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

In the Matter of the First Amended Accusation Against: **CALIFORNIA PHARMACY AND COMPOUNDING CENTER** 4000 Birch Street, Suite 120 Newport Beach, CA 92660 **Pharmacy Permit No. PHY** 49828 **Sterile Compounding License No. LSC 99542** and **DAVID JOSEPH SCHAPIRO** 14501 Larch Avenue Irvine, CA 92606 **Pharmacist License No. RPH 26704** Respondents.	Case No. 4628 **FIRST AMENDED** **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about April 1, 2009, the Board of Pharmacy issued Pharmacy Permit Number PHY 49828 to California Pharmacy and Compounding Center (Respondent). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2016, unless renewed.

3. On or about April 2, 2009, the Board of Pharmacy issued Sterile Compounding License Number LSC 99542 to California Pharmacy and Compounding Center (Respondent). The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2016, unless renewed.

4. On or about July 16, 1970, the Board of Pharmacy issued Pharmacist License Number RPH 26704 to David Joseph Schapiro (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2017, unless renewed. Respondent Schapiro was the Pharmacist-In-Charge ("PIC") of CPCC and has been the PIC since April 1, 2009.

JURISDICTION

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

6. Section 4300 of the Code states:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
>
> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.
>
> . . .

(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 AND REGULATORY PROVISIONS

8. 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."

9. Section 4040 of the Code states in part:

(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

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(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to either Section 4052.1 or 4052.2.

. . .

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

. . . .

10. Section 4071 of the Code states:

Notwithstanding any other provision of law, a prescriber may authorize his or her agent on his or her behalf to orally or electronically transmit a prescription to the furnisher. The furnisher shall make a reasonable effort to determine that the person who transmits the prescription is authorized to do so and shall record the name of the authorized agent of the prescriber who transmits the order.

11. Section 4076 of the Code states in part:

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) . . .either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber . . .

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription. . . .

12. Section 4110 of the Code states in part:

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred. . . .

13. Section 4113 of the Code states in part:

(a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.

. . .

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

. . . .

14. Section 4169 of the Code states in part:

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

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

. . .

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code. . . .

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15. Section 4127.1 of the Code states in part:

...

(f) Adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

...

16. Section 4301 of the Code states in 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. . . .

17. Section 11164 of the Health and Safety Code states in part:

Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

...

(b)(1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiallty of the prescription. . . .

18. Section 111330 of the Health and Safety Code states, "Any drug or device is misbranded if its labeling is false or misleading in any particular."

19. Section 111335 of the Health and Safety Code states, "Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

20. Section 111340 of the Health and Safety Code states:

> Any drug or device is misbranded unless it bears a label containing all of the following information:
>
> (a) The name and place of business of the manufacturer, packer, or distributor.
>
> (b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.
>
> Reasonable variations from the requirements of subdivision (b) shall be permitted. Requirements for placement and prominence of the information and exemptions as to small packages shall be established in accordance with regulations adopted pursuant to Section 110380.

21. Section 111440 of the Health and Safety Code states, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

22. Section 111445 of the Health and Safety Code states: "It is unlawful for any person to misbrand any drug or device.

23. Title 16, California Code of Regulations ("CCR"), section 1735 states in part:

> (a) "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
>
> . . . .

24. Title 16, CCR, section 1735.4 states:

> (a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).
>
> (b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.

(c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date.

25. Title 16, CCR, section 1735.2 states in part:

...

(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.

...

26. Title 16, CCR, section 1735.5 states in part:

...

(c) The policy and procedure manual shall include the following

...

(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

...

27. Title 16, CCR, section 1761 states in part:

(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

. . . .

COST RECOVERY

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

DRUGS

29. Releana®, a brand name for human chorionic gonadotropin is a Schedule III controlled substance pursuant to Health and Safety Code section 11056(f)(32) and is a dangerous drug pursuant to Business and Professions Code section 4022.

30. Valium/Flexeril/lidocaine suppository is a compounded product containing a combination of the following ingredients: cyclobenzaprine (Flexeril), diazepam (Valium) and lidocaine. It is a Schedule IV controlled substance as designated by Health and Safety Code Section 11057(d)(9), and is a dangerous drug pursuant to Business and Professions Code section 4022. It is used as a muscle relaxant.

RELEANA® PRESCRIPTIONS

31. At all times mentioned herein, Respondent Schapiro was the PIC of Respondent California Pharmacy and Compounding Center (hereinafter "CPCC"). On or about November 4, 2010, the Board received a telephone complaint from J.S. alleging CPCC filled a prescription "without the dosage." On December 14, 2010, the Board received an anonymous complaint that CPCC was involved in the illegal practice of compounding and selling an oral preparation of human chorionic gonadotropin ("HCG"), which was being sold under the trade name of "Releana."

32. On or about January 11, 2011, an inspector for the Board conducted an inspection of CPCC following the receipt of these complaints concerning the pharmacy, which is further described below.

33. On or about August 20, 2010, a prescription was faxed to CPCC for J.S. for sixty vaginal suppositories of Valium/Flexeril/lidocaine. The prescription appeared to be signed by S.S., a physician's assistant. The prescription showed it was faxed from a fax machine with the name and telephone number of J.S. to CPCC. CPCC filled the prescription on the same day under prescription number RX 652991. CPCC dispensed twelve suppositories of a compounded medication containing "cyclo/diaz/lido" (cyclobenzaprine/diazepam/lidocaine). A duplicate label provided by Respondent Schapiro showed the drug dispensed was "cyclo/diaz/lido" 10/5/62.5 mg suppository and the prescriber was identified as Dr. M.C., not S.S.

34. There was no notation that CPCC ensured the security, integrity and/or authority of the prescription by verifying the prescription with the prescriber. Likewise, there was no notation CPCC attempted to determine whether J.S. was authorized by PA S.S. to transmit the prescription on behalf of PA S.S. nor that J.S. was so authorized by PA S.S.

35. During the inspection of CPCC on January 11, 2011, Respondent Schapiro explained that CPCC reached an exclusive agreement with Millenium Medical Spa ("Millenium") to compound Releana®. Millenium was located in Newport Beach, California and was not licensed with the Board as a pharmacy or wholesaler in California. Millenium held the patent for Releana®, a medication containing the human chorionic gonadotropin ("HCG") as an active ingredient. HCG formulations are used to facilitate weight loss and body contouring. According to Respondent Schapiro, Millenium was responsible for marketing Releana® and receiving orders from physicians throughout the country for Respondent CPCC to fill. Millenium processed the orders and invoiced the physicians. Millenium then e-mailed the order form and a "Prescription Fill-in Form" to CPCC. The Prescription Fill-in Form contained prescriptions written for each patient and is further described in paragraph 34(c), below.

36. According to Respondent Schapiro, after CPCC received a prescription for Releana® by e-mail, CPCC processed the prescription, compounded the Releana® vehicle, which is a proprietary formula, and packaged the HCG in a separate container. CPCC dispensed the medication in a Ziploc bag with a prescription label with the patient's name, prescription number, the instruction to "Use as directed by physician," the prescribing physician, the date dispensed and the expiration date. Releana® was dispensed in the form of a small vial containing the HCG powder and a larger bottle containing the Releana® vehicle, a buffered solution. The medication was shipped to the prescribing physician's office where the medication was mixed by the physician and the larger container was dispensed to the patient. Millenium paid CPCC for all materials and dispensing fees.

37. In addition to physicians in California, Millenium sold Releana® to physicians in Alabama, Arizona, Florida, Georgia, Hawaii, Iowa, Illinois, Indiana, Maryland, Missouri, Mississippi, Nebraska, Nevada, New York, Ohio, Oklahoma, South Carolina, Texas, Virginia and

Washington. Respondent CPCC compounded the medication for dispensing to physicians in these states.

38. On March 8, 2011, Board inspectors conducted further investigation of CPCC's practice regarding dispensing Releana®. The process by which Releana® was ordered was as follows:

a. The physician ordered Releana® from Millenium. The order form was faxed to Millenium along with the prescriptions for Releana® written on a prescription form with the Releana® logo.

b. The order was processed by Millenium. A packing slip was generated with the quantity purchased, the payment method (credit card name) and the amount due from the prescriber.

c. Millenium then e-mailed the following documents to CPCC:

i) the packing slip with Releana®'s logo for the quantity ordered and addressed to the physician;

ii) an order form with the name, address and telephone number of the physician, the description of the drug ("human chorionic gonadotropin proprietary formula") and the quantity ordered; and,

iii) a Prescription Fill-in Form with the prescriber's information and two columns of five boxes to fill in the patient's name, address, telephone number, the pre-printed description of the drugs as "Human Chorionic Gonadotropin proprietary formula" and quantity to either select from "[1], [2], or [3]" or to fill in. The prescription form did not state the date each prescription was written nor the strength of the drug.

39. CPCC's Drug Recall Report for Releana® showed that CPCC dispensed 5958 prescriptions for Releana® from October 1, 2010 to March 8, 2011. Thirty patients from the Drug Recall Report were randomly selected and their Patient Drug Histories from March 8, 2010 to March 8, 2011 and prescriptions for Releana® were reviewed by Board inspectors.

40. The Drug Histories and Releana® prescriptions for the following patients were reviewed:

Patient initials	Prescriber's initials	Releana® Rx Number	Date dispensed
K.C.	D.T.	Not available[1]	Not available
G.D.	A.H.	623609	11/12/2009
E.T.	R.G.	672251	2/22/2011
M.W.	D.I.	662399	12/29/2010
M.F.	F.V.	662302	12/28/2010
D.G.	N.L.	650860	7/26/2010
A.K.	D.B.	655068	9/10/2010
H.M.	D.D.	652872	8/20/2010
G.M.	L.E.	655753	9/21/2010
B.C.	H.M.	661771	12/16/2010
P.C.	S.E.	635667	3/8/2010
Q.W.	S.B.	658717	11/1/2010
D.R.	R.W.	630300	1/26/2010
L.P.	J.B.	658030	10/21/2010
L.D.	J.W.	658261	10/26/2010
V.F.	T.P.	670762	1/31/2011
M.E.	L.K.	632162	2/9/2010
K.D.	A.T.	660151	11/18/2010
B.F.	P.M.	645830	6/1/2010
T.F.	G.J.	657118	10/11/2010
C.C.	G.J.	657120	10/11/2010
D.C.	U.K.	647200	6/15/2010
J.B.	T.L.	656880	10/8/2010

[1] According to K.C.'s Patient Drug History, seven prescriptions for Releana® were dispensed for this patient. However, a sample Releana® prescription was not provided to the Board inspectors. A prescription for testosterone was provided instead.

Patient initials	Prescriber's initials	Releana® Rx Number	Date dispensed
S.B.	M.S.	656960	10/8/2010
A.A.	D.P.	631816	2/8/2010
A.B.	H.S.	633855	2/24/2010
D.A.	A.D.	660830	12/2/2010
B.A.	E.M.	634248	2/26/2010
J.A.	A.D.	660833	12/2/2010
P.A.	R.C.	670879	2/1/2011

41. A review of the original prescriptions revealed that the Releana® prescriptions for each patient were cut out from the prescription form sent by Millenium to CPCC and affixed to a blank telephone prescription pad. A date was stamped on the prescription pads that appeared to be the date the prescriptions were filled. The prescriptions contained the name and address of the patient, the pre-printed drug name "human chorionic gonadotropin proprietary formula" and the provider's signature. The prescriptions did not have the strength of HCG and the quantity prescribed was specified in units of "1", "2" or "3." There were no notations on the prescriptions indicating the pharmacist verified the prescriptions with the physicians since the prescriptions were electronically received from Millenium instead of from the prescribing physicians. Many of the prescribing physicians were located out of the state of California.

42. Affixed to the prescriptions were the prescription backer labels. The backer labels indicated the prescription number assigned, the patient's name, the physician's name, the drug dispensed (Releana – Chorionic Gonadotropin), the quantity, the instruction "Use as Directed by Physician," and notations with CPCC's compounding lot number for the product dispensed and the pharmacist's initials. The prescription backer label did not state the concentration, volume or weight of the active ingredient nor the quantity of the drug dispensed. Prescriptions labels that were duplicates of the prescription labels on the drug containers were also obtained. The duplicate prescription labels did not state the concentration, volume or weight of the active ingredient nor the quantity of the drug dispensed.

FIRST CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER

AND DAVID JOSEPH SCHAPIRO

(Violation of Pharmacy Law – Failure to Ensure Integrity of Prescription)

43. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section 4301, subdivisions (j) and (o), for violating Code section 4071 and Health and Safety Code section 11164 in that Respondents failed to ensure the security, integrity and/or authority of J.S.'s prescription by failing to verify the prescription with the prescribing physician, as more fully set forth in paragraphs 29 – 30, which are incorporated by this reference as though set forth in full herein.

SECOND CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER

AND DAVID JOSEPH SCHAPIRO

(Violation of Pharmacy Law - Erroneous and Uncertain Prescriptions)

44. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section 4301, subdivisions (j) and (o), for violating Code section 4040; title 16, CCR, section 1761; and, Health and Safety Code section 11164. Respondents compounded and/or dispensed prescriptions for Releana® containing significant errors, omissions, irregularities and/or uncertainties as more fully set forth in paragraphs 29 – 38, which are incorporated by this reference as though set forth in full herein, and as follows:

a. The prescriptions for Releana® did not specify the quantity to dispense, the directions for use and the date the prescription was issued.

b. The electronically transmitted prescriptions for Releana® were not valid in that the prescriptions were received by CPCC from Millenium instead of the prescriber and were not verified with the prescribing physician by the CPCC.

c. The electronically transmitted prescriptions for Releana® that were produced into a hard copy did not bear the date the prescription was transcribed or the signature of the transcribing pharmacist.

d. The electronically transmitted prescriptions for Releana® did not have the name of the person at the prescriber's office who transmitted the prescriptions.

THIRD CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER AND DAVID JOSEPH SCHAPIRO

(Selling to Unlicensed Entity)

45. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section 4301, subdivision (o) for violation of section 4169, subdivision (a)(1), for selling dangerous drugs to an entity not licensed by the Board. Respondents compounded and sold Releana® to Millenium, an entity not licensed by the Board as a pharmacy or wholesaler in California, as is more fully set forth in paragraphs 29 – 38, which are incorporated by this reference as though set forth in full herein.

FOURTH CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER AND DAVID JOSEPH SCHAPIRO

(Selling Misbranded Drugs)

46. Respondents CPCC and Schapiro are subject to discipline pursuant to Code sections 4301, subdivisions (j) and (o) for violation of section 4169, subdivision (a)(3), and Health and Safety Code sections 11130, 111440 and 11340, for selling, delivering, transferring, holding or offering for sale, any drug that Respondents knew or should reasonably have known were misbranded. The Releana® drugs were misbranded in that the label affixed to each individual container of Releana® powder and Releana® vehicle, did not specify the name and address of the manufacturer, packer or distributor and they did not specify the quantity of the contents of each of the two containers sold in terms of weight or measure, as is more fully set forth in paragraphs 29–38, which are incorporated by this reference as though set forth in full herein.

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FIFTH CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER

AND DAVID JOSEPH SCHAPIRO

(Dispensing Incorrectly Labeled Prescriptions)

47. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section 4301, subdivision (o) for violation of section 4076, subdivision (a)(7) and (8) and title 16, CCR, 1735.4, for dispensing incorrectly labeled Releana® prescriptions in that Respondents dispensed Releana® with prescription labels that did not state the concentration or strength of the active ingredient nor the quantity of the drug dispensed, either in volume, weight or numerical count, as is more fully set forth in paragraphs 29 – 38, which are incorporated by this reference as though set forth in full herein.

SIXTH CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER

AND DAVID JOSEPH SCHAPIRO

(Aiding or Abetting Millenium in Sale of Controlled Substances)

48. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section 4301, subdivision (o) for assisting in or abetting the violation of Code section 4110 by Millenium, in that Millenium sold Releana® to physicians in California, among other states, without having a license as a pharmacy or wholesaler in the State of California, as more fully set forth in paragraphs 29 – 38 and incorporated by this reference as though set forth in full herein.

COMPOUNDED CARBOXYMETHYLCELLULOSE 0.2%

49. On January 28, 2015, an annual renewal sterile compounding inspection was conducted at Respondent pharmacy. As part of the inspection, the compounding record for prescription #719944 (Rx #719944) made on January 15, 2015 was reviewed. The original compounding records with integrated master formula for compounding carboxymethulcellulose 0.2% preservative free eye drops were reviewed. The pharmacy's policies and procedures for cleaning the autoclave to compound Rx #719944 and the convection oven next to the autoclave were requested but were not available for review during the inspection.

50. Sodium carboxymethulcellulose ("CMC") powder, lot # 14C03-U02-017876 was the active ingredient used to compound Rx #719944. The compounding record for carboxymethulcellulose 0.2% erroneously stated that the expiration date of CMC powder, lot # 14C03-U02-017876, was January 15, 2016, when the correct expiration date was January 15, 2015.

51. The expiration date assigned to the compounded drug Rx #719944 was March 1, 2015, 45 days after the expiration of CMC powder, which was the active ingredient used to compound Rx #719944.

SEVENTH CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER AND DAVID JOSEPH SCHAPIRO

(No Policy and Procedures for Autoclave and Convection Oven)

52. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section 4301, subdivision (o) in conjunction with 16, title CCR, section 1735.5(a) for failing to maintain a written policy and procedure manual that includes the procedures for maintaining, storing, calibrating, cleaning, and disinfecting the autoclave and convection oven, equipment used in compounding, as more fully set forth in paragraph 49 above and which is incorporated by this reference as though set forth in full herein.

EIGHTH CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER AND DAVID JOSEPH SCHAPIRO

(Erroneous Expiration Date Assigned)

53. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section 4301, subdivision (o) in conjunction with 16, title CCR, section 1735.2(h), for assigning an erroneous expiration date to Rx #719944 that exceeded the shortest expiration date of any component in the compounded drug product, as more fully set forth in paragraphs 49-51 above and which are incorporated by this reference as though set forth in full herein.

///

ADVERSE EVENT REPORT

54. On April 1, 2015, the Board was notified of an adverse event pertaining to an Avastin syringe compounded by Respondents. On July and November, 2014, O.B. received Avastin injections in her eye at her doctor's office. The Avastin injection was a compounded sterile product obtained by O.B.'s physician from Respondent. It was used to treat wet age-related macular degeneration.

55. On February 2, 2015, O.B. received another Avastin injection compounded by Respondents (lot number B120714). On March 4, 2015, O.B. notified her doctor that she had an eye infection. On March 6, 2015, O.B.'s doctor called Respondents about O.B.'s eye infection and her use of Avastin.

56. On March 16, 2015, O.B.'s doctor's office notified Respondents that a culture of the patient was done and the results were negative.

NINTH CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER AND DAVID JOSEPH SCHAPIRO

(Failure to Report Adverse Event to Board Within 12 Hours)

57. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section 4301, subdivision (o) in conjunction with Code section 4127.1(f) in that Respondents failed to report the adverse event regarding O.B. to the Board within 12 hours, as more fully set forth in paragraphs 54-56 above and which are incorporated by this reference as though set forth in full herein.

DISCIPLINARY CONSIDERATIONS

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

a. On or about August 22, 2014, Citation and Fine Number CI 2014 62109 was issued against California Pharmacy and Compounding Center, Pharmacy Permit No. PHY 49828 for violation of Code section 4169(a)(1), purchasing, trading, selling or transferring dangerous drugs to unlicensed person or entity; and,

b. On or about August 22, 2014, Citation and Fine Number CI 2014 62118 was issued against David Joseph Shapiro, License No. RPH 26704 for violation of Code section 4169(a)(1), purchasing, trading, selling or transferring dangerous drugs to unlicensed person or entity.

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 49828 issued to California Pharmacy and Compounding Center;

2. Revoking or suspending Sterile Compounding License Number LSC 99542 issued to California Pharmacy and Compounding Center;

3. Revoking or suspending Pharmacist License Number RPH 26704 issued to David Joseph Schapiro;

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

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

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

DATED: 8/27/15

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

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

In the Matter of the Accusation Against: **CALIFORNIA PHARMACY AND COMPOUNDING CENTER** 4000 Birch Street, Suite 120 Newport Beach, CA 92660 **Pharmacy Permit No. PHY 49828** **Sterile Compounding License No. LSC 99542** and **DAVID JOSEPH SCHAPIRO** 14501 Larch Avenue Irvine, CA 92606 **Pharmacist License No. RPH 26704** Respondents.	Case No. 4628 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about April 1, 2009, the Board of Pharmacy issued Pharmacy Permit Number PHY 49828 to California Pharmacy and Compounding Center (Respondent). The Pharmacy

Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2014, unless renewed.

3. On or about April 2, 2009, the Board of Pharmacy issued Sterile Compounding License Number LSC 99542 to California Pharmacy and Compounding Center (Respondent). The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2014, unless renewed.

4. On or about July 16, 1970, the Board of Pharmacy issued Pharmacist License Number RPH 26704 to David Joseph Schapiro (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2013, unless renewed. Respondent Schapiro was the Pharmacist-In-Charge ("PIC") of CPCC and has been the PIC since April 1, 2009.

JURISDICTION

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

6. Section 4300 of the Code states:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
>
> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.
>
> . . .
>
> (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 AND REGULATORY PROVISIONS

8. 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."

9. Section 4040 of the Code states in part:

(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or

naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to either Section 4052.1 or 4052.2.

. . .

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

. . . .

10. Section 4071 of the Code states:

Notwithstanding any other provision of law, a prescriber may authorize his or her agent on his or her behalf to orally or electronically transmit a prescription to the furnisher. The furnisher shall make a reasonable effort to determine that the person who transmits the prescription is authorized to do so and shall record the name of the authorized agent of the prescriber who transmits the order.

11. Section 4076 of the Code states in part:

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) . . .either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber . . .

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or

other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription. . . .

12. Section 4110 of the Code states in part:

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred. . . .

13. Section 4113 of the Code states in part:

(a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.

. . .

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

. . . .

14. Section 4169 of the Code states in part:

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

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

. . .

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code. . . .

15. Section 4301 of the Code states in 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. . . .

16. Section 11164 of the Health and Safety Code states in part:

Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

. . .

(b)(1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription. . . .

17. Section 111330 of the Health and Safety Code states, "Any drug or device is misbranded if its labeling is false or misleading in any particular."

18. Section 111335 of the Health and Safety Code states, "Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

19. Section 111340 of the Health and Safety Code states:

Any drug or device is misbranded unless it bears a label containing all of the following information:

(a) The name and place of business of the manufacturer, packer, or distributor.

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

Reasonable variations from the requirements of subdivision (b) shall be permitted. Requirements for placement and prominence of the information and exemptions as to small packages shall be established in accordance with regulations adopted pursuant to Section 110380.

20. Section 111440 of the Health and Safety Code states, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

21. Section 111445 of the Health and Safety Code states: "It is unlawful for any person to misbrand any drug or device.

22. Title 16, California Code of Regulations ("CCR"), section 1735 states in part:

> (a) "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
>
> . . . .

23. Title 16, CCR, section 1735.4 states:

> (a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).
>
> (b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.
>
> (c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date.

24. Title 16, CCR, section 1761 states in part:

> (a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.
>
> . . . .

COST RECOVERY

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

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

DRUGS

26. Releana®, a brand name for human chorionic gonadotropin is a Schedule III controlled substance pursuant to Health and Safety Code section 11056(f)(32) and is a dangerous drug pursuant to Business and Professions Code section 4022.

27. Valium/Flexeril/lidocaine suppository is a compounded product containing a combination of the following ingredients: cyclobenzaprine (Flexeril), diazepam (Valium) and lidocaine. It is a Schedule IV controlled substance as designated by Health and Safety Code Section 11057(d)(9), and is a dangerous drug pursuant to Business and Professions Code section 4022. It is used as a muscle relaxant.

FACTS

28. At all times mentioned herein, Respondent Schapiro was the PIC of Respondent California Pharmacy and Compounding Center (hereinafter "CPCC"). On or about November 4, 2010, the Board received a telephone complaint from J.S. alleging CPCC filled a prescription "without the dosage." On December 14, 2010, the Board received an anonymous complaint that CPCC was involved in the illegal practice of compounding and selling an oral preparation of human chorionic gonadotropin ("HCG"), which was being sold under the trade name of "Releana."

29. On or about January 11, 2011, an inspector for the Board conducted an inspection of CPCC following the receipt of these complaints concerning the pharmacy, which is further described below.

30. On or about August 20, 2010, a prescription was faxed to CPCC for J.S. for sixty vaginal suppositories of Valium/Flexeril/lidocaine. The prescription appeared to be signed by S.S., a physician's assistant. The prescription showed it was faxed from a fax machine with the name and telephone number of J.S. to CPCC. CPCC filled the prescription on the same day under prescription number RX 652991. CPCC dispensed twelve suppositories of a compounded medication containing "cyclo/diaz/lido" (cyclobenzaprine/diazepam/lidocaine). A duplicate label

provided by Respondent Schapiro showed the drug dispensed was "cyclo/diaz/lido" 10/5/62.5 mg suppository and the prescriber was identified as Dr. M.C., not S.S.

31. There was no notation that CPCC ensured the security, integrity and/or authority of the prescription by verifying the prescription with the prescriber. Likewise, there was no notation CPCC attempted to determine whether J.S. was authorized by PA S.S. to transmit the prescription on behalf of PA S.S. nor that J.S. was so authorized by PA S.S.

32. During the inspection of CPCC on January 11, 2011, Respondent Schapiro explained that CPCC reached an exclusive agreement with Millenium Medical Spa ("Millenium") to compound Releana®. Millenium was located in Newport Beach, California and was not licensed with the Board as a pharmacy or wholesaler in California. Millenium held the patent for Releana®, a medication containing the human chorionic gonadotropin ("HCG") as an active ingredient. HCG formulations are used to facilitate weight loss and body contouring. According to Respondent Schapiro, Millenium was responsible for marketing Releana® and receiving orders from physicians throughout the country for Respondent CPCC to fill. Millenium processed the orders and invoiced the physicians. Millenium then e-mailed the order form and a "Prescription Fill-in Form" to CPCC. The Prescription Fill-in Form contained prescriptions written for each patient and is further described in paragraph 34(c), below.

33. According to Respondent Schapiro, after CPCC received a prescription for Releana® by e-mail, CPCC processed the prescription, compounded the Releana® vehicle, which is a proprietary formula, and packaged the HCG in a separate container. CPCC dispensed the medication in a Ziploc bag with a prescription label with the patient's name, prescription number, the instruction to "Use as directed by physician," the prescribing physician, the date dispensed and the expiration date. Releana® was dispensed in the form of a small vial containing the HCG powder and a larger bottle containing the Releana® vehicle, a buffered solution. The medication was shipped to the prescribing physician's office where the medication was mixed by the physician and the larger container was dispensed to the patient. Millenium paid CPCC for all materials and dispensing fees.

34. In addition to physicians in California, Millenium sold Releana® to physicians in Alabama, Arizona, Florida, Georgia, Hawaii, Iowa, Illinois, Indiana, Maryland, Missouri, Mississippi, Nebraska, Nevada, New York, Ohio, Oklahoma, South Carolina, Texas, Virginia and Washington. Respondent CPCC compounded the medication for dispensing to physicians in these states.

35. On March 8, 2011, Board inspectors conducted further investigation of CPCC's practice regarding dispensing Releana®. The process by which Releana® was ordered was as follows:

a. The physician ordered Releana® from Millenium. The order form was faxed to Millenium along with the prescriptions for Releana® written on a prescription form with the Releana® logo.

b. The order was processed by Millenium. A packing slip was generated with the quantity purchased, the payment method (credit card name) and the amount due from the prescriber.

c. Millenium then e-mailed the following documents to CPCC:

i) the packing slip with Releana®'s logo for the quantity ordered and addressed to the physician;

ii) an order form with the name, address and telephone number of the physician, the description of the drug ("human chorionic gonadotropin proprietary formula") and the quantity ordered; and,

iii) a Prescription Fill-in Form with the prescriber's information and two columns of five boxes to fill in the patient's name, address, telephone number, the pre-printed description of the drugs as "Human Chorionic Gonadotropin proprietary formula" and quantity to either select from "[1], [2], or [3]" or to fill in. The prescription form did not state the date each prescription was written nor the strength of the drug.

36. CPCC's Drug Recall Report for Releana® showed that CPCC dispensed 5958 prescriptions for Releana® from October 1, 2010 to March 8, 2011. Thirty patients from the

Drug Recall Report were randomly selected and their Patient Drug Histories from March 8, 2010 to March 8, 2011 and prescriptions for Releana® were reviewed by Board inspectors.

37. The Drug Histories and Releana® prescriptions for the following patients were reviewed:

Patient initials	Prescriber's initials	Releana® Rx Number	Date dispensed
K.C.	D.T.	Not available[1]	Not available
G.D.	A.H.	623609	11/12/2009
E.T.	R.G.	672251	2/22/2011
M.W.	D.I.	662399	12/29/2010
M.F.	F.V.	662302	12/28/2010
D.G.	N.L.	650860	7/26/2010
A.K.	D.B.	655068	9/10/2010
H.M.	D.D.	652872	8/20/2010
G.M.	L.E.	655753	9/21/2010
B.C.	H.M.	661771	12/16/2010
P.C.	S.E.	635667	3/8/2010
Q.W.	S.B.	658717	11/1/2010
D.R.	R.W.	630300	1/26/2010
L.P.	J.B.	658030	10/21/2010
L.D.	J.W.	658261	10/26/2010
V.F.	T.P.	670762	1/31/2011
M.E.	L.K.	632162	2/9/2010
K.D.	A.T.	660151	11/18/2010
B.F.	P.M.	645830	6/1/2010

[1] According to K.C.'s Patient Drug History, seven prescriptions for Releana® were dispensed for this patient. However, a sample Releana® prescription was not provided to the Board inspectors. A prescription for testosterone was provided instead.

T.F.	G.J.	657118	10/11/2010
C.C.	G.J.	657120	10/11/2010
Patient initials	**Prescriber's initials**	**Releana® Rx Number**	**Date dispensed**
D.C.	U.K.	647200	6/15/2010
J.B.	T.L.	656880	10/8/2010
S.B.	M.S.	656960	10/8/2010
A.A.	D.P.	631816	2/8/2010
A.B.	H.S.	633855	2/24/2010
D.A.	A.D.	660830	12/2/2010
B.A.	E.M.	634248	2/26/2010
J.A.	A.D.	660833	12/2/2010
P.A.	R.C.	670879	2/1/2011

38. A review of the original prescriptions revealed that the Releana® prescriptions for each patient were cut out from the prescription form sent by Millenium to CPCC and affixed to a blank telephone prescription pad. A date was stamped on the prescription pads that appeared to be the date the prescriptions were filled. The prescriptions contained the name and address of the patient, the pre-printed drug name "human chorionic gonadotropin proprietary formula" and the provider's signature. The prescriptions did not have the strength of HCG and the quantity prescribed was specified in units of "1", "2" or "3." There were no notations on the prescriptions indicating the pharmacist verified the prescriptions with the physicians since the prescriptions were electronically received from Millenium instead of from the prescribing physicians. Many of the prescribing physicians were located out of the state of California.

39. Affixed to the prescriptions were the prescription backer labels. The backer labels indicated the prescription number assigned, the patient's name, the physician's name, the drug dispensed (Releana – Chorionic Gonadotropin), the quantity, the instruction "Use as Directed by Physician," and notations with CPCC's compounding lot number for the product dispensed and

the pharmacist's initials. The prescription backer label did not state the concentration, volume or weight of the active ingredient nor the quantity of the drug dispensed. Prescriptions labels that were duplicates of the prescription labels on the drug containers were also obtained. The duplicate prescription labels did not state the concentration, volume or weight of the active ingredient nor the quantity of the drug dispensed.

FIRST CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER AND DAVID JOSEPH SCHAPIRO

(Violation of Pharmacy Law – Failure to Ensure Integrity of Prescription)

40. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section 4301, subdivisions (j) and (o), for violating Code section 4071 and Health and Safety Code section 11164 in that Respondents failed to ensure the security, integrity and/or authority of J.S.'s prescription by failing to verify the prescription with the prescribing physician, as more fully set forth in paragraphs 29 – 30, which are incorporated by this reference as though set forth in full herein.

SECOND CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER AND DAVID JOSEPH SCHAPIRO

(Violation of Pharmacy Law - Erroneous and Uncertain Prescriptions)

41. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section 4301, subdivisions (j) and (o), for violating Code section 4040; title 16, CCR, section 1761; and, Health and Safety Code section 11164. Respondents compounded and/or dispensed prescriptions for Releana® containing significant errors, omissions, irregularities and/or uncertainties as more fully set forth in paragraphs 29 – 38, which are incorporated by this reference as though set forth in full herein, and as follows:

a. The prescriptions for Releana® did not specify the quantity to dispense, the directions for use and the date the prescription was issued.

b. The electronically transmitted prescriptions for Releana® were not valid in that the prescriptions were received by CPCC from Millenium instead of the prescriber and were not verified with the prescribing physician by the CPCC.

c. The electronically transmitted prescriptions for Releana® that were produced into a hard copy did not bear the date the prescription was transcribed or the signature of the transcribing pharmacist.

d. The electronically transmitted prescriptions for Releana® did not have the name of the person at the prescriber's office who transmitted the prescriptions.

THIRD CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER AND DAVID JOSEPH SCHAPIRO

(Selling to Unlicensed Entity)

42. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section 4301, subdivision (o) for violation of section 4169, subdivision (a)(1), for selling dangerous drugs to an entity not licensed by the Board. Respondents compounded and sold Releana® to Millenium, an entity not licensed by the Board as a pharmacy or wholesaler in California, as is more fully set forth in paragraphs 29 – 38, which are incorporated by this reference as though set forth in full herein.

FOURTH CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER AND DAVID JOSEPH SCHAPIRO

(Selling Misbranded Drugs)

43. Respondents CPCC and Schapiro are subject to discipline pursuant to Code sections 4301, subdivisions (j) and (o) for violation of section 4169, subdivision (a)(3), and Health and Safety Code sections 11130, 111440 and 11340, for selling, delivering, transferring, holding or offering for sale, any drug that Respondents knew or should reasonably have known were misbranded. The Releana® drugs were misbranded in that the label affixed to each individual container of Releana® powder and Releana® vehicle, did not specify the name and address of the

manufacturer, packer or distributor and they did not specify the quantity of the contents of each of the two containers sold in terms of weight or measure, as is more fully set forth in paragraphs 29–38, which are incorporated by this reference as though set forth in full herein.

FIFTH CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER AND DAVID JOSEPH SCHAPIRO

(Dispensing Incorrectly Labeled Prescriptions)

44. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section 4301, subdivision (o) for violation of section 4076, subdivision (a)(7) and (8) and title 16, CCR, 1735.4, for dispensing incorrectly labeled Releana® prescriptions in that Respondents dispensed Releana® with prescription labels that did not state the concentration or strength of the active ingredient nor the quantity of the drug dispensed, either in volume, weight or numerical count, as is more fully set forth in paragraphs 29 – 38, which are incorporated by this reference as though set forth in full herein.

SIXTH CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER AND DAVID JOSEPH SCHAPIRO

(Aiding or Abetting Millenium in Sale of Controlled Substances)

45. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section 4301, subdivision (o) for assisting in or abetting the violation of Code section 4110 by Millenium, in that Millenium sold Releana® to physicians in California, among other states, without having a license as a pharmacy or wholesaler in the State of California, as more fully set forth in paragraphs 29 – 38 and incorporated by this reference as though set forth in full herein.

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 49828 issued to California Pharmacy and Compounding Center;

2. Revoking or suspending Sterile Compounding License Number LSC 99542 issued to California Pharmacy and Compounding Center;

3. Revoking or suspending Pharmacist License Number RPH 26704 issued to David Joseph Schapiro;

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

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

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

DATED: 3/27/14

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

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