

1 KAMALA D. HARRIS
Attorney General of California
2 FRANK H. PACOE
Supervising Deputy Attorney General
3 JUSTIN R. SURBER
Deputy Attorney General
4 State Bar No. 226937
455 Golden Gate Avenue, Suite 11000
5 San Francisco, CA 94102-7004
Telephone: (415) 355-5437
6 Facsimile: (415) 703-5480
Attorneys for Complainant
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8 **BEFORE THE**
BOARD OF PHARMACY
9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

10 In the Matter of the Accusation Against:

Case No. 5653

11 **MEDICAL TREE PHARMACY INC.**
12 **dba MEDICAL CLINIC PHARMACY**
2025 Soquel Ave.
13 **Santa Cruz, CA 95062**

A C C U S A T I O N

14 **Original Permit No. PHY 21201**
15 **Original Sterile Compounding Permit No.**
LSC 99173

16 **THOMAS F. DEMBSKI**
17 **8 Kite Hill Road**
Santa Cruz, CA 95062

18 **Pharmacist License No. RPH 41096**

19 Respondent.

20
21 Complainant alleges:

22 **PARTIES**

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

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

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

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

6 17. California Code of Regulations Title 16, Section 1735.2¹ states:

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

9 “(1) Active ingredients to be used.

10 “(2) Equipment to be used.

11 “(3) Expiration dating requirements.

12 “(4) Inactive ingredients to be used.

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

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

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

16 “... .

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

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

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

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

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

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

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

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

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

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

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

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

21 “(A) Aseptic technique,

22 “(B) Pharmaceutical calculations and terminology.

23 “(C) Sterile product compounding documentation.

24 “(D) Quality assurance procedures.

25 “(E) Aseptic preparation procedures.

26 “(F) Proper gowning and gloving technique.

27 “(G) General conduct in the controlled area.

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

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

3 **DRUGS INVOLVED**

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

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

8 26. Alprostadil is a dangerous drug pursuant to business and professions code section
9 4022. It is used to treat erectile dysfunction.

10 **MARCH 2015 INVESTIGATION**

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

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

15 b. A compound log of alprostadil 1000 mcg/ml solution, dated December 4, 2013, lot
16 12042013TFD. The compound log documented the compound was tested with a potency of 128.2
17 percent, with a beyond use date of June 4, 2014 (180 days from the date of compounding). No
18 documentation was noted on the log which showed the compound was adjusted to the proper
19 concentration. Ethyl alcohol liquid, lot TJ0470, was used in the compound. This liquid did not
20 have an expiration date.

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

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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

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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	Whitworth	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
Aminosalicyclic Acid	Spectrum	D1305
Dehydrated Alcohol	Spectrum	TJ0470

1 **SECOND CAUSE FOR DISCIPLINE**

2 (Compounding requirements)

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

12 **THIRD CAUSE FOR DISCIPLINE**

13 (Misbranded Drugs)

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

20 **FOURTH CAUSE FOR DISCIPLINE**

21 (Compounding Quality Assurance)

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

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1 **FIFTH CAUSE FOR DISCIPLINE**

2 (Records Of Compounded Drugs)

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

10 **SIXTH CAUSE FOR DISCIPLINE**

11 (Records of Compounded Drug products)

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

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18 Chemicals	Manufacturer	Lot
Sodium borate solution	Whitworth	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%	Mallinckrodt	2612KDKR
Niacinamide	Merck	63625A
Camphor	Spectrum	77231A1

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Propylene Glycol	Medisca	TB28019701
Aminosalicyclic 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

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

3 **TENTH CAUSE FOR DISCIPLINE**

4 (Records Of Compounded Drugs)

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

12 **ELEVENTH CAUSE FOR DISCIPLINE**

13 (Records of Compounded Drug products)

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

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19 Chemicals	Manufacturer	Lot
20 Sodium borate solution	Whiteworth	N/A
21 Glycolic acid	Spectrum	ID256
22 Cocoa butter	Spectrum	SA0574
23 Sodium fluoride	Merck	N/A
24 Silver nitrate	Merck	62866
25 Potassium permanganate	Mallinckrodt	N/A
26 Ammoniated Mercury	Merck	60519
27 Potassium Bicarbonate	Spectrum	SA1635
28 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%	Mallinckrodt	2612KDKR

Niacinamide	Merck	63625A
Camphor	Spectrum	77231A1
Propylene Glycol	Medisca	TB28019701
Aminosalicyclic 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,

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

5 **FIFTEENTH CAUSE FOR DISCIPLINE**

6 (Records Of Compounded Drugs)

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

15 **MARCH 2016 INVESTIGATION**

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

24 **SIXTEENTH CAUSE FOR DISCIPLINE**

25 (Records of Compounded Drug products)

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

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

3 **SEVENTEENTH CAUSE FOR DISCIPLINE**

4 (Records of Compounded Drug products)

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

11 **EIGHTEENTH CAUSE FOR DISCIPLINE**

12 (Staff Training)

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

19 **NINETEENTH CAUSE FOR DISCIPLINE**

20 (Equipment Use and Maintenance)

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

3 **TWENTIETH CAUSE FOR DISCIPLINE**

4 (Beyond Use Dates)

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

11 **TWENTY-FIRST CAUSE FOR DISCIPLINE**

12 (Equipment Maintenance)

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

18 **TWENTY-SECOND CAUSE FOR DISCIPLINE**

19 (Documentation of Quarantine or End Product Testing)

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

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1 **TWENTY-THIRD CAUSE FOR DISCIPLINE**

2 (Incomplete Dispensing Records)

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

9 **TWENTY-FOURTH CAUSE FOR DISCIPLINE**

10 (Incomplete/Inaccurate Compounding Records)

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

16 **TWENTY-FIFTH CAUSE FOR DISCIPLINE**

17 (Sale of Adulterated Compounded Drugs)

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

24 **TWENTY-SIXTH CAUSE FOR DISCIPLINE**

25 (Compounding with Non-FDA Approved Products)

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

1 from The California State Board of Pharmacy observed compounding records dated November
2 12, 2015 and February 24, 2016, for diclo/arnica 4% gel. The preparation of diclo/arnica 4% gel
3 used a herbal ingredient, arnica, which is not an FDA approved medication.

4 **TWENTY-SEVENTH CAUSE FOR DISCIPLINE**

5 (Records of Compounded Drug products)

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

11 **TWENTY-EIGHTH CAUSE FOR DISCIPLINE**

12 (Records of Compounded Drug products)

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

19 **TWENTY-NINTH CAUSE FOR DISCIPLINE**

20 (Staff Training)

21 57. Respondent Medical Tree's Original Sterile Compounding Permit is subject to
22 disciplinary action under code section 4301, subsection (o), in conjunction with California Code
23 of Regulations Title 16, section 1751.6, subsection (e)(1)(A)-(H), in that on or about March 1,
24 2016, during an inspection, the staff training program was incomplete. Specifically, Respondent
25 was lacking observation of hand washing, gloving, garbing, cleaning and aseptic technique.
26 Didactic and pharmaceutical calculations were unavailable for review.

27 **THIRTIETH CAUSE FOR DISCIPLINE**

28 (Equipment Use and Maintenance)

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

11 **THIRTY-FIRST CAUSE FOR DISCIPLINE**

12 (Beyond Use Dates)

13 59. Respondent Medical Tree's Original Sterile Compounding Permit is subject to
14 disciplinary action under code section 4301, subsection (o), in conjunction with California Code
15 of Regulations Title 16, section 1751.7, subsection (a)(4), in that on or about March 1, 2016,
16 during an inspection, Respondent Medical Tree assigned a 180 day expiration date to alprostadi
17 1000 mcg/ml, a high risk compounded non-sterile to sterile injectable product. Respondent
18 Medical Tree had no written justification for this beyond use date.

19 **THIRTY-SECOND CAUSE FOR DISCIPLINE**

20 (Equipment Maintenance)

21 60. Respondent Medical Tree's Original Sterile Compounding Permit is subject to
22 disciplinary action under code section 4301, subsection (o), in conjunction with California Code
23 of Regulations Title 16, section 1714, subsection (c), in that on or about March 1, 2016, during an
24 inspection, Respondent Medical Tree failed to maintain it equipment in a clean and orderly
25 condition. Motar, pestils, beakers, and spatulas were in the sink with cereal bowls, drinking
26 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

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

5 **THIRTY-SEVENTH CAUSE FOR DISCIPLINE**

6 (Compounding with Non-FDA Approved Products)

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

14 **THIRTY-EIGHTH CAUSE FOR DISCIPLINE**

15 (Records of Compounded Drug products)

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

22 **THIRTY-NINTH CAUSE FOR DISCIPLINE**

23 (Records of Compounded Drug products)

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

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

3 **FORTIETH CAUSE FOR DISCIPLINE**

4 (Staff Training)

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

11 **FORTY-FIRST CAUSE FOR DISCIPLINE**

12 (Equipment Use and Maintenance)

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

23 **FORTY-SECOND CAUSE FOR DISCIPLINE**

24 (Beyond Use Dates)

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

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

4 **FORTY-THIRD CAUSE FOR DISCIPLINE**

5 (Equipment Maintenance)

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

12 **FORTY-FOURTH CAUSE FOR DISCIPLINE**

13 (Documentation of Quarantine and end Product Testing)

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

21 **THIRTY-FIFTH CAUSE FOR DISCIPLINE**

22 (Incomplete Dispensing Records:)

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

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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

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

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

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

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

20 **PRAYER**

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

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

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

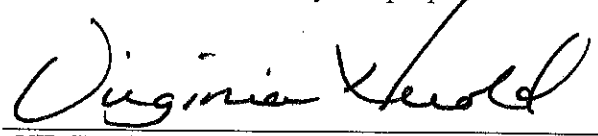
27 3. Revoking or suspending Pharmacist License No. RPH 41096, issued to Thomas F.
28 Dembski

1 4. Ordering Thomas F. Dembski to pay the Board of Pharmacy the reasonable costs of
2 the investigation and enforcement of this case, pursuant to Business and Professions Code section
3 125.3;

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

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

8
9 DATED: 5/27/17



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

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