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

In the Matter of the Accusation Against: **CENTER PHARMACY, INC.,** **DBA FOUNTAIN VALLEY CANCER CENTER PHARMACY** **11190 Warner Avenue #11,** **Fountain Valley, California 92708** **Pharmacy Permit No. PHY 43274** **Sterile Compounding Permit No. LSC 99020** **and** **MARC LOUIS HORWITZ, RPH AND PRESIDENT** **FOUNTAIN VALLEY CANCER CENTER PHARMACY** **11190 Warner Avenue #11,** **Fountain Valley, California 92708** **Pharmacist License No. RPH 40786** Respondents.	Case No. 4551 **ACCUSATION**

Complainant alleges:

PARTIES

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

2. On or about March 24, 1987, the Board issued Pharmacist License No. RPH 40786 to Marc Louis Horwitz (Respondent Horwitz). The license will expire on October 31, 2014 unless renewed.

3. On December 16, 1997, the Board issued Pharmacy Permit No. PHY 43274 to Center Pharmacy, Inc. to do business as Fountain Valley Cancer Center Pharmacy. Pharmacy Permit No. PHY 43274 was suspended by Order dated July 30, 2013.

4. On July 3, 2003, the Board issued Sterile Compounding Permit Number LSC 99020 to Center Pharmacy, Inc. to do business as Fountain Valley Cancer Center Pharmacy to compound injectable sterile drug products. Mark L. Horwitz, RPH 40786 is and has been the president of Center Pharmacy, Inc. since December 16, 1997, and Pharmacist-in-Charge since November 15, 2004. Sterile Compounding Permit No. LSC 99020 was suspended by Order dated July 30, 2013.

JURISDICTION

5. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

6. 6. Section 4300 of the Code states in relevant part:

"(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.

". . . .

"(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."

7. 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."

STATUTORY AUTHORITIES

8. Section 4301 of the Code states in relevant part:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or 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, of 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.

". . ."

9. Section 4022 of the Code states

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

"(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

"(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

"(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."

10. Section 4081 of the Code states:

"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

"(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

"(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate."

11. Section 4169 of the Code states in relevant part:

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

". . .

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"(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

". . .

"(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

". . . ."

12. Health and Safety Code section 111255 states:

"Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health."

REGULATIONS

13. California Code of Regulations (CCR), title 16, section 1751.7 states:

"**Sterile Injectable Compounding Quality Assurance and Process Validation.**

"(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:

"(1) Cleaning and sanitization of the parenteral medication preparation area.

"(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.

"(3) Actions to be taken in the event of a drug recall.

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

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"(b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

"(c) Batch-produced sterile injectable drug products compounded from one or more non-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.

"(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures."

14. CCR, title 16, section 1735.3 provides:

"**Records of Compounded Drug Products.**

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

"(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.

"(7) A pharmacy assigned reference or lot number for the compounded drug product.

"(8) The expiration date of the final compounded drug product.

"(9) The quantity or amount of drug product compounded.

"(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

"(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.

"(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created."

COSTS

15. 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.

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FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Failure to Validate the Competency of Individuals Compounding Drugs)

16. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in that they failed to produce records of validation of the competency of each individual involved in the preparation of sterile injectable products in violation of CCR, title, 16, section 1751.7, subdivision (b), the circumstances are as follows:

17. On or about November 8, 2012, the Board's investigators performed an annual Licensed Sterile Compounding (LSC) inspection of Center Pharmacy, Inc., doing business as Fountain Valley Cancer Pharmacy. Respondent Horwitz was present during the inspection.

18. During the inspection, the Board's investigator requested records of training and demonstrated competency for performing sterile compounding. Respondents produced no records of compliance.

19. During the inspection, Respondent Horwitz advised the investigator that he as the only person at the pharmacy involved in compounding drugs. Respondent Horwitz demonstrated his method of performing a self-evaluation for aseptic technique to the inspector using Tryptic Soy Broth as the growth media, which was inconsistent with the methodology described in the pharmacy's policy and procedure. Respondents' policy and procedure read, "a practical test will be a demonstration of aseptic technique and performance of Q.T. Medical's PATT-2 test that involves aliquot manipulations of a test agent per manufacturer procedure."

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Failure to Maintain Complete Records of Compounded Drugs)

20. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (o), in that from November 4, 2010 to October 8, 2012, they failed to maintain complete records for 76 compounded drugs in violation of CCR, title 16, section 1735.3, subdivision (a)(6). The circumstances are set forth in paragraph 17, above, which is incorporated here by this reference, and include the following:

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21. On November 8, 2012, during the inspection of Respondent Center Pharmacy, Inc., the Board's inspector reviewed compounding logs which revealed: (1) numerous logs were incomplete, missing the manufacturer lot numbers and/or the expiration date of one or more ingredients; (2) the pharmacy compounded stock solutions from one or more non-sterile ingredients, and then used the stock solution in medications for more than one patient; and (3) although Respondents' compounding logs had a preprinted section for sterility testing, pyrogens testing and quarantine start and end dates, numerous stock solutions used in making batches did not undergo proper end product testing or quarantine prior to use. After this discovery, the inspector requested the Respondents' compounding logs for the last 3 years for any product that included a non-sterile ingredient.

22. From November 4, 2010 to October 8, 2012, every one of Respondents' compounding logs for Sterile Injectable Solutions showed one or more ingredients missing the manufacturer lot number and/or expiration date as follows:

Table 1[1]

Sterile Injectable Solution Compounded	Date Compounded	Pharmacy Lot #	Ingredient(s) Missing MFG Lot# and Exp. Date*	Exhibit 5 Page Number
Clonidine	03/21/2011	CLO110321	clonidine, Water PF INJ	1
Baclofen	02/13/2012	1362517120213	NaCl 0.9% PF	2
fentanyl citrate	09/20/2012	FEN120920	fentanyl, NaOH, sterile water	3
fentanyl Base/clonidine	01/02/2012	312780	fentanyl, clonidine, NaCl	4
morphine/bupivicaine/baclofen	02/23/2011	310905110211	baclofen	5
TriMix	08/12/2011	1335054110722B	papaverine, phentolamine, alprostadil, NaCl	6
TriMix	05/27/2011	1336642110527	papaverine, phentolamine, alprostadil	7
TriMix/atropine	04/15/2011	308590101104	phentolamine, alprostadil	8

[1] TriMix = Papaverine/Phentolamine/Alprostadil (PGE), MFG = manufacturer, EXP. = expiration, *unless otherwise noted in table.

Sterile Injectable Solution Compounded	Date Compounded	Pharmacy Lot #	Ingredient(s) Missing MFG Lot# and Exp. Date*	Exhibit 5 Page Number
TriMix	04/13/2011	312051110412	papaverine, phentolamine, alprostadil	9
TriMix	04/12/2011	307615110412	papaverine, phentolamine, alprostadil	10
TriMix/atropine	04/14/2011	308615110414	papaverine, phentolamine, alprostadil, atropine, NaCl	11
TriMix	05/24/2011	1336630052411	papaverine, phentolamine, alprostadil	12
TriMix	08/29/2011	1335054110722B	papaverine, phentolamine, alprostadil, NaCl	13
TriMix	07/11/2011	TM11072011	papaverine, phentolamine, alprostadil	14
TriMix/lidocaine	08/02/2011	311881110802	papaverine, phentolamine, alprostadil, lidocaine, NaCl	15
TriMix	06/01/2011	1336414110601	papaverine, phentolamine, alprostadil	16
TriMix	05/24/2011	13364141105	papaverine, phentolamine, alprostadil	17
TriMix	02/17/2011	310841110217	papaverine, alprostadil	18
TriMix	02/14/2011	TM110214	papaverine, phentolamine, alprostadil, NaCl	19
TriMix/lidocaine	10/28/2011	134356111028	alprostadil, NaCl 0.9	20
TriMix/atropine	10/31/2011	None	phentolamine, alprostadil	21
TriMix/lidocaine	10/07/2011	1343561111007	Alprostadil	22
TriMix	10/07/2011	1350091111007	Alprostadil	23
TriMix	10/19/2011	1350130111019	papaverine, phentolamine, alprostadil, water, NaCl	24
TriMix/lidocaine	10/25/2011	134356111025	papaverine, phentolamine, alprostadil, lidocaine, NaCl 23.4% and 0.9	25

Sterile Injectable Solution Compounded	Date Compounded	Pharmacy Lot #	Ingredient(s) Missing MFG Lot# and Exp. Date*	Exhibit 5 Page Number
TriMix/lidocaine	04/05/2011	311881110504	phentolamine, alprostadil	26
TriMix/lidocaine	12/16/2010	309418101213	alprostadil, NaCl	27
TriMix	02/08/2011	310598110208	phentolamine, alprostadil	28
TriMix	10/08/2012	1383190121008	papaverine, phentolamine, alprostadil	29
TriMix/lidocaine	07/24/2012	1376947120724	papaverine, phentolamine, alprostadil, lidocaine, water	30
TriMix	07/26/2012	1352550120725	papaverine, phentolamine, alprostadil, water	31
TriMix	08/20/2012	1354074120820	papaverine, phentolamine, alprostadil	32
TriMix/lidocaine	10/01/2012	1376947120724	alprostadil, lidocaine, water	33
TriMix/lidocaine	02/24/2012	1356206120224	papaverine, phentolamine, alprostadil, lidocaine, water	34
TriMix	09/11/2012	Tm3015120911	papaverine, phentolamine, alprostadil	35
TriMix	09/11/2012	1380978120911	Alprostadil	36
TriMix	02/21/2012	1336630052411	papaverine, phentolamine, alprostadil	37
TriMix	12/27/2011	1357336111227	Alprostadil	38
TriMix	03/20/2012	1335054120320	papaverine, phentolamine, alprostadil, NaCl	39
TriMix	09/27/2012	1380978120911	Alprostadil	40
TriMix	04/03/2012	1367493120403	papaverine, phentolamine, alprostadil	41
TriMix	03/02/2012	1364470120302	papaverine, phentolamine, alprostadil	42
TriMix	03/02/2012	1364470120302	papaverine, phentolamine, alprostadil	43
TriMix	04/10/2012	1367493120403	papaverine, phentolamine, alprostadil	44

Sterile Injectable Solution Compounded	Date Compounded	Pharmacy Lot #	Ingredient(s) Missing MFG Lot# and Exp. Date*	Exhibit 5 Page Number
TriMix	04/03/2012	1367493120403	papaverine, phentolamine, alprostadil	45
TriMix	02/07/2012	1362088120207	phentolamine, alprostadil	46
TriMix	04/23/2012	1369116120423	Alprostadil	47
papaverine/alprostadil	12/10/2010	309411101210	NaCl, papaverine* missing either lot or exp. Date	49
TriMix	11/11/2010	308615101105	Water	50
TriMix	12/02/2011	1336646111202	Alprostadil	51
TriMix	11/08/2011	1353269110811	Alprostadil	52
TriMix	12/13/2011	1356304111212	papaverine, phentolamine, alprostadil	53
TriMix	06/12/2012	1373547120612	papaverine, phentolamine, alprostadil	54
TriMix	06/12/2012	1373507120612	papaverine, alprostadil. Phentolamine* missing only exp. Date	55
Alprostadil	06/02/2011	1337696110602	alprostadil, NaCl	56
Alprostadil	06/01/2011	CLA110601	alprostadil, NaCl	57
Alprostadil	05/19/2011	Alp11059	alprostadil, NaCl	58
Alprostadil	05/19/2011	1336315110519	alprostadil, NaCl	59
Alprostadil	11/15/2011	ALP111511	Alcohol	60
Alprostadil	05/14/2012	1361733120514	alprostadil, NaCl	61
Alprostadil	11/04/2010	ALP101104	alprostadil, NaCl	62
Alprostadil	08/09/2012	1361733120809	alprostadil, NaCl	63
Alprostadil	08/09/2012	1378247	alprostadil, NaCl	64
Alprostadil	07/03/2012	1375418120703	alprostadil, NaCl	65
Alprostadil	05/24/2012	1337486120524	alprostadil, NaCl	66
Alprostadil	02/03/2012	1361733120203	alprostadil, NaCl	67
Alprostadil	12/23/2011	1357425122311	alprostadil, NaCl	68
Alprostadil	12/02/2011	1337486110819	alprostadil, NaCl	69

Sterile Injectable Solution Compounded	Date Compounded	Pharmacy Lot #	Ingredient(s) Missing MFG Lot# and Exp. Date	Exhibit 5 Page Number
Alprostadil	10/28/2011	1352463111028	alprostadil, NaCl	70
Alprostadil	10/28/2011	1337696111028	alprostadil, NaCl	71
Alprostadil	09/22/2011	1337696110922	alprostadil, NaCl	72
Alprostadil	07/05/2011	1340648110705	alprostadil, NaCl	73
Alprostadil	07/01/2011	Alp110701	alprostadil, NaCl	74
Alprostadil	06/06/2011	1337898110606	alprostadil, NaCl	75
TriMix/atropine	08/12/2011	1344326110809	alprostadil, NaCl	76

THIRD CAUSE FOR DISCIPLINE

(Failure to Document End Product Testing of Compounded Drugs and to Maintain Compounded Drugs in Quarantine until End Product Testing)

23. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (o), in that from September 7, 2010 to December 9, 2012, he failed to document end product testing for 58 batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients, and failed to maintain them in quarantine until the end product testing confirmed sterility and acceptable levels of pyrogens in violation of CCR, title 16, section 1751.7, subdivision (c). The circumstances are set forth in paragraph 17, above, which is incorporated here by this reference and includes the following:

24. After collecting records on the day of the inspection, the inspector reviewed the compounding logs and compiled a list of compounds where a stock solution was used in compounding for multiple patients. For some compounds, the compounding log for the stock solution was available and showed no end product testing or quarantine was performed to determine sterility and acceptable levels of pyrogens. For other compounds, the compounding log for the stock solution was unavailable; therefore proof of end product testing and quarantine was unavailable. The following table shows compounded medications which used a stock solution for at least one of its ingredients. These products are considered batch-produced sterile

injectable drug products. For each of the stock solutions listed, the compounding log showed no evidence of end product testing.

Table 2[2]

Sterile Injectable Solution Compounded	Date Compounded	Pharmacy Lot #	Made from Stock Sol. Lot #	Stock Sol. tested for sterility or pyrogens?	Stock Sol. Cmpd Log Available?	Exhibit 6: Page Numbers
Alprostadil	08/09/2011	1337486110819	ALP110722	No	Yes	1
Alprostadil	08/25/2011	1345856110825	ALP110722	No	Yes	2
Alprostadil	11/11/2011	ALP111111	ALP110722	No	Yes	3
Alprostadil	11/29/2011	1340639111129	ALP110722	No	Yes	4
TriMix	11/18/2011	1354074111811	ALP110722	No	Yes	5
TriMix	11/29/2011	1335054111129	ALP110722	No	Yes	6
Alprostadil STOCK	07/22/2011	ALP110722	STOCK	No	Yes	7
TriMix	11/29/2011	1335054111129	PHE110527	No	Yes	8
TriMix	11/18/2011	1354074111811	PHE110527	No	Yes	9
TriMix	11/08/2011	1353269110811	PHE110527	No	Yes	10
TriMix	12/02/2011	1336646111202	PHE110527	No	Yes	11
TriMix/Lidocaine	12/09/2011	134356111209	PHE110527	No	Yes	12
TriMix	10/04/2011	1335054111004	PHE110527	No	Yes	13
TriMix	10/07/2011	1350091111007	PHE110527	No	Yes	14
TriMix/Lidocaine	10/07/2011	1343561111007	PHE110527	No	Yes	15
TriMix/Lidocaine	10/28/2011	134356111028	PHE110527	No	Yes	16
TriMix	08/12/2011	1344291110812	PHE110527	No	Yes	17
Phentolamine STOCK	05/27/2011	PHE110527	STOCK	No	Yes	18+19
TriMix	12/27/2011	1357336111227	PHE122711	?	No	20
TriMix	01/23/2012	1335054120123	PHE122711	?	No	21
Morphine	06/25/2010	305341100625	MOR100604	?	No	22
Morphine	06/25/2010	305340100625	MOR100604	?	No	23
Morphine/Clonidine	09/08/2010	307131	MOR100907	No	Yes	24
Morphine/Clonidine	09/08/2010	307111	MOR100907	No	Yes	25
Morphine	09/08/2010	307109100907	MOR100907	No	Yes	26
Morphine	09/08/2010	307110	MOR100907	No	Yes	27
Morphine STOCK	09/08/2010	MOR100907	STOCK	No	Yes	28
Morphine	04/29/2011	312359110429	MOR110429	No	Yes	29
Morphine	04/29/2011	312360110429	MOR110429	No	Yes	30
Morphine STOCK	04/29/2011	MOR110429	Stock	No	Yes	31

[2] TriMix=Papaverine/Phentolamine/Alprostadil(PGE), ?= unknown since no compounding log as available. The color highlighting is used to show where stock compounds were used.

Sterile Injectable Solution Compounded	Date Compounded	Pharmacy Lot #	Made from Stock Sol. Lot #	Stock Sol. tested for sterility or pyrogens?	Stock Sol. Cmpd Log Available?	Exhibit 6: Page Numbers
Fentanyl	09/23/2010	307555100923	FENT100925	No	Yes	32
Fentanyl	09/23/2010	307566100923	FENT100923	No	Yes	33
Fentanyl STOCK	09/23/2010	FENT100923	STOCK	No	Yes	34
Baclofen	07/05/2012	312823	BAC120622	No	Yes	35
Baclofen	06/22/2012	312821	BAC120622	No	Yes	36
Baclofen STOCK	06/22/2012	BAC120622	STOCK	No	Yes	37
Baclofen	12/27/2010	309686	BAC101227	No	Yes	38
Baclofen	02/07/2011	310399110207	BAC101227	No	Yes	39
Baclofen STOCK	12/27/2010	BAC101227	STOCK	No	Yes	40
Baclofen	09/08/2010	307133	BAC100823	?	No	41
Baclofen	09/08/2010	307132	BAC100823	?	No	42
Baclofen	09/07/2010	307107100907	BAC100823	?	No	43
Baclofen	09/13/2010	307233	BAC100823	?	No	44
Alprostadil	04/13/2011	305593110412	ALP110201	No	Yes	45
Alprostadil	03/29/2011	310829110329	ALP110201	No	Yes	46
Alprostadil	03/25/2011	311623110325	ALP110201	No	Yes	47
Alprostadil	03/25/2011	305005110325	ALP110201	No	Yes	48
Alprostadil	03/07/2011	310313110307	ALP110201	No	Yes	49
Alprostadil STOCK	02/28/2011	ALP110201	STOCK	No	Yes	50
Alprostadil	09/22/2010	304450100820	ALP100604	?	No	51
Alprostadil	02/01/2011	305005110201	ALP100604	?	No	52
Alprostadil	01/25/2011	310313110125	ALP100604	?	No	53
Alprostadil	02/16/2011	ALP110216	ALP100604	?	No	54
Alprostadil	11/24/2010	ALP101124	ALP100604	?	No	55
Alprostadil	11/17/2010	ALP101117	ALP100604	?	No	56
TriMix	10/12/2010	PPPT101012	ALP100604/ PHE100702	?	No	57
TriMix	11/01/2010	308469101101	ALP100604/ PHE100702	?	No	58
TriMix/Atropine	11/17/2010	308907101117	ALP100604/ PHE100702	?	No	59
Papaverine/PGE1	12/10/2010	309411101210	ALP100604	?	No	60
TriMix	01/07/2011	307615110107	ALP100604	?	No	61
TriMix	02/01/2011	305112110131	ALP100604	?	No	62
TriMix	11/11/2010	308615101105	PHE100702	?	No	63
TriMix	01/07/2011	307615110107	PHE101216	No	Yes	64
TriMix	02/08/2011	310598110208	PHE101216	No	Yes	65
TriMix/Lidocaine	12/16/2010	309418101213	PHE101216	No	Yes	66
TriMix/Atropine	01/27/2011	308615110127	PHE101216	No	Yes	67
Phentolamine STOCK	12/16/2010	PHE101216	STOCK	No	Yes	68+69

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Selling, Holding or Offering for Sale Adulterated Drugs)

25. Respondents are subject to disciplinary action under section 4301, subdivision (j), in that from September 7, 2010 to July 5, 2012, Respondents sold, held, or offered for sale 58

dangerous drugs that Respondent Horwitz knew or should have known were adulterated as defined in Health and Safety Code section 111255, in violation of Code section 4169, subdivision (a). The circumstances are set forth in paragraphs 17 and 23-24, above, which are incorporated here by this reference and include the following:

26. Without proper documentation for end product testing, there was no evidence to support the safe use of the stock compounds listed in Table 2. The final product issued to patients may have been rendered injurious to health.

DISCIPLINARY CONSIDERATIONS

27. On or about February 23, 2012, Respondents were issued a Letter of Admonishment by the Board pursuant to Code sections 4005 and 4315, et seq. for the failure to comply with laws and regulations that govern the practice of pharmacy in California. The circumstances are as follows: on July 22, 2011, Respondent Horwitz, while Pharmacist-In-Charge of Center Pharmacy, Inc., doing business as Fountain Valley Medical Center Pharmacy located at 11100 Warner Avenue in Fountain Valley, California, did not have certain dangerous drugs in stock, ordered them from Mckesson, a wholesaler and resold them to Priority Pharmaceutical located at 4040 Sorrento Valley Blvd., Suite D, San Diego, Ca 92121. Fountain Valley Medical Center Pharmacy did not have independent knowledge of any temporary shortage. Fountain Valley Medical Center Pharmacy depended on Priority Pharmaceutical to identify the shortages, know what quantity of dangerous drugs was needed to alleviate specific shortages, if a temporary shortage actually existed, or if lack of the drug would result in a denial of health care, thus increasing the shortage. Respondents did not contest the Letter of Admonishment.

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 Pharmacy Permit Number PHY 43274 issued to Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy.

2. Revoking or suspending Sterile Compounding Permit Number LSC 99020 issued to Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy;

3. Revoking or suspending Pharmacy License Number RPH 40786 issued to Respondent Horwitz;

4. Ordering Marc L. Horwitz to pay the Board the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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

DATED: 8/9/13

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