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

In the Matter of the Second 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 OAH No. 2014060941 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER [AS TO CALIFORNIA PHARMACY AND COMPOUNDING CENTER ONLY]**

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on September 9, 2016.

It is so ORDERED on August 10, 2016.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

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IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy. She brought this action solely in her official capacity and is represented in this matter by Kamala

D. Harris, Attorney General of the State of California, by Marichelle S. Tahimic, Deputy Attorney General.

2. Respondent California Pharmacy and Compounding Center ("Respondent") is represented in this proceeding by attorney Ivan Petrzelka, whose address is: 2855 Michelle Drive, Suite 180, Irvine, CA 92606-1027 , telephone (530) 366-8485.

3. On or about April 1, 2009, the Board of Pharmacy issued Pharmacy Permit No. 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 in Second Amended Accusation No. 4628, and will expire on April 1, 2017, unless renewed.

4. On or about April 2, 2009, the Board of Pharmacy issued Sterile Compounding License No. LSC 99542 to Respondent. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought in Second Amended Accusation No. 4628, and will expire on April 1, 2017, unless renewed.

JURISDICTION

5. Second Amended Accusation No. 4628 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on March 27, 2014. Respondent timely filed its Notice of Defense contesting the Accusation. Second Amended Accusation No. 4628 was filed before the Board on May 2, 2016.

6. A copy of Second Amended Accusation No. 4628 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

7. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Second Amended Accusation No. 4628. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

8. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Second Amended Accusation; the right to confront

and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

9. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

10. Respondent understands and agrees that the charges and allegations in Second Amended Accusation No. 4628, if proven at a hearing, constitute cause for imposing discipline upon Respondent's Pharmacy Permit and Sterile Compounding License.

11. For the purpose of resolving the Second Amended Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Second Amended Accusation, and that Respondent hereby gives up its right to contest those charges.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

14. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 49828 and Sterile Compounding License No. LSC 99542 issued to California Pharmacy and Compounding Center (Respondent) are revoked. However, the revocation is stayed and Respondent is placed on probation for four (4) years on the following terms and conditions.

1. **Obey All Laws**

Respondent owner shall obey all state and federal laws and regulations.

Respondent owner shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- ☐ an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- ☐ a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- ☐ a conviction of any crime
- ☐ discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's pharmacy permit or sterile compounding license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2. **Report to the Board**

Respondent owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. **Interview with the Board**

Upon receipt of reasonable prior notice, respondent owner shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff**

Respondent owner shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

5. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, respondent owner shall pay to the board its costs of investigation and prosecution in the amount of $31,458.83. Respondent owner shall make said payments as directed by the Board. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

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6. **Probation Monitoring Costs**

Respondent owner shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. **Status of License**

Respondent owner shall, at all times while on probation, maintain current licensure with the board. If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondent owner's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondent owner's license shall be subject to all terms and conditions of this probation not previously satisfied.

8. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should respondent owner discontinue business, respondent owner may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondent owner shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written

notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent owner may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondent owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. **Notice to Employees**

Respondent owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent owner shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

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10. **Owners and Officers: Knowledge of the Law**

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. **Posted Notice of Probation**

Respondent owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. **Violation of Probation**

If a respondent owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent license, and probation shall be automatically extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent owner violates probation in any respect, the board, after giving respondent owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be

automatically extended until the petition to revoke probation or accusation is heard and decided and the charges and allegations in the Second Amended Accusation shall be deemed true and correct.

13. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of probation, respondent license will be fully restored.

14. **Consultant for Owner or Pharmacist-In-Charge**

During the period of probation, Respondent shall retain an independent consultant who specializes in compounding, at its own expense, who shall be responsible for reviewing pharmacy operations on a monthly basis for compliance by Respondent with state and federal laws and regulations governing the practice of a compounding pharmacy and for compliance by Respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. During the period of probation, the Board or its designee, retains the discretion to reduce the frequency of the pharmacist consultant's review of Respondent California Pharmacy and Compounding Center's operations. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Ivan Petrzelka. I understand the stipulation and the effect it will have California Pharmacy and Compounding's Pharmacy Permit and Sterile Compounding License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 05/25/16

GLEN OLSHEIM, Authorized Agent for
CALIFORNIA PHARMACY AND COMPOUNDING CENTER
Respondent

I have read and fully discussed with Respondent California Pharmacy and Compounding Center the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: May 25, 2016

IVAN PETRZELKA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

Dated: May 25, 2016

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
ANTOINETTE CINCOTTA
Supervising Deputy Attorney General

MARICHELLE S. TAHIMIC
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Second Amended Accusation No. 4628

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Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Second 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 Second 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 confidentiality 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 1751.7 states in part:

...

(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.

...

28. 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

29. 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

30. Oxytocin, sold under the brand name Pitocin, is a dangerous drug pursuant to Business and Professions Code section 4022. It is used to induce labor.

31. 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.

32. Trimix is an injectible compounded product consisting of three active ingredients: alprostadil, papaverine and phenolamine, all of which are dangerous drugs pursuant to Business and Professions Code 4022. Trimix is used to treat erectile dysfunction.

33. 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

34. 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."

35. 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.

36. 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.

37. 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.

38. 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.

39. 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.

40. 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.

41. 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.

42. 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.

43. 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

[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
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
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

44. 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.

45. 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)

46. 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 34 – 45, 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)

47. 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 34 – 45, 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)

48. 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 34 – 45, which are incorporated by this reference as though set forth in full herein.

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FOURTH CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER

AND DAVID JOSEPH SCHAPIRO

(Selling Misbranded Drugs)

49. 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 34–45, 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)

50. 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 34 – 45, which are incorporated by this reference as though set forth in full herein.

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SIXTH CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER AND DAVID JOSEPH SCHAPIRO

(Aiding or Abetting Millenium in Sale of Controlled Substances)

51. 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 34 – 45 and incorporated by this reference as though set forth in full herein.

COMPOUNDED CARBOXYMETHYLCELLULOSE 0.2%

52. 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.

53. 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.

54. 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.

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SEVENTH CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER

AND DAVID JOSEPH SCHAPIRO

(No Policy and Procedures for Autoclave and Convection Oven)

55. 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 52 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)

56. 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 52-54 above and which are incorporated by this reference as though set forth in full herein.

ADVERSE EVENT REPORT

57. 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.

58. 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.

59. 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)

60. 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 57-59 above and which are incorporated by this reference as though set forth in full herein.

JULY 24, 2015 INSPECTION

61. On July 24, 2015, an inspector for the Board conducted an inspection of CPCC following the receipt of a copy of a Warning Letter issued by the Food and Drug Administration (WL# 23-15) to CPCC on June 17, 2015.

62. During the inspection, the Board inspector observed batch oxytocin, a compounded product, in CPCC's refrigerator where they were "quarantined" before they are released into the market. The oxytocin was to be used intranasally in an investigational study of individuals with high functioning autism. The oxytocin was labeled as follows: Oxytocin 360u/ml lot#B063015R, expiration 06/01/16 and Oxytocin 1200u/ml lot#B050815R, expiration 05/02/16. The "beyond use date" ("BUD") assigned to these products of almost one year exceeded the mandatory compounding limitation of 180 days from preparation or the shortest expiration date of any component in the compounded drug product. Respondent Schapiro explained that CPCC has document to justify the extended BUD assigned to these products.

63. The Board inspector requested stability studies to justify the extended BUD given to the oxytocin. Respondent provided a study performed by the Department of Pharmacy of the

University of California, San Diego ("UCSD study"). The UCSD study did not comply with the Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH").[2] The ICH requires rigorous studies under three major categories, chemical, physical and microbiological. The UCSD study did not record the physical observation of the oxytocin used over the period of the test, nor was there any documentation or record of the chemical stability or chemical composition of the active pharmaceutical ingredients ("API") as they reacted with the excipients. Furthermore, Respondent was compounding oxytocin 360u/ml, but the UCSD study only measured and recorded the potency of the API in oxytocin 60u/ml and 120u/ml during the period of testing.

64. The Board inspector discussed the inadequacies of the UCSD study with Respondent Schapiro and on September 1, 2015, the inspector requested a copy of the full stability study done by UCSD's laboratory.

65. On or about September 19, 2015, the Board inspector received a full copy of the oxytocin stability study, which was the same study presented during the inspection on July 24, 2015. The study did not record the physical appearance of the compounded products at various time points and did not record how the API interacted with the excipients. The UCSD study did not discuss whether a sterility study had been done. The UCSD study only focused on the potency of the API.

66. A review of CPCC's qualitative and quantitative testing reports received by the Board on July 24, 2015 showed that CPCC was not testing all end products from non-sterile batches that were compounded for sterility and endotoxin. For example, CPCC performed sterility testing of the individual components that made up Trimix but not the resultant Trimix end product that was dispensed to patients.

[2] The objective of ICH is to increase international harmonisation of technical requirements to ensure that safe, effective, and high quality medicines are developed and registered in the most efficient and cost-effective manner. These activities have been undertaken to promote public health, prevent unnecessary duplication of clinical trials in humans, and minimize the use of animal testing without compromising safety and effectiveness. (www.ich.org/about/faqs.html.)

67. The individual compounded ingredients used in the formulation of Trimix, its byproducts and the resultant Trimix product were not tested for endotoxin even though the Trimix product was made from non-sterile products. Between January 1, 2013 and May 31, 2014, CPCC compounded 49 batches of Trimix from non-sterile bulk ingredients. These 49 batches of Trimix were not tested for pyrogens as required. They were not quarantined until end product testing confirmed sterility and acceptable levels of pyrogens. Instead, Respondents Schapiro, Truong and Han authorized the release of these batches for dispensing to patients. CPCC dispensed 924 prescriptions of Trimix between January 1, 2013 and May 31, 2014.

TENTH CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER AND DAVID JOSEPH SCHAPIRO

(Erroneous Expiration Date Assigned)

68. 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 erroneous expiration dates to compounded oxytocin. Between April 1, 2012 and September 1, 2015, Respondents compounded oxytocin 120/u/ml and 360u/ml and assigned a BUD of one year without adequate supporting stability studies to justify the extended BUD, as more fully set forth in paragraphs 61 – 66 above and incorporated by this reference as though set forth in full.

ELEVENTH CAUSE FOR DISCIPLINE

AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER AND DAVID JOSEPH SCHAPIRO

(Failure to Conduct and Document End Product Testing and Failure to Quarantine)

69. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section 4301, subdivision (o) in conjunction with 16, title CCR, section 1751.7(c), for failure to test and document end product testing of 49 batches of Trimix for sterility and pyrogens and failure to quarantine until the end product testing confirmed sterility and acceptable levels of pyrogens as more fully set forth in paragraphs 61 – 66 above and incorporated by this reference as though set forth in full.

DISCIPLINARY CONSIDERATIONS

70. 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,

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

DATED: 5/2/16

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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