STATE OF MISSOURI
MISSOURI BOARD OF PHARMACY

IN RE:	)	
	)	
TRACY D. DRYER	)	
License No. 042208	)	Complaint No. 2016-001048
2246 SW Wall Street	)	
Blue Springs, MO 64015	)	

SETTLEMENT AGREEMENT

Come now Tracy D. Dryer, R.Ph. ("Respondent" or "Licensee") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's license to practice pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that she understands the various rights and privileges afforded her by law, including the right to a hearing of the charges against her; the right to appear and be represented by counsel; the right to have all charges against her proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against her; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against her and, subsequently, the right to a disciplinary hearing before the Board at which time she may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against her license. Being aware of these rights provided her by operation of law, Respondent knowingly and

voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document as they pertain to her.

Respondent acknowledges that she has received a copy of the draft Complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's license.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's license to practice pharmacy, numbered 042208, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

JOINT STIPULATION OF FACTS

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.140, RSMo (2016) for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Respondent Tracy D. Dryer is licensed as a pharmacist under the laws of the State of Missouri, License No. 042208. Respondent's license was at all times relevant herein current and active.

3. At all times relevant hereto, Respondent was employed as the pharmacist-in-charge ("PIC") at The Medicine Shoppe, 1450 NE Douglas Rd., Lee's Summit, MO 64086 until her employment was terminated on April 14, 2016.

4. Thereafter, Respondent became employed as a staff pharmacist at Sterling Pharmacy, 19321 East US 40 Hwy, Suit P, Independence, MO 64055.

The Medicine Shoppe

5. On March 1, 2016, the Board received a Technician Discipline/Action Form from Respondent regarding technician A.M.

6. Respondent had terminated A.M. for suspicious activity related to the loss of controlled substances.

7. Board Inspector Elaina Wolzak was assigned to investigate the reported losses on behalf of the Board.

8. During the investigation, Inspector Wolzak requested The Medicine Shoppe's prescription records, compound log and documents, and policies and procedures for review.

I. Dispensing and recordkeeping violations

Prescription no. 2103208

9. The Medicine Shoppe's records show that prescription no. 2103208 was written by Dr. Thad Stephens on April 13, 2015, for morphine 20mg/Silvadene 200gm compound, quantity of 200gm, one jar, no refills.

10. 25gm of prescription no. 2103208 was prepared and dispensed on April 18, 2015, using morphine sulfate[1] powder lot no. C155311.

11. Respondent was the responsible pharmacist for the dispensing on April 18, 2015.

12. The certificate of analysis for morphine sulfate powder lot no. C155311 shows an expiration date of March 31, 2015, resulting in prescription no. 2103208 being dispensed with expired morphine.

13. Dr. Stephens was not contacted about and did not authorize the dispensing of 25gm of the compound or of expired morphine sulfate on prescription no. 2103208.

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[1] Morphine is a schedule II controlled substance pursuant to § 195.017.4(1)(a)m, RSMo, 2000, as amended. All statutory references are to the 2000 Revised Statutes of Missouri, as amended, unless otherwise stated.

14. 200gm of prescription no. 2103208 was prepared and dispensed again on April 29, 2015, using morphine sulfate powder lot no. C168959 by pharmacist J.B.

15. Respondent knowingly verified and dispensed a compound made with expired morphine powder and filled a prescription for a quantity greater than prescribed and failed to obtain a prescription for the morphine sulfate compound dispensed on April 18, 2015.

Prescription no. 4116247

16. The Pharmacy's records show that prescription no. 4116247 was written by Dr. Marilyn Richardson on November 2, 2015, for E2/Test/DHEA[2] 3/3/3 mg troche, quantity of 30, five (5) refills, and for the patient to take one troche every day.

17. The Medicine Shoppe's dispensing records show that prescription no. 4116247 was dispensed for a quantity of 30 on November 2, 2015, December 1, 2015, December 29, 2015, February 1, 2016, and March 2, 2016.

18. The Medicine Shoppe's compound log shows that that prescription no. 4116247 also was dispensed on March 17, 2016, for a quantity of 60 troches, which exceeded the amount authorized by the prescriber.

19. A handwritten note in the compound log for prescription no. 4116247 states "wrong address written down – re-making twice for inconv."

20. Other than the compound record, The Medicine Shoppe has no record showing that prescription no. 4116247 was dispensed on March 17, 2016. Nor does The Medicine Shoppe have any record indicating that the prescription dispensed on March 2, 2016 was ever delivered to the patient or, if delivered, returned to The Medicine Shoppe.

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[2] This compound is a combination of estrogen, testosterone and dehydroepiandrosterone. Testosterone is a Schedule III controlled substance pursuant to §195.017.6(6), RSMo.

21. Respondent was the responsible pharmacist for dispensing prescription no. 4116247 on March 2, 2016, and on March 17, 2016.

Prescription no. 4116119

22. The Medicine Shoppe's records show that prescription no. 4116119 for E2/Prog/Test/DHEA 1/100/4/3/20 mg troche was written for a quantity of 30 with five (5) refills.

23. The compound log records for prescription no. 4116119 state "remake, patient complained of very different texture and taste this time – it seems like Base C may have been added by mistake, remake at no charge."

24. Dispensing records show that prescription no. 4116119 was dispensed on October 14, 2015, November 14, 2015, December 15, 2015, January 15, 2016, February 15, 2016, and March 15, 2016.

25. Compound log records show that prescription no. 4116119 also was dispensed on October 19, 2015.

26. Compound log records show Respondent as the responsible pharmacist for prescription no. 4116119 dispensed on October 14, 2015, and October 19, 2015.

27. The Medicine Shoppe has no record indicating that the prescription dispensed on October 14, 2015 was returned to The Medicine Shoppe.

Prescription no. 4108179

28. The Medicine Shoppe failed to produce a hard copy of prescription no. 4108179.

29. The Medicine Shoppe's records show that prescription no. 4108179 was prepared and dispensed on July 24, 2013, for E2/Prog/Test/DHEA/Preg 3/175/4/30/25 mg troche for a quantity of 30.

30. Spearmint oil flavor, lot no. C145367, was used in the preparation of this compound.

31. The certificate of analysis for spearmint oil flavor, lot no. C145367, shows an expiration date of August 21, 2013.

32. The compound log for prescription no. 4108179 shows the compound was assigned a beyond-use date of January 24, 2014.

33. Respondent was the responsible pharmacist for prescription no. 4108179 dispensed on July 24, 2013.

34. Respondent has admitted in writing that the beyond-use date assigned to prescription no. 4108909 was incorrect.

Prescription no. 4108909

35. The Medicine Shoppe's records show that prescription no. 4108909 was written for Testosterone/DHEA Troche 30/8mg, troche, quantity of 30, by Dr. Paul Joubert on June 27, 2013.

36. Prescription no. 4108909 was prepared and dispensed for a quantity of 30 on June 27, 2013, using bubble gum liquid concentrate, lot no. C151178.

37. The certificate of analysis for the bubble gum liquid concentrate, lot no. C151178, shows an expiration date of July 5, 2013.

38. The compound log for prescription no. 4108909 shows the compound was assigned a beyond-use date of July 30, 2013.

39. Respondent was the responsible pharmacist for prescription no. 4108909 dispensed on June 27, 2013.

40. Respondent has admitted in writing that the beyond-use date assigned to prescription no. 4108909 was incorrect.

Prescription no. 7022689

41. The Medicine Shoppe's records show that prescription no. 7022689 for thyroid 76mg capsules, quantity of 100, was prepared and dispensed on April 12, 2012, using thyroid powder porcine, lot no. C136783.

42. The certificate of analysis for the thyroid powder porcine lot no. C136783 shows an expiration date of April 6, 2012.

43. The thyroid powder porcine was expired on the date of compounding and dispensing.

44. The compound log for prescription no. 7022689 shows the compound was assigned a beyond-use date of October 12, 2012.

45. Respondent was the responsible pharmacist for prescription no. 7022689 dispensed on April 12, 2012.

Prescription No. 7040649

46. The Medicine Shoppe failed to produce a hard copy of prescription no. 7040649.

47. Compound log documents and patient profile records for prescription no. 7040649, Neomy/Poly-B 25/125000 units/mL show that this compound was dispensed on April 16, 2014, and April 23, 2014.

Prescription no. 7049452

48. The Medicine Shoppe's records show that prescription no. 7049452 was written by Dr. Rabiya Suleman on April 8, 2015, for Progesterone 75mg capsule, quantity of 30, three (3) refills, and for the patient to take one capsule every day.

49. The Medicine Shoppe's dispensing records show that prescription no. 7049452 was dispensed for a quantity of 30 on May 6, 2015, June 4, 2015, June 29, 2015, and July 27, 2015.

50. The Medicine Shoppe's compound log shows that that prescription no. 7049452 also was dispensed on August 10, 2015, for a quantity of 15.

51. An additional 15 capsules were dispensed that were not originally authorized by the prescriber.

52. The dispensing records do not show any dispensing of prescription no. 7049452 on August 10, 2015.

53. Respondent was the responsible pharmacist for dispensing prescription no. 7049452 on August 10, 2015.

Dispensing without prescriber authorization and/or in excess of amount prescribed

54. Missouri law imposes the following before a prescription may be validly dispensed:

> (1) To be valid for purposes of dispensing, a prescription shall conform to all requirements of sections 338.056 or 338.196, RSMo, and shall contain the following information:
>
> > (A) The date of prescribing;
> > (B) The name of the patient(s), or if an animal, species and owner's name;
> > (C) The prescriber's name, if an oral prescription, or written or electronic signature if a written, faxed, or an electronically transmitted prescription. Electronic signatures shall comply with all applicable provisions of 20 CSR 2220-2.085;
> > (D) Name, strength and dosage of drug, device or poison prescribed and the directions for use;
> > (E) The number of refills, if applicable;
> > (F) The quantity prescribed in weight, volume, or number of units;
> > (G) An indication of whether generic substitution has been authorized by the prescriber, as required by section 338.056, RSMo;
> > (H) Any change or alteration made to the prescription dispensed based on contact with the prescriber to show a clear audit trail. This shall include, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug;
> > (I) The address of the prescriber and the patient when the prescription is for a controlled substance;
> > (J) The prescriber's Drug Enforcement Administration (DEA) number when the prescription is for a controlled substance; and

> (K) Controlled substance prescriptions shall also comply with all requirements of federal and state controlled substance laws.
> 20 CSR § 2220-2.018(1)(H)

55. Alterations to prescriptions also must be maintained in a pharmacy's electronic recording keeping system, to-wit:

> (2) EDP systems shall comply with the requirements of section 338.100, RSMo, and shall be capable of storing and retrieving the following information concerning the original filling or refilling of any prescription:
>
> > (Q) Any other change or alteration made in the original prescription based on contact with the prescriber to show a clear audit trail. This shall include, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug. 20 CSR § 2220-2.080(2)(Q).

56. Dispensing prescription nos. 2103208, 4116247, 7049452 and 4116119 in excess of the amount prescribed and/or which were not authorized by a prescription is unauthorized dispensing in violation of 20 CSR § 2220-2.018(1)(H) and 20 CSR § 2220-2.080(2)(Q).

57. Dispensing prescription no. 7047935 without a prescription that met the requirements of 20 CSR § 2220-2.018(1), including but not limited to 20 CSR § 2220-2.018(1)(C), violated Missouri law.

58. Dispensing prescription drugs without authorization by a prescriber or in excess of the amount prescribed constitutes grounds for discipline under § 338.055.2(5), RSMo.

Dispensing compounds with expired ingredients

59. Dispensing compounds with expired ingredients constitutes violates the drug laws of Missouri and constitutes misconduct in the practice of pharmacy.

Dispensing Schedule II Drug Without a Prescription

60. Section 195.060.1, RSMo, provides:

> 1. Except as provided in subsection 4 of this section, a pharmacist, in good faith, may sell and dispense controlled substances to any person only upon

> a prescription of a practitioner as authorized by statute . . . no prescription for a drug in Schedule I or II shall be refilled; no prescription for a drug in Schedule III or IV shall be filled or refilled more than six months after the date of the original prescription or be refilled more than five times unless renewed by the practitioner.

61. Federal law contains a similar prohibition, to-wit:

> (a) A pharmacist may dispense directly a controlled substance listed in Schedule II that is a prescription drug as determined under section 503 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) only pursuant to a written prescription signed by the practitioner, except as provided in paragraph (d) of this section. A paper prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original manually signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraph (e), (f), or (g) of this section. The original prescription shall be maintained in accordance with § 1304.04(h) of this chapter.
>
> 21 CFR § 1306.11(a)

62. Respondent violated §195.060.1, RSMo, and 21 CFR § 1306.11(a) by dispensing a non-prescribed amount of morphine sulfate compound on April 18, 2015 under prescription no. 210320, and by dispensing the compound with expired morphine powder, a Schedule II controlled substance. Pharmacy staff further violated §195.060.1, RSMo by refilling said prescription on April 29, 2018.

Dispensing Schedule III Drug in Excess of Amount Prescribed

63. 21 CFR § 1306.21(a) states:

> (a) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V that is a prescription drug as determined under section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) only pursuant to either a paper prescription signed by a practitioner, a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, an electronic prescription that meets the requirements of this part and part 1311 of this chapter, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in § 1306.05, except for the signature of the practitioner.

64. Respondent violated §195.060.1, RSMo, and 21 CFR § 1306.11(a) by dispensing 60 troches containing testosterone, a Schedule III controlled substance, on prescription no. 4116247 which only authorized 30, and by refilling prescription no. 4116119 six (6) times without renewal by the prescriber after the fifth refill.

Recordkeeping Violations – Failure to Maintain Prescriptions

65. Section 338.100.1, RSMo, requires licensed pharmacies to store, for not less than five years,

> the original or order of each drug or biological product which has been compounded or dispensed at such pharmacy, according to and in compliance with standards provided by the board. . . .

66. Missouri law also states that:

> (4) Each licensed pharmacy shall maintain at least three (3) separate files of prescriptions and they shall be as follows:
>
> (A) All prescriptions for controlled drugs listed in Schedules I and II shall be maintained in a separate prescription file;
>
> (B) All prescriptions for controlled drugs listed in Schedules III, IV and V shall be maintained in a separate prescription file; and
>
> (C) All other prescriptions for noncontrolled drugs shall be maintained in a separate prescription file(s).

20 CSR § 2220-2.010(4).

67. The Medicine Shoppe violated § 338.100.1, RSMo, and 20 CSR § 2220-2.010(4)(B)-(C) by failing to retain and maintain the original of prescription nos. 4108179 and 7040649.

II. Compounding Violations

Assigning a Beyond Use Date Greater than a Compound Ingredient's Expiration Date

68. Missouri law states:

> (4) Beyond-use date: A date after which a compounded preparation should not be used and is determined from the date the preparation is compounded. Because compounded preparations are intended for administration

immediately or following short-term storage, their beyond-use dates must be assigned based on criteria different from those applied to assigning expiration dates to manufactured drug products.

20 CSR § 2220-2.400(4).

69. In addition, Missouri law requires that:

(6) Proper controls shall be maintained over drug products/ingredients, containers and container closures.

(C) Pharmacists shall only use nondrug substances for compounding that are free of any contaminants and which maintain full potency.

20 CSR § 2220-2.400(6)(C)

70. Pursuant to 20 CSR § 2220-2.400(8)(A):

(8) Management of Compounding.

(A) A pharmacist dispensing any compounded drug is responsible for ensuring that the product has been prepared, labeled, controlled, stored, dispensed and distributed properly. The pharmacist is responsible for ensuring that quality is built into the preparation of products, with key factors including at least the following general principles:

1. Personnel are capable and qualified to perform their assigned duties;
2. Ingredients used in compounding have their expected identity, quality and purity. Drug components must meet compendial standards or maintain a certificate of analysis on file when bulk drug substances are involved. Visual inspection of bulk drug substances must be performed;
3. Reasonable assurance that processes are always carried out as intended or specified;
4. Preparation conditions and procedures are adequate for preventing mix-ups or other errors; and
5. All finished products, as a condition of release, must be individually inspected for evidence of visible particulates or other foreign matter and for container-closure integrity and any other apparent visual defects.

71. By assigning beyond-use dates to prescription nos. 4108909 and 4108179 greater than their ingredients' expiration dates, Respondent violated 20 CSR § 2220-2.400(4), (6)(C) and (8)(A)2.

Failure to Follow Compounding Procedures to Ensure Quality

72. Respondent violated 20 CSR § 2220-2.400(8)(A)2-4 by dispensing prescription nos. 2103208 and 7022689 containing expired ingredients and by failing to properly weigh the compound ingredients in prescription no. 2103208.

Failure of Computer System to Properly Identify Responsible Pharmacist

73. The Medicine Shoppe maintains an electronic record-keeping system.

74. Inspector Wolzak discovered during her investigation that the pharmacists were handwriting their initials on the sticker on the back of the hardcopy of the prescription as the record of the verifying pharmacist.

75. Missouri requires the following with regard to electronic data processing record keeping systems:

> (1) In lieu of a non-electronic (manual) record-keeping system, a pharmacy may elect to maintain an electronic data processing (EDP) record keeping-system. All information concerning the compounding, dispensing, or selling by a pharmacy of any drug, device, or poison pursuant to a lawful prescription which is entered into an EDP system at any pharmacy shall be entered only by a licensed pharmacist or by a technician or intern pharmacist under the direct supervision and review of a licensed pharmacist. Prior to dispensing, a pharmacist shall personally verify the accuracy of prescription data entered into the EDP for each original prescription. The EDP system shall comply with all applicable state and federal controlled substance laws and regulations.
>
> (2) EDP systems shall comply with the requirements of section 338.100, RSMo, and shall be capable of storing and retrieving the following information concerning the original filling or refilling of any prescription:
>
> > (L) Identity of the pharmacist responsible for verifying the accuracy of prescription data prior to dispensing on each original prescription;
>
> 20 CSR § 2220-2.080

76. The Medicine Shoppe's EDP system did not identify the pharmacist responsible for verifying the accuracy of prescription data prior to dispensing prescriptions, and, therefore, violated 20 CSR § 2220-2.080(2)(L).

PIC Violations

77. All of the above referenced violations committed by Respondent, The Medicine Shoppe and its staff may be imputed to Respondent, who is ultimately charged with responsibility to ensure that The Medicine Shoppe is operated in full compliance of all state and federal laws and regulations concerning the practice of pharmacy.

78. Further, the above referenced violations committed by Respondent, The Medicine Shoppe and its staff may be imputed to Respondent, who is ultimately charged with responsibility to ensure that The Medicine Shoppe policies and procedures are in force to ensure safety for the public concerning any action by pharmacy staff members or any action within the pharmacy physical plant.

79. As PIC, Respondent also is charged with responsibility to ensure that The Medicine Shoppe is operated in full compliance of all state and federal laws and regulations concerning the practice of pharmacy pursuant to § 338.210.5, RSMo, which states:

> 5. If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation.

80. As pharmacist-in-charge, Respondent's failure to supervise pharmacy personnel to assure full compliance with state and federal pharmacy laws and regulations, and Respondent's failure to implement and enforce policies and procedures to effectively insure the public safety is in violation of 20 CSR 2220-2.090(2) (E), (H), (N), (P), (V), (W) and (Y) which states, in pertinent part:

(2) The responsibilities of a pharmacist-in-charge, at a minimum, will include:

* * *

(E) Assurance that all procedures of the pharmacy in the handling, dispensing and recordkeeping of controlled substances are in compliance with state and federal laws;

* * *

(H) The prescription files are maintained according to the requirements of this board and the other state and federal controlled substance laws and regulations;

* * *

(N) The pharmacist-in-charge will be responsible for the supervision of all pharmacy personnel, to assure full compliance with the pharmacy laws of Missouri;

* * *

(P) Policies and procedures are in force to insure safety for the public concerning any action by pharmacy staff members or within the pharmacy physical plant;

* * *

(V) No outdated drugs are dispensed or maintained within the active inventory of the pharmacy, including prescription and related nonprescription items;

(W) Assure full compliance with all state and federal drug laws and rules;

* * *

(Y) Assure that all state and federal laws concerning drug distribution and control are complied with and that no violations occur that would cause a drug or device or any component thereof to become adulterated or misbranded.

Sterling Pharmacy

81. On or about August 15, 2017, Inspectors Wolzak and Katie DeBold inspected Sterling Pharmacy.

82. During that inspection, they discovered that the PIC of Sterling Pharmacy and Respondent who is a staff pharmacist had received a written reprimand regarding a calculation

error that resulted in a thyroid capsule being compounded "in marked excess" of the product prescribed.

83. Board Inspectors investigated the calculation error on behalf of the Board.

84. On or around February 21, 2017, Respondent compounded a prescription no. 6945328 for T3/T4[3] 52.5mcg/90mcg vegetarian capsules.

85. Calculations for the compound were erroneously prepared assuming the T3 and T4 triturations were 1:1000 strength instead of the actual 1:10 strength, resulting in a final product that had 100 times more T3 and T4 than intended per capsule.

86. The patient consumed these compounded thyroid capsules and was hospitalized on March 1, 2017 for "thyroid storm."[4] The patient suffered high T3 and T4 levels and undetectable TSH[5] levels.

87. Respondent was the pharmacist responsible for the formula and for performing the calculations for the compound, and she prepared and verified the T3 and T4 triturations, and the T3/T4 prescription.

88. Respondent alleges her compounding technician, R.H., who worked with Respondent at The Medicine Shoppe, and the PIC double-checked Respondent's calculations and also did not discover the errors.

89. Respondent failed to properly exercise her professional discretion in compounding prescription no. 6945328.

90. On or around January 31, 2018, the Board received a Uniform Complaint Report from patient A. F.-D. alleging that Sterling Pharmacy dispensed two different compounded

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[3] T3 is an abbreviation for the thyroid hormone triiodothyronine. T4 is an abbreviation for the thyroid hormone thyroxine.
[4] Thyroid storm is a life-threatening medical condition caused by high thyroid levels.
[5] TSH is an abbreviation for thyroid-stimulating hormone. Low TSH levels correspond with high T3 and T4 levels.

preparation prescriptions to her on January 24, 2018, in two separate bottles with both bottles containing the same label which read "T3/T4 22.5/57 mcg."

91. Inspector Wolzak investigated the complaint on behalf of the Board.

92. Patient A. F.-D. was expecting three compounded prescription medications from Sterling Pharmacy for:

A. T3/T4 22.5/57 mcg capsule (Liothyronine/ Levothyroxine);

B. E2/E3 1.5/0.1 mg capsule (Estradiol/Estriol); and

C. Progesterone 300mg capsule.

93. Two of the bottles she received contained the following identical information on the labels, even though the prescription numbers were different :

A. Prescription no. 6998577, T3/T4 22.5mcg/57mcg, take one capsule by mouth every morning on empty stomach, 60 EAC.

B. Prescription no. 6998538, T3/T4 22.5mcg/, take one capsule by mouth every morning on empty stomach, 60 EAC.

94. The bottle for prescription no. 6998577 contained orange/white capsules.

95. The bottle for prescription no. 6998538 contained yellow/pink capsules.

96. Patient A. F.-D. contacted the Sterling Pharmacy and spoke with technician R.H. Technician R.H. agreed that one of the medications was incorrectly labeled.

97. Sterling Pharmacy replaced the medication with orange/white capsules. The replacement medication contained orange/white capsules and a label showing prescription no. 6998547 for E2/E3 (estrogen).

98. The bottle was mislabeled because two labels were generated for the T3/T4 compound prescription and one of the extra labels was affixed to the estrogen medication bottle.

99. The incorrectly labeled prescription was returned to Sterling Pharmacy and replaced the same day it was dispensed.

100. Respondent was the responsible pharmacist for patient A. F.-D.'s prescriptions dispensed on January 24, 2018, and admitted the error.

101. The compound log dated January 22, 2018 for prescription no. 6998547 shows ingredient E2 ALI. It further shows a beyond-use date for ingredient E2 ALI of July 15, 2018, whereas the compound was assigned beyond-use date of July 23, 2018.

102. The compound log dated January 25, 2018, for re-made prescription no. 6998547 shows ingredient E3 ALI.

103. In a written response dated February 16, 2018, Respondent stated that an E3 aliquot should have been used for prescription no. 6998547 and not an E2. "This was further error."

104. By verifying an incorrect label which was affixed to prescription no. 6998547 and dispensed to patient A. D.-F., Respondent committed misconduct in the practice of pharmacy.

105. By assigning a beyond-use date to prescription no. 6998547 greater than its ingredients' expiration dates, Respondent committed misconduct in the practice of pharmacy.

106. By assigning a beyond-use date to prescription no. 6998547 greater than its ingredients' expiration dates, Respondent committed misconduct in the practice of pharmacy.

JOINT CONCLUSIONS OF LAW

107. Respondent's conduct is cause for disciplinary action against her license to practice pharmacy under § 338.055.2(5), (6), (13), and (15), RSMo, which provides:

> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

(13) Violation of any professional trust or confidence;

* * *

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government.

JOINT AGREED DISCIPLINARY ORDER

A. Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of §621.045.4(3), RSMo. Respondent's pharmacist license, number 042208 shall be placed on **PROBATION for a period of TWO (2) YEARS** ("disciplinary period"). The terms of discipline shall be:

The following terms apply for the entire disciplinary period.

1. Respondent shall comply with all applicable provisions of Chapter 338, Chapter 195, Chapter 196 and all applicable federal and state pharmacy/drug laws and regulations and all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

2. Respondent shall not serve as pharmacist-in-charge or manager-in-charge of any entity licensed or regulated by the Board, or as a preceptor for pharmacy interns or as a teaching member of any school or college of pharmacy. Additionally, Respondent shall not serve as a consultant required by a Board disciplinary order for any pharmacy/drug distributor.

3. Respondent shall keep the Board apprised of her current home, electronic mail (e-mail) and work addresses and telephone numbers. Respondent shall notify the Board of any

change in Respondent's employer or Respondent's home or work address within ten (10) days of such change in a manner approved by the Board. For employer/work changes, Respondent's notification shall include the reasons for the change. If at any time Respondent is employed by a temporary employment agency or maintains employment that requires frequent daily or weekly changes of work location she must provide the Board a list of locations worked if requested by the Board or Board's representative.

4. If Respondent's license expires or becomes void/invalid, upon renewal or reapplication, Respondent's license shall be subject to all terms and conditions of discipline not previously satisfied, including any remaining suspension/probationary period.

5. Respondent shall cooperate with the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of this Settlement Agreement. Respondent shall make herself available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings shall be at the Board's discretion and may occur periodically during the disciplinary period.

6. Respondent shall respond to any written inquiry of the Board and provide any requested documentation/records within three (3) days of receipt of a written request from the Board or the Board's authorized designee, or as otherwise requested by the Board/Board designee.

7. If requested by the Board, Respondent shall submit to a criminal history background check via the Board's approved vendor at Respondent's cost. Unless otherwise directed by the Board, Respondent shall submit the required fingerprints and undergo the requested criminal history background check within ten (10) days of the Board's request.

8. Respondent shall submit to any drug, alcohol or urinalysis testing requested by the Board, at Respondent's cost. Testing may be conducted on any human sample, including, but not necessarily limited to, urine, blood, breath, hair, nails, skin or saliva. The timing, manner and scheduling for testing is within the Board's sole discretion.

9. Respondent shall report any of the following occurrences to the Board, in writing, within seventy-two (72) hours of such occurrence:
    a. Any arrest or issuance of a criminal complaint;
    b. Any municipal/local arrest, citation or complaint relating to drugs, theft, shoplifting, burglary, possession of drug paraphernalia, driving or operating a motor vehicle under the influence/while intoxicated or illegally possessing, selling or purchasing alcohol, any drug or drug paraphernalia;
    c. A finding or plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment, including, but not limited to, any deferred or diverted adjudication, order or agreement;
    d. A conviction of any crime, including, but not limited to, any Suspended Imposition of Sentence ("SIS") or Suspended Execution of Sentence ("SES");

e. A finding by a court that Respondent has violated any term of her criminal probation/parole;
f. Any discipline, citation, or other administrative action filed or taken against Respondent by any state board/committee of pharmacy, or any other state or federal agency.

Failure to timely report any of the foregoing occurrences shall be considered a disciplinary violation.

10. If Respondent is currently or begins serving any period of criminal probation/parole, Respondent shall provide the name of her probation/parole officer to the Board, in writing, within ten (10) days of the effective date of this Agreement or within ten (10) days of the designation of a probation/parole officer. If Respondent's probation/parole officer is changed for any reason, Respondent shall submit the name of the replacement officer to the Board within ten (10) days of the change/modification. Respondent shall execute a release authorizing her probation or parole officer to provide to the Board any information relating to Respondent's probation or parole. Respondent shall maintain the release in effect and shall provide an updated release if requested by the Board.

11. Respondent shall file a "Disciplinary Compliance Report" with the Board in a form/manner approved by the Board. The Disciplinary Compliance Report shall be due by January 1 and July 1 of each calendar year. Respondent's final Disciplinary Compliance Report shall be filed no later than ninety (90) days before the end of the probationary period.

12. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Agreement.

13. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

NOTICE TO EMPLOYERS

14. If applicable, Respondent shall notify any employer of the employer's need to apply for and receive the necessary state (misdemeanor/felony) and federal (felony) waivers from the Bureau of Narcotics and Dangerous Drugs and the Drug Enforcement Administration in order to be employed within a facility that maintains state or federal registrations for the purpose of storing, distributing or dispensing controlled substances.

15. Except as otherwise provided herein, "Employment" within the meaning of this Agreement shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist in or any position for which a pharmacist license, pharmacy intern license or pharmacy technician registration is a requirement or criterion for employment in, regardless of whether Respondent is an employee, independent contractor, volunteer, instructor or consultant. "Employment" shall also include any entity where legend drugs are stored, sold, dispensed or distributed.

16. Respondent shall notify any current or future employers of this action by providing a copy of this Settlement Agreement to the pharmacist-in-charge or manager-in-charge of any pharmacy or drug distributorship where Respondent is employed, on or before the effective date of discipline or prior to accepting any offer of employment.
    a. If Respondent is not or will not be employed by a pharmacy or drug distributor, the notice shall be provided to Respondent's direct supervisor at Respondent's current/prospective place of employment, as defined herein, within the timeframes required by this section.
    b. For purposes of this Agreement, a pharmacy shall also include, but is not limited to, any location providing pharmacy services for inpatients of a licensed hospital or residents of a long term care facility.

17. Respondent shall cause the pharmacist-in-charge, manager-in-charge or supervisor of any employer to sign a written acknowledgment on a form approved by the Board indicating that he/she has received and reviewed the Settlement Agreement and the terms and conditions imposed thereby. The written acknowledgement shall be signed and dated by the applicable pharmacist-in-charge, manager-in-charge or supervisor and shall be submitted to the Board by Respondent for verification within ten (10) days of the dated signature. Respondent shall be responsible for ensuring the required signed acknowledgments are timely submitted to the Board.

18. If at any time Respondent is employed by a temporary employment agency, Respondent must provide each employment agency a copy of this Settlement Agreement prior to being assigned to a temporary employment site. Respondent shall also provide a copy of the Settlement Agreement to each pharmacist-in-charge or manager-in-charge of each pharmacy or drug distributor where Respondent is assigned to work. If the pharmacist-in-charge or manager-in-charge is not present at the employment site, a copy of the Settlement Agreement shall be left at the applicable site for the pharmacist-in-charge/manager-in-charge to review. Respondent shall provide an accurate listing of all employment/work sites where Respondent has been assigned if requested by the Board or the Board's authorized designee.

19. Licensee shall execute any release or provide any authorization necessary for the Board to obtain records of Respondent's employment during the period covered by this Settlement Agreement.

CONTINUING EDUCATION

20. Within three (3) months of the effective date of this Settlement Agreement, Respondent shall take and pass the Board approved Pharmacy Practice Guide Continuing Education Examination, if available. Respondent shall register and complete the required examination via the Board's website or as otherwise requested by the Board.

21. Respondent shall take a minimum of 6.0 continuing education (0.60 CEUs) hours in pharmacy law during each biennial pharmacist renewal period that is completed while

Respondent is on discipline. The continuing education required by this section shall comply with 20 CSR 2220-7.080 and may be used to satisfy the licensee's biennial continuing education requirement. Proof of compliance with the continuing education requirements of this section shall be submitted to the Board on or before October 31st of each biennial pharmacist renewal period.

22. Respondent shall also complete 10 additional hours of continuing education related to pharmacy compounding or compounding calculations *during the first year of the disciplinary period.* The required continuing education shall comply with 20 CSR 2220-7.080 and shall be in addition to the number of hours required by law for renewal of Respondent's pharmacist license. Continuing education completed prior to the effective date of this Disciplinary Order/Settlement Agreement shall not be accepted to fulfill this requirement. Proof of compliance with the continuing education requirements of this section shall be submitted to the Board within one (1) year of the effective date of this order.

B. Upon the expiration of said discipline, Respondent's license as a pharmacist in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that Respondent has violated any term or condition of this Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke or otherwise lawfully discipline Respondent.

C. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline.

The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

D. No order shall be entered by the Board pursuant to the preceding paragraph of this Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

E. The terms of this Settlement Agreement are contractual, legally enforceable, and binding, not merely recital. Except as otherwise contained herein, neither this settlement agreement not any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

F. Respondent, together with her heirs and assigns, and her attorneys, do hereby waive and release, acquit and forever discharge the Board, its respective members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. § 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

_____ **REQUESTS**

TDD ✓ **DOES NOT REQUEST**

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S LICENSE.

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's license and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's license. Effective fifteen (15) days from the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's license, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement Agreement goes into effect fifteen (15) days after the document is signed by the Board's Executive Director.

RESPONDENT	PETITIONER
TRACY D. DRYER	MISSOURI BOARD OF PHARMACY
Tracy D. Dryer Tracy D. Dryer	By: _____ Kimberly Grinston Executive Director
Date: 6/19/18	Date: 6.29.18

NEWMAN, COMLEY & RUTH P.C.

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