Ohio 43812

(R.Ph. No. 03-1-12257)

(TDDD No. 02-0084550 and 02-0517450)

This Settlement Agreement is entered into by and between B. Elise Miller, Miller Pharmacy and Three Rivers O.P.T.I.O.N. Care, Inc. (hereinafter referred to as "Respondents") and the Ohio State Board of Pharmacy, a state agency charged with enforcing the Pharmacy Practice Act and Dangerous Drug Distribution Act, Chapter 4729. of the Ohio Revised Code.

Respondents voluntarily enter into this Agreement being fully informed of all their rights afforded under Chapter 119. of the Ohio Revised Code, including the right to representation by counsel, the right to a formal adjudication hearing on the issues contained herein, and the right to appeal. Respondents each acknowledge that by entering into this agreement each has waived all rights under Chapter 119. of the Revised Code.

Whereas, the Board is empowered by Sections 4729.16 and 4729.57 of the Ohio Revised Code to suspend, revoke, place on probation, refuse to grant or renew an identification card or enforce a monetary penalty on the license holder for violation of any of the enumerated grounds therein.

Whereas, B. Elise Miller is licensed to practice pharmacy in the State of Ohio.

Whereas, Miller Pharmacy and Three Rivers O.P.T.I.O.N. Care, Inc. are licensed as Terminal Distributors of Dangerous Drugs in the State of Ohio.

Whereas, on or about September 17, 2003, pursuant to Chapter 119. of the Ohio Revised Code, Respondents were notified of the allegations or charges against them, their rights to hearings, their rights in such hearings, and their rights to submit contentions in writing. Respondents requested hearings; they were scheduled, consolidated and continued. The September 17, 2003, Notice of Opportunity for Hearing letters contain the following allegations or charges:

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B. Elise Miller:

- (1) Records of the Board of Pharmacy indicate that B. Elise Miller was originally licensed in the State of Ohio as a pharmacist on March 6, 1978, pursuant to examination and that her license expired on September 15, 2001. Records further reflect during the relevant time periods stated herein, B. Elise Miller was indicated as the Responsible Pharmacist at Miller Pharmacy.
- (2) B. Elise Miller did, from September 15, 2001, through March 24, 2003, while not a registered pharmacist or pharmacy intern under the supervision of a registered pharmacist, practice pharmacy, to wit: after B. Elise Miller's license to practice pharmacy lapsed, she admittedly continued to practice pharmacy and dispense dangerous drugs. Such conduct is in violation of Section 4729.28 of the Ohio Revised Code.
- (3) B. Elise Miller did, on or about March 24, 2003, and on occasions previous thereto, knowingly make false statements when the statements were made with purpose to mislead a public official in performing the public official's official function, to wit: B. Elise Miller repeatedly lied to Board of Pharmacy specialists and agents as follows:
 - (a) B. Elise Miller twice stated that she was not practicing pharmacy during the period of her pharmacist's license lapse;
 - (b) B. Elise Miller lied to agents of the Board about the status of the Responsible Pharmacist at facilities that she owns and that are licensed with the Board as terminal distributors;
 - (c) B. Elise Miller lied to an agent of the Board when she indicated that she submitted her renewal application during the week of March 17, 2003;
 - (d) B. Elise Miller lied to an agent of the Board when she indicated that a Board specialist had approved her system of managing Synagis dispensings.

Such conduct is in violation of Section 2921.13 of the Ohio Revised Code.

- (4) B. Elise Miller did, on or about dates immediately preceding March 24, 2003, allow access to the physical confines of the pharmacy when not under the personal supervision of a pharmacist, to wit: in Three Rivers O.P.T.I.O.N. Care, Inc. she allowed the lone pharmacist to leave for lunch breaks or to work elsewhere without coverage by another pharmacist and without physically securing the pharmacy and its dangerous drug stocks. Such conduct is in violation of Rule 4729-9-11 of the Ohio Administrative Code.
- (5) B. Elise Miller did, on or about the following dates, knowingly make false statements when the statements were made with purpose to secure the issuance by a governmental agency of a license, to wit: B. Elise Miller submitted applications to the Board for renewal of the following terminal distributor of dangerous drugs licenses, where B. Elise Miller listed herself as a registered pharmacist in the position of Responsible Pharmacist:

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02-0084550	date signed: 10-01-01
02-0517450	date signed: 10-04-01
02-0084550	date signed: 09-20-02
02-0517450	date signed: 01-02-03

Such conduct is in violation of Section 2921.13 of the Ohio Revised Code.

Miller Pharmacy:

- (1) Records of the Board of Pharmacy indicate that Miller Pharmacy is licensed with the State Board of Pharmacy as a Terminal Distributor of Dangerous Drugs and James H. Sycks, R.Ph. is the Responsible Pharmacist pursuant to Rule 4729-5-11 of the Ohio Administrative Code and Sections 4729.27 and 4729.55 of the Ohio Revised Code.
- (2) Miller Pharmacy did, from September 15, 2001, through March 24, 2003, cease to satisfy the qualifications of a terminal distributor of dangerous drugs as set forth in Section 4729.55 of the Ohio Revised Code, to wit: the pharmacy did not have a registered pharmacist in full and actual charge of the pharmacy during this time period, and adequate safeguards were not assured to prevent the sale or distribution of dangerous drugs by persons other than a pharmacist or licensed prescriber. Such conduct is in violation of Section 4729.27 of the Ohio Revised Code.

Three Rivers O.P.T.I.O.N. Care, Inc.:

- (1) Records of the Board of Pharmacy indicate that Three Rivers O.P.T.I.O.N. Care, Inc. is licensed with the State Board of Pharmacy as a Terminal Distributor of Dangerous Drugs and B. Elise Miller is the owner of Three Rivers O.P.T.I.O.N. Care, Inc.
- (2) Three Rivers O.P.T.I.O.N. Care, Inc. did, from September 15, 2001, through March 24, 2003, while not a pharmacist or pharmacy intern under the personal supervision of a pharmacist, compound, dispense, or sell dangerous drugs or otherwise engage in the practice of pharmacy, to wit: the pharmacy, through its owner, B. Elise Miller, whose pharmacist license had lapsed, dispensed dangerous drugs and/or practiced pharmacy. Such conduct is in violation of Section 4729.28 of the Ohio Revised Code.
- (3) Three Rivers O.P.T.I.O.N. Care, Inc. did, from September 15, 2001, through March 24, 2003, allow access to the physical confines of the pharmacy when not under the personal supervision of a pharmacist, to wit: when the lone pharmacist on duty was permitted to leave to cover for lunch breaks of the pharmacist at Miller Pharmacy, the pharmacy was left without coverage by another pharmacist and the pharmacy and its dangerous drug stocks were not physically secured. Such conduct is in violation of Rule 4729-9-11 of the Ohio Administrative Code.
- (4) Three Rivers O.P.T.I.O.N. Care, Inc. did, from September 15, 2001, through March 24, 2003, cease to satisfy the qualifications of a terminal distributor of dangerous drugs as set forth in Section 4729.55 of the Ohio Revised Code, to wit: the pharmacy did not have a registered pharmacist in full and actual charge of the

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pharmacy during this time period, and adequate safeguards were not assured to prevent the sale or distribution of dangerous drugs by persons other than a pharmacist or licensed prescriber. Such conduct is in violation of Section 4729.27 of the Ohio Revised Code.

- (5) Three Rivers O.P.T.I.O.N. Care, Inc. did, on or about May 3, 2003, and dates subsequent, cease to satisfy the qualifications of a terminal distributor of dangerous drugs as set forth in Section 4729.55 of the Ohio Revised Code, to wit: the pharmacy's Responsible Pharmacist resigned, and was not replaced with another Responsible Pharmacist. As such, the pharmacy did not have a registered pharmacist in full and actual charge of the pharmacy during this time period, and adequate safeguards were not assured to prevent the sale or distribution of dangerous drugs by persons other than a pharmacist or licensed prescriber. Such conduct is in violation of Section 4729.27 of the Ohio Revised Code.
- (6) Three Rivers O.P.T.I.O.N. Care, Inc. did, on or about April 23, 2003, and on dates subsequent, fail to keep records of the practice of pharmacy subject to inspection by the Board, and it did fail to make records readily available and/or promptly produce such records upon the request of a Board of Pharmacy agent, to wit: though an agent of the Board requested records of drugs dispensed, the pharmacy has failed to produce the records as requested. Such conduct is in violation of Section 4729.37 of the Ohio Revised Code and/or Rules 4729-5-27 and 4729-5-28 of the Ohio Revised Code.

Respondents neither admit nor deny the allegations stated in the Notice of Opportunity for Hearing letters dated September 17, 2003; however, the Board has evidence sufficient to sustain the allegations and hereby adjudicates the same.

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

- (A) B. Elise Miller's pharmacist identification card, No. 03-1-12257, will be suspended for six months from the effective date of this Agreement.
- (B) B. Elise Miller agrees to the imposition of a monetary penalty of three thousand dollars (\$3,000.00), due and owing within thirty (30) days from the effective date of this Agreement.
- (C) Miller Pharmacy agrees to the imposition of a monetary penalty of three thousand dollars (\$3,000.00), due and owing within thirty (30) days from the effective date of this Agreement.
- (D) Three Rivers O.P.T.I.O.N. Care, Inc. agrees to the imposition of a monetary penalty of seventeen thousand five hundred dollars (\$17,500), due and owing within thirty (30) days from the effective date of this agreement.

B. Elise Miller, R.Ph.

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Checks should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed forms to the State Board of Pharmacy, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126.

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

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

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

B. Elise Miller, Individually and on behalf of Miller Pharmacy
and Three Rivers O.P.T.I.O.N. Care, Inc.

03/31/04
Date of Signature

Michael L. Close, Attorney for Respondent

04/01/04
Date of Signature

Robert P. Giacalone, President, Ohio State Board of Pharmacy

04/05/04
Date of Signature

Sally Ann Steuk, Ohio Assistant Attorney General

04/05/04
Date of Signature