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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MEDICAL TREE PHARMACY INC.** **dba MEDICAL CLINIC PHARMACY** **2025 Soquel Ave.** **Santa Cruz, CA 95062** **Original Permit No. PHY 21201** **Original Sterile Compounding Permit No. LSC 99173** **THOMAS F. DEMBSKI** **8 Kite Hill Road** **Santa Cruz, CA 95062** **Pharmacist License No. RPH 41096** Respondent.	Case No. 5653 **A C C U S A T I O N**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about May 17, 1980, the Board of Pharmacy issued Original Permit Number PHY 21201 to Medical Tree Pharmacy Inc. dba Medical Clinic Pharmacy (Respondent Medical Tree). The Original Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2018, unless renewed.

3. On or about February 20, 2004, the Board of Pharmacy issued Original Sterile Compounding Permit Number LSC 99173 to Respondent Medical Tree. The Original Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and expired on April 1, 2016.

4. On or about August 17, 1987, the Board of Pharmacy issued Pharmacist License No. RPH 41096 to Thomas F. Dembski (Respondent Dembski). The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2019, unless renewed.

5. Respondent Dembski has been the pharmacist in charge of Respondent Medical Tree since January 15, 2002. Respondent Dembski is the President and 50% shareholder of Respondent Medical Tree.

JURISDICTION

6. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

7. Section 4300 of the Code states:

"(a) Every license issued may be suspended or revoked.

"(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

"(3) Suspending his or her right to practice for a period not exceeding one year.

"(4) Revoking his or her license.

"(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

. . .

"(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary certificate of licensure for any violation of the terms and conditions of probation. Upon satisfactory completion of probation, the board shall convert the probationary certificate to a regular certificate, free of conditions.

"(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

8. Section 4300.1 of the Code states:

"The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license."

9. Section 4342 of the Code states:

(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

STATUTORY AND REGULATORY PROVISIONS

10. Section 4301 of the Code states:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

"(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.

. . .

"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency. . ."

11. Section 4169 of the Code states:

"(a) A person or entity shall not do any of the following:

. . .

"(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

. . ."

12. Health and Safety Code section 111330 states:

"Any drug or device is misbranded if its labeling is false or misleading in any particular."

13. Health and Safety Code section 111440 states:

"It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

14. Health and Safety Code section 111445 states:

"It is unlawful for any person to misbrand any drug or device."

15. California Code of Regulations Title 16, Section 1717 states:

". . .(b) In addition to the requirements of Business and Professions Code section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist before they are dispensed."

. . ."

16. California Code of Regulations Title 16, Section 1714 states:

". . .(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes."

17. California Code of Regulations Title 16, Section 1735.2[1] states:

". . .(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

"(1) Active ingredients to be used.

"(2) Equipment to be used.

"(3) Expiration dating requirements.

"(4) Inactive ingredients to be used.

"(5) Process and/or procedure used to prepare the drug.

"(6) Quality reviews required at each step in preparation of the drug.

"(7) Post-compounding process or procedures required, if any.

. . .

"(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist."

18. California Code of Regulations Title 16, Section 1735.3 states:

"(a) For each compounded drug product, the pharmacy records shall include:

[1] The regulations cited are the versions in effect at the time of the violation

"(1) The master formula record.

"(2) The date the drug product was compounded.

"(3) The identity of the pharmacy personnel who compounded the drug product.

"(4) The identity of the pharmacist reviewing the final drug product.

"(5) The quantity of each component used in compounding the drug product.

"(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code."

. . .

"(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration."

19. California Code of Regulations Title 16, Section 1735.6 states:

". . .(b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications."

20. California Code of Regulations Title 16, Section 1735.8 states:

"(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

. . ."

"(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength."

21. California Code of Regulations Title 16, Section 1751.6 states:

"(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.

"(b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents.

"(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

"(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products.

"(e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:

"(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

"(A) Aseptic technique,

"(B) Pharmaceutical calculations and terminology.

"(C) Sterile product compounding documentation.

"(D) Quality assurance procedures.

"(E) Aseptic preparation procedures.

"(F) Proper gowning and gloving technique.

"(G) General conduct in the controlled area.

"(H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.

"(I) Sterilization technique.

"(J) Container, equipment, and closure system selection.

"(2) Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years."

22. California Code of Regulations Title 16, Section 1751.7 states:

"(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including , in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

. . .

"(4) Written justification of the chosen expiration dates for compounded sterile injectable products.

. . .

"(c) Batch-produced sterile injectable drug products compounded from one or more on-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens."

COSTS

23. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of

the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUGS INVOLVED

24. Trimix is a dangerous drug pursuant to business and professions code section 4022. It is used to treat erectile dysfunction.

25. Prostin is a dangerous drug pursuant to business and professions code section 4022. It is used to treat erectile dysfunction.

26. Alprostadil is a dangerous drug pursuant to business and professions code section 4022. It is used to treat erectile dysfunction.

MARCH 2015 INVESTIGATION

27. On March 13, 2015, a Board Inspector went to Medical Clinic Pharmacy (respondent Medical Tree's Pharmacy) to complete an inspection. The inspector was assisted by Pharmacist David Ferri. During the inspection the Inspector found:

a. Multiple chemicals and liquids without expiration dates or certificates of analysis.

b. A compound log of alprostadil 1000 mcg/ml solution, dated December 4, 2013, lot 12042013TFD. The compound log documented the compound was tested with a potency of 128.2 percent, with a beyond use date of June 4, 2014 (180 days from the date of compounding). No documentation was noted on the log which showed the compound was adjusted to the proper concentration. Ethyl alcohol liquid, lot TJ0470, was used in the compound. This liquid did not have an expiration date.

c. The alprostadil 1000 mcg/ml solution, dated December 4, 2013, lot 12042013TFD was used to make the following prescriptions:

Compound	RX Number	Date Dispensed	Amount Alprostadil 1000 mcg/ml Used (ml)	Beyond Use Date Given
Trimix	711215	3/5/2015	0.025	4/20/2015
Trimix Fortified	671090	1/28/2014	0.05	3/11/2014
Alprostadil	678825	1/27/2014	0.2	4/27/2014

20 mcg/ml				
Trimix Fortified	676519 682484	2/3/2014	0.05	3/11/2014
Trimix	680972 681683	1/31/2014 2/4/2014	0.025	3/11/2014
Trimix	679298	2/14/2014	0.025	3/11/2014
Trimix	691101	2/14/2014	0.025	3/11/2014
Alpostadil 10 Mcg/ml	690929	2/14/2014	0.1	3/29/2014
Trimix Fortified	629813	2/14/2014	0.05	3/11/2014
Trimix	672207	2/14/2014	0.025	3/11/2014
Trimix	685876	2/20/2014	0.025	3/11/2014
Alpostadil 20 Mg/ml	664507	2/20/2014	0.2	None documented
Trimix Fortified	691879	2/26/2014	0.05	3/11/2014
Trimix Fortified	664205	2/26/2014	0.05	3/11/2014
Trimix	691878 691734	2/26/2014	0.025	3/11/2014
Trimix Regular	677090	2/28/2014	0.025	4/12/2014
Trimix Fortified	691348 x 2 693114	3/8/2014 3/12/2014	0.05	4/21/2014
Trimix	693042 682491	3/11/2014 3/14/2014	0.025	4/20/2014
Trimix Fortified	693043	3/11/2014	0.05	4/28/2014
Trimix	672267	3/27/2014	0.025	5/9/2014
Alpostadil 20 mcg/ml	677787	3/27/2014	0.2	5/15/2014
Trimix	694947	4/4/2014	0.025	5/18/2014
Trimix	695440	4/9/2014	0.025	None documented
Trimix	690620	4/14/2014	0.025	5/26/2014
Alpostadil 40 mcg/ml	671844	4/22/2014	0.4	6/4/2014
Alpostadil 20 mcg/ml	677787 683099	4/22/2014	0.2	6/4/2014
Trimix	Stock	4/23/2014	0.025	None documented
Alpostadil 20 mcg/ml	696858	4/30/2014	0.2	6/4/2014
Trimix Fortified	696656 691348 696857	4/30/2014	0.05	6/4/2014
Trimix	676980 685876	5/1/2014	0.025	6/4/2014

Trimix	672267 680972	5/14/2014 5/14/2014	0.025	6/4/2014
Trimix Fortified	696231 695805	5/7/2014 5/13/2014	None documented	6/4/2014
Trimix	685876 694947 695806	5/16/2014	0.025	6/4/2014
Trimix Fortified	695214	5/21/2014	0.05	6/4/2014
Trimix	698701	5/21/2014	0.025	6/4/2014
Alpostadil 20 mcg/ml	698787	5/23/2014	0.2	6/4/2014
Trimix	679813	5/23/2014	0.05	6/4/2014
Trimix	681683	5/27/2014	0.025	6/4/2014

FIRST CAUSE FOR DISCIPLINE

(Records of Compounded Drug products)

28. Respondent Medical Tree's Original permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.3, subsection (c), in that on or about March 13, 2015, the following chemicals and liquids did not have documented expirations dates or certificates of analysis:

Chemicals	Manufacturer	Lot
Sodium borate solution	Whiteworth	N/A
Glycolic acid	Spectrum	ID256
Cocoa butter	Spectrum	SA0574
Sodium fluoride	Merck	N/A
Silver nitrate	Merck	62866
Potassium permanganate	Mallinckrodt	N/A
Ammoniated Mercury	Merck	60519
Potassium Bicarbonate	Spectrum	SA1635
Precipitated sulphur	Merck	N/A
Camphor	Lonza	N/A
Bismuth subgallate	Mallinckrodt	DJH
Sulfanilamide	Spectrum	TB0087
Benzoic acid	Spectrum	KD058
Trichloroacetic acid	Ricca Chemic	1403851
HCl 37%	Mallickrodt	2612KDKR
Niacinamide	Merck	63625A
Camphor	Spectrum	77231A1
Propylene Glycol	Medisca	TB28019701
Aminosalycyclic Acid	Spectrum	DI305
Dehydrated Alcohol	Spectrum	TJ0470

SECOND CAUSE FOR DISCIPLINE

(Compounding requirements)

29. Respondent Medical Tree's Original permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with code section 4169, subsection (a)(4), and/or California Code of Regulations Title 16, section 1735.2, subsection (h), in that on or about March 5, 2015, Respondent Medical Tree dispensed a compounded Trimix solution, RX 711215. Respondent Medical Tree compounded the Trimix with an expired alprostadil 1000 mcg/ml solution. The beyond use date of the alprostadil 1000 mcg/ml was June 4, 2014. Respondent Medical tree gave the compounded Trimix solution a beyond use date of April 20, 2015, well beyond the beyond use date of the alprostadil. In addition, the alprostadil 1000 mcg/ml was compounded with an ethyl alcohol that did not contain an expiration date.

THIRD CAUSE FOR DISCIPLINE

(Misbranded Drugs)

30. Respondent Medical Tree's Original permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction Health and Safety Code section 111445 in that Respondent manufactured, sold, delivered, held, or offered for sale misbranded drugs. The misbranded drugs are contained in the table in paragraph 27, above. They were misbranded because they were given use by dates despite the fact that they were compounded with components that did not contain an expiration date.

FOURTH CAUSE FOR DISCIPLINE

(Compounding Quality Assurance)

31. Respondent Medical Tree's Original permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.8, subsections (a) and (d), in that on or about March 13, 2015, Respondent Medical Tree did not have a written procedure in its quality assurance plan regarding the action to be taken when a compounded drug product was found out of standard with regards to potency.

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FIFTH CAUSE FOR DISCIPLINE

(Records Of Compounded Drugs)

32. Respondent Medical Tree's Original permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.3, subsection (a)(6), in that or about March 13, 2015, Respondent Medical Tree's staff provided the Board inspector with numerous compounding worksheets which did not contain the name of the manufacturer of the components that were used to compound the drug products. Respondent Medical Tree's records failed include the manufacturer of the components used to compound drugs.

SIXTH CAUSE FOR DISCIPLINE

(Records of Compounded Drug products)

33. Respondent Medical Tree's Original Sterile Compounding Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.3, subsection (c), in that on or about March 13, 2015 the following chemicals and liquids did not have documented expirations dates or certificates of analysis:

Chemicals	Manufacturer	Lot
Sodium borate solution	Whiteworth	N/A
Glycolic acid	Spectrum	ID256
Cocoa butter	Spectrum	SA0574
Sodium fluoride	Merck	N/A
Silver nitrate	Merck	62866
Potassium permanganate	Mallinckrodt	N/A
Ammoniated Mercury	Merck	60519
Potassium Bicarbonate	Spectrum	SA1635
Precipitated sulphur	Merck	N/A
Camphor	Lonza	N/A
Bismuth subgallate	Mallinckrodt	DJH
Sulfanilamide	Spectrum	TB0087
Benzoic acid	Spectrum	KD058
Trichloroacetic acid	Ricca Chemic	1403851
HCl 37%	Mallickrodt	2612KDKR
Niacinamide	Merck	63625A
Camphor	Spectrum	77231A1

Propylene Glycol	Medisca	TB28019701
Aminosalycyclic Acid	Spectrum	DI305
Dehydrated Alcohol	Spectrum	TJ0470

SEVENTH CAUSE FOR DISCIPLINE

(Compounding requirements)

34. Respondent Medical Tree's Original Sterile Compounding Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with code section 4169, subsection (a)(4), and/or California Code of Regulations Title 16, section 1735.2, subsection (h), in that on or about March 5, 2015, Respondent Medical Tree dispensed a compounded Trimix solution, RX 711215. Respondent Medical Tree compounded the Trimix with an expired alprostadil 1000 mcg/ml solution. The beyond use date of the alprostadil 1000 mcg/ml was June 4, 2014. Respondent Medical tree gave the compounded Trimix solution a beyond use date of April 20, 2015, well beyond the beyond use date of the alprostadil. In addition, the alprostadil 1000 mcg/ml was compounded with an ethyl alcohol that did not contain an expiration date.

EIGHTH CAUSE FOR DISCIPLINE

(Misbranded Drugs)

35. Respondent Medical Tree's Original Sterile Compounding Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction Health and Safety Code section 111445 in that Respondent manufactured, sold, delivered, held, or offered for sale misbranded drugs. The misbranded drugs are contained in the table in paragraph 27, above. They were misbranded because they were given use by dates despite the fact that they were compounded with components that did not contain an expiration date.

NINTH CAUSE FOR DISCIPLINE

(Compounding Quality Assurance)

36. Respondent Medical Tree's Original Sterile Compounding Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.8, subsections (a) and (d), in that on or about March 13, 2015, Respondent Medical Tree did not have a written procedure in its quality assurance plan

regarding the action to be taken when a compounded drug product was found out of standard with regards to potency.

TENTH CAUSE FOR DISCIPLINE

(Records Of Compounded Drugs)

37. Respondent Medical Tree's Original Sterile Compounding Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.3, subsection (a)(6), in that or about March 13, 2015, Respondent Medical Tree's staff provided the Board inspector with numerous compounding worksheets which did not contain the name of the manufacturer of the components that were used to compound the drug products. Respondent Medical Tree's records failed include the manufacturer of the components used to compound drugs.

ELEVENTH CAUSE FOR DISCIPLINE

(Records of Compounded Drug products)

38. Respondent Dembski's Pharmacist License is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.3, subsection (c), in that on or about March 13, 2015, the following chemicals and liquids did not have documented expirations dates or certificates of analysis:

Chemicals	Manufacturer	Lot
Sodium borate solution	Whiteworth	N/A
Glycolic acid	Spectrum	ID256
Cocoa butter	Spectrum	SA0574
Sodium fluoride	Merck	N/A
Silver nitrate	Merck	62866
Potassium permanganate	Mallinckrodt	N/A
Ammoniated Mercury	Merck	60519
Potassium Bicarbonate	Spectrum	SA1635
Precipitated sulphur	Merck	N/A
Camphor	Lonza	N/A
Bismuth subgallate	Mallinckrodt	DJH
Sulfanilamide	Spectrum	TB0087
Benzoic acid	Spectrum	KD058
Trichloroacetic acid	Ricca Chemic	1403851
HCl 37%	Mallickrodt	2612KDKR

Niacinamide	Merck	63625A
Camphor	Spectrum	77231A1
Propylene Glycol	Medisca	TB28019701
Aminosalycyclic Acid	Spectrum	DI305
Dehydrated Alcohol	Spectrum	TJ0470

TWELFTH CAUSE FOR DISCIPLINE

(Compounding requirements)

39. Respondent Dembski's Pharmacist License is subject to disciplinary action under code section 4301, subsection (o), in conjunction with code section 4169, subsection (a)(4), and/or California Code of Regulations Title 16, section 1735.2, subsection (h), in that on or about March 5, 2015, Respondent Medical Tree dispensed a compounded Trimix solution, RX 711215. Respondent Medical Tree compounded the Trimix with an expired alprostadil 1000 mcg/ml solution. The beyond use date of the alprostadil 1000 mcg/ml was June 4, 2014. Respondent Medical tree gave the compounded Trimix solution a beyond use date of April 20, 2015, well beyond the beyond use date of the alprostadil. In addition, the alprostadil 1000 mcg/ml was compounded with an ethyl alcohol that did not contain an expiration date. Respondent Dembski was the Pharmacist in charge of Respondent Medical Tree.

THIRTEENTH CAUSE FOR DISCIPLINE

(Misbranded Drugs)

40. Respondent Dembski's Pharmacist License is subject to disciplinary action under code section 4301, subsection (o), in conjunction Health and Safety Code section 111445 in that Respondent manufactured, sold, delivered, held, or offered for sale misbranded drugs. The misbranded drugs are contained in the table in paragraph 27, above. They were misbranded because they were given use by dates despite the fact that they were compounded with components that did not contain an expiration date. Respondent Dembski was the Pharmacist in charge of Respondent Medical Tree.

FOURTEENTH CAUSE FOR DISCIPLINE

(Compounding Quality Assurance)

41. Respondent Dembski's Pharmacist License is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16,

section 1735.8, subsections (a) and (d), in that on or about 3/13/15 Respondent Medical Tree did not have a written procedure in its quality assurance plan regarding the action to be taken when a compounded drug product was found out of standard with regards to potency. Respondent Dembski was the Pharmacist in charge of Respondent Medical Tree.

FIFTEENTH CAUSE FOR DISCIPLINE

(Records Of Compounded Drugs)

42. Respondent Dembski's Pharmacist License is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.3, subsection (a)(6), in that or about 3/13/15 Respondent Medical Tree's staff provided the Board inspector with numerous compounding worksheets which did not contain the name of the manufacturer of the components that were used to compound the drug products. Respondent Medical Tree's records failed include the manufacturer of the components used to compound drugs. Respondent Dembski was the Pharmacist in charge of Respondent Medical Tree.

MARCH 2016 INVESTIGATION

43. On or about March 1, 2016, a Board Inspector went to Medical Clinic Pharmacy (respondent Medical Tree's Pharmacy) to perform a routine sterile licensing renewal inspection. During the inspection the inspector identified several violations of Pharmacy law. Master formulas for recently compounded products were not available for review, staff training was not complete, non-sterile to sterile compounded products were sterilized using an in line IV filter that was not designed for end product sterilization, documentation of equipment maintenance was not complete and the quality assurance plan for verification, monitoring and review of end product testing was not complete.

SIXTEENTH CAUSE FOR DISCIPLINE

(Records of Compounded Drug products)

44. Respondent Medical Tree's Original Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.2, subsection (d), in that on or about March 1, 2016, during an inspection,

Respondent Medical Tree did not have master formulas for all compounded products. Respondent did not have a master formula for alprostadil 1000 mcg/ml.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Records of Compounded Drug products)

45. Respondent Medical Tree's Original Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.2, subsection (d)(6)(7), in that on or about March 1, 2016, during an inspection, Respondent Medical Tree did not have complete master formulas for all compounded products. Specifically, master formulas lacked quality reviews required at each step in the preparation of the drug and they failed to contain post-compounding process or procedures.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Staff Training)

46. Respondent Medical Tree's Original Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1751.6, subsection (e)(1)(A)-(H), in that on or about March 1, 2016, during an inspection, the staff training program was incomplete. Specifically, Respondent was lacking observation of hand washing, gloving, garbing, cleaning and aseptic technique. Didactic and pharmaceutical calculations were unavailable for review.

NINETEENTH CAUSE FOR DISCIPLINE

(Equipment Use and Maintenance)

47. Respondent Medical Tree's Original Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.6, subsection (b), in that on or about March 1, 2016, during an inspection it was found that Respondent Medical Tree did not maintain and use their compounding equipment according to manufacturer's specifications. Specifically, replacement of the IV hood gloves, sleeves and filters were not documented and the IV hood was cleaned with paper towels when the manufacturer specified the IV hood should be cleaned with non-linting wipes. PALL Posidyne

ELD filter was used to end product sterilize high risk compounded products and per the manufacturer it was designed for use with an IV administration set, not end product sterilization.

TWENTIETH CAUSE FOR DISCIPLINE

(Beyond Use Dates)

48. Respondent Medical Tree's Original Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1751.7, subsection (a)(4), in that on or about March 1, 2016, during an inspection, Respondent Medical Tree assigned a 180 day expiration date to alprostadil 1000 mcg/ml, a high risk compounded non-sterile to sterile injectable product. Respondent Medical Tree had no written justification for this beyond use date.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Equipment Maintenance)

49. Respondent Medical Tree's Original Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1714, subsection (c), in that on or about March 1, 2016, during an inspection, Respondent Medical Tree failed to maintain it equipment in a clean and orderly condition. Mortars, pestles, beakers, and spatulas were in the sink with cereal bowls, drinking glasses, utensils and sponges.

TWENTY-SECOND CAUSE FOR DISCIPLINE

(Documentation of Quarantine or End Product Testing)

50. Respondent Medical Tree's Original Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1751.7, subsection (c), in that on or about March 1, 2016, during an inspection, Respondent had not documented and could not state specifically how and where stock bottles of alprostadil 1000mcg/ml were quarantined until end product testing was finished. There was no end product testing for: Alprostadil after dilution, Trimix, and Trimix Forte.

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TWENTY-THIRD CAUSE FOR DISCIPLINE

(Incomplete Dispensing Records)

51. Respondent Medical Tree's Original Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1717, subsection (b)(1), in that on or about March 1, 2016, during an inspection, the inspector found five instances where the dispensing record did not match the compounding log. The date dispensed and name or initials of the dispensing pharmacist were not available for these prescriptions.

TWENTY-FOURTH CAUSE FOR DISCIPLINE

(Incomplete/Inaccurate Compounding Records)

52. Respondent Medical Tree's Original Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.3, subsection (a), in that on or about March 1, 2016, during an inspection, the inspector found twenty seven instances where there was no compounding log for the dispensed compounded medication and at least 45 compounding records with inaccurate information.

TWENTY-FIFTH CAUSE FOR DISCIPLINE

(Sale of Adulterated Compounded Drugs)

53. Respondent Medical Tree's Original Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with code section 4169 subsection(a)(2) and Health and Safety Code Section 111295, in that on or about March 1, 2016, during an inspection, inspector from The California State Board of Pharmacy observed compounding records showing Respondent used bacteriostatic water expiring in February 2016 in products labeled with a beyond use date of March 9, 2016, on at least six occasions.

TWENTY-SIXTH CAUSE FOR DISCIPLINE

(Compounding with Non-FDA Approved Products)

54. Respondent Medical Tree's Original Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with Health and Safety Code Sections 111400 and 111375, subsection (c), in that on or about March 1, 2016, during an inspection, an inspector

from The California State Board of Pharmacy observed compounding records dated November 12, 2015 and February 24, 2016, for diclo/arnica 4% gel. The preparation of diclo/arnica 4% gel used a herbal ingredient, arnica, which is not an FDA approved medication.

TWENTY-SEVENTH CAUSE FOR DISCIPLINE

(Records of Compounded Drug products)

55. Respondent Medical Tree's Original Sterile Compounding Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.2, subsection (d), in that on or about March 1, 2016, during an inspection, Respondent Medical Tree did not have master formulas for all compounded products. Respondent did not have a master formula for alprostadil 1000 mcg/ml.

TWENTY-EIGHTH CAUSE FOR DISCIPLINE

(Records of Compounded Drug products)

56. Respondent Medical Tree's Original Sterile Compounding Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.2, subsection (d)(6)(7), in that on or about March 1, 2016, during an inspection, Respondent Medical Tree did not have complete master formulas for all compounded products. Specifically, master formulas lacked quality reviews required at each step in the preparation of the drug and they failed to contain post-compounding process or procedures.

TWENTY-NINTH CAUSE FOR DISCIPLINE

(Staff Training)

57. Respondent Medical Tree's Original Sterile Compounding Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1751.6, subsection (e)(1)(A)-(H), in that on or about March 1, 2016, during an inspection, the staff training program was incomplete. Specifically, Respondent was lacking observation of hand washing, gloving, garbing, cleaning and aseptic technique. Didactic and pharmaceutical calculations were unavailable for review.

THIRTIETH CAUSE FOR DISCIPLINE

(Equipment Use and Maintenance)

58. Respondent Medical Tree's Original Sterile Compounding Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.6, subsection (b), in that on or about March 1, 2016, during an inspection, it was found that Respondent Medical Tree did not maintain and use their compounding equipment according to manufacturer's specifications. Specifically, replacement of the IV hood gloves, sleeves and filters were not documented and the IV hood was cleaned with paper towels when the manufacturer specified the IV hood should be cleaned with non-linting wipes. PALL Posidyne ELD filter was used to end product sterilize high risk compounded products and per the manufacturer it was designed for use with an IV administration set, not end product sterilization.

THIRTY-FIRST CAUSE FOR DISCIPLINE

(Beyond Use Dates)

59. Respondent Medical Tree's Original Sterile Compounding Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1751.7, subsection (a)(4), in that on or about March 1, 2016, during an inspection, Respondent Medical Tree assigned a 180 day expiration date to alprostadil 1000 mcg/ml, a high risk compounded non-sterile to sterile injectable product. Respondent Medical Tree had no written justification for this beyond use date.

THIRTY-SECOND CAUSE FOR DISCIPLINE

(Equipment Maintenance)

60. Respondent Medical Tree's Original Sterile Compounding Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1714, subsection (c), in that on or about March 1, 2016, during an inspection, Respondent Medical Tree failed to maintain it equipment in a clean and orderly condition. Motar, pestils, beakers, and spatulas were in the sink with cereal bowls, drinking glasses, utensils and sponges.

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THIRTY-THIRD CAUSE FOR DISCIPLINE

(Documentation of Quarantine or end Product Testing)

61. Respondent Medical Tree's Original Sterile Compounding Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1751.7, subsection (c), in that on or about March 1, 2016, during an inspection, Respondent had not documented and could not state specifically how and where stock bottles of alprostadil 1000mcg/ml were quarantined until end product testing was finished. There was no end product testing for: Alprostadil after dilution, Trimix, and Trimix Forte.

THIRTY-FOURTH CAUSE FOR DISCIPLINE

(Incomplete Dispensing Records:)

62. Respondent Medical Tree's Original Sterile Compounding Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1717, subsection (b)(1), in that on or about March 1, 2016, during an inspection, the inspector found five instances where the dispensing record did not match the compounding log. The date dispensed and name or initials of the dispensing pharmacist were not available for these prescriptions.

THIRTY-FIFTH CAUSE FOR DISCIPLINE

(Incomplete/Inaccurate Compounding Records:)

63. Respondent Medical Tree's Original Sterile Compounding Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.3, subsection (a), in that on or about March 1, 2016, during an inspection, the inspector found twenty seven instances where there was no compounding log for the dispensed compounded medication and at least 45 compounding records with inaccurate information.

THIRTY-SIXTH CAUSE FOR DISCIPLINE

(Sale of Adulterated Compounded Drugs)

64. Respondent Medical Tree's Original Sterile Compounding Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with code section 4169

subsection(a)(2) and Health and Safety Code Section 111295, in that on or about March 1, 2016, during an inspection, an inspector from The California State Board of Pharmacy observed compounding records showing Respondent used bacteriostatic water expiring in February 2016 in products labeled with a beyond use date of March 9, 2016, on at least six occasions.

THIRTY-SEVENTH CAUSE FOR DISCIPLINE

(Compounding with Non-FDA Approved Products)

65. Respondent Medical Tree's Original Sterile Compounding Permit is subject to disciplinary action under code section 4301, subsection (o), in conjunction with Health and Safety Code Sections 111400 and 111375, subsection (c), in that on or about 3/1/2016, during an inspection, an inspector from The California State Board of Pharmacy observed compounding records dated: November 12, 2015 and February 24, 2016, for diclo/arnica 4% gel. The preparation of diclo/arnica 4% gel used an herbal ingredient, arnica, which is not an FDA approved medication.

THIRTY-EIGHTH CAUSE FOR DISCIPLINE

(Records of Compounded Drug products)

66. Respondent Dembski's Pharmacist License is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.2, subsection (d), in that on or about March 1, 2016, during an inspection, Respondent Medical Tree did not have master formulas for all compounded products. Respondent did not have a master formula for alprostadil 1000 mcg/ml. Respondent Dembski was the Pharmacist in charge of Respondent Medical Tree.

THIRTY-NINTH CAUSE FOR DISCIPLINE

(Records of Compounded Drug products)

67. Respondent Dembski's Pharmacist License is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.2, subsection (d)(6)(7), in that on or about March 1, 2016, during an inspection, Respondent Medical Tree did not have complete master formulas for all compounded products. Specifically, master formulas lacked quality reviews required at each step in the preparation of the

drug and they failed to contain post-compounding process or procedures. Respondent Dembski was the Pharmacist in charge of Respondent Medical Tree.

FORTIETH CAUSE FOR DISCIPLINE

(Staff Training)

68. Respondent Dembski's Pharmacist License is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1751.6, subsection (e)(1)(A)-(H), in that on or about March 1, 2016, during an inspection, the staff training program was incomplete. Specifically, Respondent was lacking observation of hand washing, gloving, garbing, cleaning and aseptic technique. Didactic and pharmaceutical calculations were unavailable for review.

FORTY-FIRST CAUSE FOR DISCIPLINE

(Equipment Use and Maintenance)

69. Respondent Dembski's Pharmacist License is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.6, subsection (b), in that on or about March 1, 2016, during an inspection it was found that Respondent Medical Tree did not maintain and use their compounding equipment according to manufacturer 's specifications. Specifically, replacement of the IV hood gloves, sleeves and filters were not documented and the IV hood was cleaned with paper towels when the manufacturer specified the IV hood should be cleaned with non-linting wipes. PALL Posidyne ELD filter was used to end product sterilize high risk compounded products and per the manufacturer it was designed for use with an IV administration set, not end product sterilization. Respondent Dembski was the Pharmacist in charge of Respondent Medical Tree.

FORTY-SECOND CAUSE FOR DISCIPLINE

(Beyond Use Dates)

70. Respondent Dembski's Pharmacist License is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1751.7, subsection (a)(4), in that on or about March 1, 2016, during an inspection, Respondent Medical Tree assigned a 180 day expiration date to alprostadil 1000 mcg/ml, a high

risk compounded non-sterile to sterile injectable product. Respondent Medical Tree had no written justification for this beyond use date. Respondent Dembski was the Pharmacist in charge of Respondent Medical Tree.

FORTY-THIRD CAUSE FOR DISCIPLINE

(Equipment Maintenance)

71. Respondent Dembski's Pharmacist License is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1714, subsection (c), in that on or about March 1, 2016, during an inspection, Respondent Medical Tree failed to maintain it equipment in a clean and orderly condition. Mortars, pestles, beakers, and spatulas were in the sink with cereal bowls, drinking glasses, utensils and sponges. Respondent Dembski was the Pharmacist in charge of Respondent Medical Tree.

FORTY-FOURTH CAUSE FOR DISCIPLINE

(Documentation of Quarantine and end Product Testing)

72. Respondent Dembski's Pharmacist License is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1751.7, subsection (c), in that on or about March 1, 2016, during an inspection, Respondent had not documented and could not state specifically how and where stock bottles of alprostadil 1000mcg/ml were quarantined until end product testing was finished. There was no end product testing for: Alprostadil after dilution, Trimix, and Trimix Forte. Respondent Dembski was the Pharmacist in charge of Respondent Medical Tree.

THIRTY-FIFTH CAUSE FOR DISCIPLINE

(Incomplete Dispensing Records:)

73. Respondent Dembski's Pharmacist License is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.3, subsection (a), in that on or about March 1, 2016, during an inspection, the inspector found twenty seven instances where there was no compounding log for the dispensed compounded medication and at least 45 compounding records with inaccurate information. Respondent Dembski was the Pharmacist in charge of Respondent Medical Tree.

FORTY-SIXTH CAUSE FOR DISCIPLINE

(Incomplete/Inaccurate Compounding Records:)

74. Respondent Dembski's Pharmacist License is subject to disciplinary action under code section 4301, subsection (o), in conjunction with California Code of Regulations Title 16, section 1735.3, subsection (a), in that on or about March 1, 2016, during an inspection, the inspector found 27 instances where there was no compounding log for the dispensed compounded medication and at least 45 compounding records with inaccurate information. Respondent Dembski was the Pharmacist in charge of Respondent Medical Tree.

FORTY-SEVENTH CAUSE FOR DISCIPLINE

(Sale of Adulterated Compounded Drugs)

75. Respondent Dembski's Pharmacist License is subject to disciplinary action under code section 4301, subsection (o), in conjunction with code section 4169 subsection(a)(2) and Health and Safety Code Section 111295, in that on or about March 1, 2016, during an inspection, an inspector from The California State Board of Pharmacy observed compounding records showing Respondent used bacteriostatic water expiring in February 2016 in products labeled with a beyond use date of March 9, 2016, on at lease six occasions.

FORTY-EIGHTH CAUSE FOR DISCIPLINE

(Compounding with Non-FDA Approved Products)

76. Respondent Dembski's Pharmacist License is subject to disciplinary action under code section 4301, subsection (o), in conjunction with Health and Safety Code Sections 111400 and 111375, subsection (c), in that on or about March 1, 2016, during an inspection, an inspector from The California State Board of Pharmacy observed compounding records dated: November 12, 2015 and February 24, 2016, for diclo/arnica 4% gel. The preparation of diclo/arnica 4% gel used an herbal ingredient, arnica, which is not an FDA approved medication. Respondent Dembski was the Pharmacist in charge of Respondent Medical Tree.

DISCIPLINARY CONSIDERATIONS

77. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that on or about April 27, 1999 in a prior disciplinary action entitled In the

Matter of the Accusation Against Thomas F. Dembski; Medical Tree Inc. before the Board of Pharmacy, in Case Number 2089, Respondent Dembski's pharmacist license and Respondent Medical Tree's Pharmacy License were revoked. However the revocations were stayed and both Respondents were placed on 3 years probation. That decision is now final and is incorporated by reference as if fully set forth.

78. To determine the degree of discipline, if any, to be imposed on Respondent Dembski, Complainant alleges that on or about March 3, 2015, in a prior action, the Board of Pharmacy issued Citation Number CI 2014 64214 to Respondent Dembski and ordered Respondent Dembski to pay a $1,750.00 fine. That Citation is now final and is incorporated by reference as if fully set forth.

79. To determine the degree of discipline, if any, to be imposed on Respondent Medical Tree, Complainant alleges that on or about March 3, 2015, in a prior action, the Board of Pharmacy issued Citation Number CI 2013 60062 to Respondent Medical Tree and ordered Respondent Medical Tree to pay a $1,750.00 fine. That Citation is now final and is incorporated by reference as if fully set forth.

80. To determine the degree of discipline, if any, to be imposed on Respondent Medical Tree, Complainant alleges that on or about July 28, 2011, in a prior action, the Board of Pharmacy issued Citation Number CI 2010 47717 to Respondent Medical Tree. That Citation is now final and is incorporated by reference as if fully set forth.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Original Permit Number PHY 21201, issued to Medical Tree Pharmacy Inc. dba Medical Clinic Pharmacy;

2. Revoking or suspending Original Sterile Compounding Permit Number LSC 99173, issued to Medical Tree Pharmacy Inc. dba Medical Clinic Pharmacy;

3. Revoking or suspending Pharmacist License No. RPH 41096, issued to Thomas F. Dembski

4. Ordering Thomas F. Dembski to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

5. Ordering Medical Tree Pharmacy Inc. to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

6. Taking such other and further action as deemed necessary and proper.

DATED: 5/27/17

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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