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8
9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

11 In the Matter of the Accusation Against:

Case No. 4347

12 **UNIVERSITY RX SPECIALIST,**
13 **DBA UNIVERSITY COMPOUNDING PHARMACY**
14 **1875 3rd Avenue**
San Diego, CA 92101

FIRST AMENDED
ACCUSATION

15 **Pharmacy Permit No. PHY 45621**
Sterile Compounding License No. LSC 99018

16 **and**

17 **JOSEPH GRASELA**
18 **4767 Ocean Blvd., #1001**
19 **San Diego, CA 92109**

20 **Pharmacist License No. RPH 40868**

21 Respondents.

1 Complainant alleges:

2 **PARTIES**

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

6 2. On or about March 31, 1987, the Board of Pharmacy issued Pharmacist License No.
7 RPH 40868 to Joseph Grasela (Respondent Joseph Grasela). The Pharmacist License was in full
8 force and effect at all times relevant to the charges brought herein and will expire on November
9 30, 2016, unless renewed.

10 3. On or about August 23, 2002, the Board of Pharmacy issued Pharmacy Permit
11 Number PHY 45621 to University RX Specialist, doing business as University Compounding
12 Pharmacy (Respondent UCP) with Joseph Grasela as the President and Pharmacist-in-Charge.
13 The Pharmacy Permit was in full force and effect at all times relevant to the charges brought
14 herein and will expire on August 1, 2016, unless renewed.

15 4. On or about July 1, 2003, the Board of Pharmacy issued Sterile Compounding
16 License Number LSC 99018 to University RX Specialist, doing business as University
17 Compounding Pharmacy (Respondent University Compounding Pharmacy). The Sterile
18 Compounding License was in full force and effect at all times relevant to the charges brought
19 herein and will expire on August 1, 2016, unless renewed.

20 **JURISDICTION**

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

24 6. Section 4011 of the Code provides that the Board shall administer and enforce both
25 the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances
26 Act [Health & Safety Code, § 11000 et seq.].

27 7. Section 4300(a) of the Code provides that every license issued by the Board may be
28 suspended or revoked.

1 8. Section 4300.1 of the Code states:

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

8 **STATUTORY PROVISIONS**

9 9. Section 4022 of the Code states:

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

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

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

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

20 10. Section 4113, subdivision (c) of the Code states: "The pharmacist-in-charge shall be
21 responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining
22 to the practice of pharmacy."

23 11. Section 4127.7 of the Code states:

24 On or after July 1, 2005, a pharmacy shall compound sterile injectable products
25 from one or more nonsterile ingredients in one of the following environments:

26 (a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The
27 cleanroom must have a positive air pressure differential relative to adjacent areas.

28 (b) An ISO class 5 cleanroom.

(c) A barrier isolator that provides an ISO class 5 environment for
compounding.

12. Section 4301 of the Code states in pertinent 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:

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(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.

....

13. Section 4307(a) of the Code states that:

Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manger, administrator, owner, member, officer, director, associate, or partner had knowledge or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manger, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

14. Health and Safety Code section 110390 states:

It is unlawful for any person to disseminate any false advertisement of any food, drug, device or cosmetic. An advertisement is false if it is false or misleading in any particular.

15. Health and Safety Code section 110403 states in pertinent part that:

It is unlawful for any person to advertise any drug or device represented to have any effect in any of the following conditions, disorders, or diseases:

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(aa) sexual impotence.

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16. Health and Safety Code section 110405 states:

An advertisement that is not unlawful under Section 110390 is not unlawful under Section 110403 if it is disseminated only to members of the medical, dental, pharmaceutical, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of drugs or devices.

REGULATORY PROVISIONS

17. California Code of Regulations, title 16, section 1735(a):

states in pertinent part:

“Compounding” means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- (1) Altering the dosage form or delivery system of a drug
- (2) Altering the strength of a drug
- (3) Combining components or active ingredients
- (4) Preparing a drug product from chemicals or bulk drug substances

...

18. California Code of Regulations, title 16, section 1735.2(h) states:

....

(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.

...

19. 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.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding process and shall also include written documentation of review of those processes by qualified pharmacy

1 personnel.

2 (c) The quality assurance plan shall include written standards for qualitative
3 and quantitative integrity, potency, quality, and labeled strength analysis of
4 compounded drug products. All qualitative and quantitative analysis reports for
5 compounded drug products shall be retained by the pharmacy and collated with the
6 compounding record and master formula.

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

10 20. California Code of Regulations, title 16, section 1751.7(a)(4) states:¹

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

19 ...

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

22 COST RECOVERY

23 21. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
24 administrative law judge to direct a licentiate found to have committed a violation or violations of
25 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
26 enforcement of the case.

27 DRUGS

28 22. Testosterone Pellets and Testosterone/Anastrozole Pellets are Schedule III controlled
substances pursuant to Health and Safety Code section 11056(f)(30) and dangerous drugs
pursuant to Business and Professions Code section 4022.

23 23. Estradiol Pellets are dangerous drugs pursuant to Business and Professions Code
24 section 4022.

25 _____
26 ¹ California Code of Regulations, title 16, section 1751.8(a)(4), in effect at the time of the
27 inspection, was renumbered as section 1751.7(a)(4) in 2013.
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1 **FACTUAL ALLEGATIONS**

2 24. At all relevant times herein, Respondent Joseph Grasela was the Pharmacist-in-
3 Charge of Respondent University Compounding Pharmacy.

4 25. From 2012 through the present, Respondents have compounded and sold testosterone
5 pellets, testosterone/anastroloze pellets and estradiol pellets, sterile injectable products, for use in
6 the treatment of symptoms arising from Andropause and Menopause for implementation in the
7 human body.

8 26. On the internet in 2012, Respondents advertised and represented that their
9 testosterone pellet therapy was “[c]onvenient and effective” and provided “continuous relief
10 from the symptoms of Andropause,” including “loss of morning erection,” “stronger libido” and
11 “stronger erections.” This advertisement was disseminated to the general public.

12 27. On or about April 23, 2012, Respondents chose an expiration date of 365 days for the
13 testosterone pellets compounded with a cholesterol base, rather than a stearic acid base, without
14 possessing a written justification for the chosen expiration date or substantiated studies of
15 finished drugs or compounded drug products which used the same components and packaging
16 showing a longer date was supported.

17 28. From April 23, 2012 to the present, including after the filing of an accusation alleging
18 a violation of Business and Professions Code section 4127.7, Respondents have and continue to
19 compound (i.e., combined components or active ingredients) sterile injectable products, i.e.,
20 testosterone pellets, estradiol pellets and testosterone/anastrozole pellets from non-sterile
21 ingredients, but failed to perform the compounding in either: (a) an ISO class 5 laminar airflow
22 hood within an ISO class 7 cleanroom with a positive air pressure differential relative to the
23 adjacent areas; (b) an ISO class 5 cleanroom or (c) a barrier isolator that provides an ISO class 5
24 environment for compounding.

25 29. In August and September 2015, the Federal Drug Administration conducted
26 inspections of University Compounding Pharmacy and issued a Form 483 against University
27 Compounding Pharmacy, making such observations as University Compounding Pharmacy
28 “failed to thoroughly conduct out of specification investigations with respect to sterility failure

1 found in three different batches of drug products,” University Compounding Pharmacy’s “aseptic
2 processing areas are deficient regarding the system for monitoring environmental conditions,”
3 and University Compounding Pharmacy’s “procedures designed to prevent microbiological
4 contamination of drug products purporting to be sterile do not include adequate validation of the
5 sterilization process.”

6 **FIRST CAUSE FOR DISCIPLINE**

7 **(Labeling Without Proper Expiration Dates for Sterile Injectable Drugs)**

8 30. Respondents are subject to disciplinary action under Code section 4301(o), for
9 violating title 16, California Code of Regulations, sections 1735.2(h) and 1751.7(a)(4) in that they
10 labeled testosterone pellets, compounded in a cholesterol base with an expiration date of 365 days
11 in the future, without possessing either a written justification for that chosen expiration date or
12 substantiated studies of finished drugs or compounded drug products using the same components
13 and packaging showing a longer date was supported, as set forth in paragraphs 22 through 29,
14 which are incorporated herein by reference.

15 **SECOND CAUSE FOR DISCIPLINE**

16 **(Failure to Compound Sterile Injectable Drugs in Authorized Environment)**

17 31. Respondents are subject to disciplinary action under Code section 4301(o), for
18 violating Business and Professions Code section 4127.7 in that from April 2012 through the
19 present, they compounded sterile injectable drugs, i.e., testosterone pellets, estradiol pellets and
20 testosterone/anastroloze pellets in an environment which was not authorized by law, as set forth
21 in paragraphs 22 through 29, which are incorporated herein by reference.

22 **THIRD CAUSE FOR DISCIPLINE**

23 **(False Advertising)**

24 32. Respondents are subject to disciplinary action under Code section 4301(j), for
25 violating Health and Safety Code sections 110390 and 110403 in that Respondents represented
26 and advertised an unapproved drug therapy, as having an effect on sexual impotence to the
27 general public, as set forth in paragraphs 22 through 29, which are incorporated herein by
28 reference.

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2 **FOURTH CAUSE FOR DISCIPLINE**

3 **(Unprofessional Conduct)**

4 33. Respondents are subject to disciplinary action under Code section 4301 for
5 unprofessional conduct in that they engaged in the activities described in paragraphs 22 through
6 29 above, which are incorporated herein by reference.

7 **OTHER MATTERS**

8 34. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number
9 PHY 45621 and Sterile Compounding License Number LSC 99018 issued to University RX
10 Specialist, doing business as University Compounding Pharmacy, they shall be prohibited from
11 serving as a manager, administrator, owner, member, officer, director, associate, or partner of a
12 licensee for five years if Pharmacy Permit Number PHY 45621 and Sterile Compounding
13 License Number LSC 99018 are placed on probation or until Pharmacy Permit Number PHY
14 45621 and Sterile Compounding License Number LSC 99018 are reinstated if they are revoked.

15 35. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit
16 Number PHY 45621 and Sterile Compounding License Number LSC 99018 issued to University
17 RX Specialist, doing business as University Compounding Pharmacy, while Joseph Grasela has
18 been an officer and owner and had knowledge of or knowingly participated in any conduct for
19 which the licensee was disciplined, Joseph Grasela shall be prohibited from serving as a
20 manager, administrator, owner, member, officer, director, associate, or partner of a licensee for
21 five years if Pharmacy Permit Number PHY 45621 and Sterile Compounding License Number
22 LSC 99018 are placed on probation or until Pharmacy Permit Number PHY 45621 and Sterile
23 Compounding License Number LSC 99018 are reinstated if they are revoked.

24 36. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License
25 No. RPH 40868 issued to Joseph Grasela, Joseph Grasela shall be prohibited from serving as a
26 manager, administrator, owner, member, officer, director, associate, or partner of a licensee for
27 five years if Pharmacist License Number RPH 40868 is placed on probation or until Pharmacist
28 License Number RPH 40868 is reinstated if it is revoked.

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2 **DISCIPLINARY CONSIDERATIONS**

3 37. To determine the degree of discipline, if any, to be imposed on Respondents,
4 Complainant alleges:

5 a. On or about June 27, 2006, the Board issued Citation number CI 2005 31081
6 against University RX Specialist, dba University Compounding Pharmacy for violating California
7 Code of Regulations, title 16, sections 1716 and 1764 and Civil Code section 56.10 in that it
8 filled a prescription in an improper amount and shipped drugs to the wrong address. It paid the
9 fine on or about July 18, 2006.

10 b. On or about July 30, 2010, the Board issued Citation number CI 2009 43472
11 against University RX Specialist, dba University Compounding Pharmacy for violating California
12 Code of Regulations, title 16, section 1751.7 in that it failed to conduct end product pyrogen
13 testing on all sterile injectable products compounded for non-sterile ingredients and failed to
14 conduct end product pyrogen testing on certain stock solutions which were made of non-sterile
15 ingredients. It paid the fine on or about August 18, 2010.

16 c. On or about January 28, 2010, the Board issued Citation number CI 2008 38495
17 against Joseph Grasela for violating California Code of Regulations, title 16, section 1715 in that
18 he failed to complete a current hospital pharmacy self-assessment. He paid the fine on or about
19 December 14, 2010.

20 d. On or about July 30, 2010, the Board issued Citation number CI 2010 45194
21 against Joseph Grasela for violating California Code of Regulations, title 16, section 1751.7 in
22 that he failed to conduct end-product pyrogen testing on all sterile injectable products
23 compounded for non-sterile ingredients and failed to conduct end-product pyrogen testing on
24 certain stock solutions which were made of non-sterile ingredients. He paid the fine on or about
25 August 18, 2010.

26 **PRAYER**

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

1 1. Revoking or suspending Pharmacy Permit Number PHY 45621, issued to University
2 RX Specialist, doing business as University Compounding Pharmacy;

3 2. Revoking or suspending Sterile Compounding License Number LSC 99018, issued to
4 University RX Specialist, doing business as University Compounding Pharmacy;

5 3. Revoking or suspending Pharmacist License Number RPH 40868, issued to Joseph
6 Grasela;

7 4. Prohibiting University RX Specialist, doing business as University Compounding
8 Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate,
9 or partner of a licensee for five years if Pharmacy Permit Number PHY 45621 and Sterile
10 Compounding License Number LSC 99018 are placed on probation or until Pharmacy Permit
11 Number PHY 45621 and Sterile Compounding License Number LSC 99018 are reinstated if
12 Pharmacy Permit Number PHY 45621 and Sterile Compounding License Number LSC 99018
13 issued to University RX Specialist, doing business as University Compounding Pharmacy are
14 revoked;

15 5. Prohibiting Joseph Grasela from serving as a manager, administrator, owner, member,
16 officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number
17 PHY 45621 and Sterile Compounding License Number LSC 99018 are placed on probation or
18 until Pharmacy Permit Number PHY 45621 and Sterile Compounding License Number LSC
19 99018 are reinstated if Pharmacy Permit Number PHY 45621 and Sterile Compounding License
20 Number LSC 99018 issued to University RX Specialist, doing business as University
21 Compounding Pharmacy are revoked;

22 6. Prohibiting Joseph Grasela from serving as a manager, administrator, owner,
23 member, officer, director, associate, or partner of a licensee for five years if Pharmacist License
24 Number RPH 40868 is placed on probation or until Pharmacist License Number RPH 40868 is
25 reinstated if Pharmacist License Number RPH 40868 issued to Joseph Grasela is revoked;

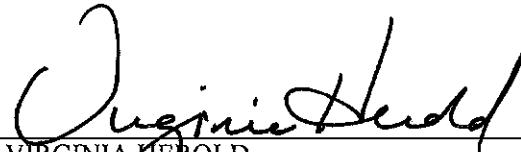
26 7. Ordering University RX Specialist, doing business as University Compounding
27 Pharmacy and Joseph Grasela to pay the Board of Pharmacy the reasonable costs of the
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investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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

DATED: 11/20/15



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

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