1	I				
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8	Attorneys for Complainant				
9	BEFORE THE BOARD OF PHARMACY				
10		CONSUMER AFFAIRS CALIFORNIA			
11	In the Matter of the First Amended Accusation	Case No. 4628			
12	Against:				
13	CALIFORNIA PHARMACY AND	FIRST AMENDED			
14	COMPOUNDING CENTER 4000 Birch Street, Suite 120	ACCUSATION			
15	Newport Beach, CA 92660				
16					
17	Sterile Compounding License No. LSC 99542				
18	and				
19	DAVID JOSEPH SCHAPIRO				
20	14501 Larch Avenue Irvine, CA 92606				
21	Pharmacist License No. RPH 26704				
22	Respondents.				
23					
24	Complainant alleges:				
25	PARTIES				
26	1. Virginia Herold (Complainant) brings this First Amended Accusation solely in her				
27	official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer				
28	Affairs.				
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1	2. On or about April 1, 2009, the Board of Pharmacy issued Pharmacy Permit Number			
2	PHY 49828 to California Pharmacy and Compounding Center (Respondent). The Pharmacy			
3	Permit was in full force and effect at all times relevant to the charges brought herein and will			
4	expire on April 1, 2016, unless renewed.			
5	3. On or about April 2, 2009, the Board of Pharmacy issued Sterile Compounding			
6	License Number LSC 99542 to California Pharmacy and Compounding Center (Respondent).			
7	The Sterile Compounding License was in full force and effect at all times relevant to the charges			
8	brought herein and will expire on April 1, 2016, unless renewed.			
9	4. On or about July 16, 1970, the Board of Pharmacy issued Pharmacist License			
10	Number RPH 26704 to David Joseph Schapiro (Respondent). The Pharmacist License was in full			
11	force and effect at all times relevant to the charges brought herein and will expire on July 31,			
12	2017, unless renewed. Respondent Schapiro was the Pharmacist-In-Charge ("PIC") of CPCC and			
13	has been the PIC since April 1, 2009.			
14	JURISDICTION			
15	5. This First Amended Accusation is brought before the Board of Pharmacy (Board),			
16	Department of Consumer Affairs, under the authority of the following laws. All section			
17	references are to the Business and Professions Code unless otherwise indicated.			
18	6. Section 4300 of the Code states:			
19	(a) Every license issued may be suspended or revoked.			
20	(b) The board shall discipline the holder of any license issued by the board,			
21	whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:			
22	(1) Suspending judgment.			
23	(2) Placing him or her upon probation.			
24	(3) Suspending his or her right to practice for a period not exceeding one			
25	(4) Revoking his or her license.			
26	(5) Taking any other action in relation to disciplining him or her as the			
27	board in its discretion may deem proper.			
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1 2 3	(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.
4	7. Section 4300.1 of the Code states:
5	The expiration, cancellation, forfeiture, or suspension of a board-issued
6	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
7 8	or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.
9	STATUTORY AND REGULATORY PROVISIONS
10	8. Section 4022 of the Code states
11	Dangerous drug" or "dangerous device" means any drug or device unsafe
12	for self-use in humans or animals, and includes the following:
13	(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
14	(b) Any device that bears the statement: "Caution: federal law restricts
15	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.
16 17	(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."
18	9. Section 4040 of the Code states in part:
19	(a) "Prescription" means an oral, written, or electronic transmission order
20	that is both of the following:
21	(1) Given individually for the person or persons for whom ordered that includes all of the following:
22	(A) The name or names and address of the patient or patients.
23	(B) The name and quantity of the drug or device prescribed and the directions for use.
24 26	(C) The date of issue.
25 26	(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license
20 27	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 1 drug is being prescribed, if requested by the patient or patients. 2 (F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or 3 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 4 drug order pursuant to either Section 4052.1 or 4052.2. 5 . . . 6 (b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains 7 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 8 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 9 prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event 10 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. 11 (c) "Electronic transmission prescription" includes both image and data 12 prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy 13 from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, 14 that is electronically transmitted from a licensed prescriber to a pharmacy. 15 10. Section 4071 of the Code states: 16 17 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 18 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 19 the name of the authorized agent of the prescriber who transmits the order. 11. Section 4076 of the Code states in part: 2021(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 22 with all of the following: 23 (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 24 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 25 active ingredients. 26 (2) The directions for the use of the drug. 27(3) The name of the patient or patients. $\mathbf{28}$ (4) The name of the prescriber ... 4 First Amended Accusation

	(5) The date of issue.				
1 2	(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.				
3	(7) The strength of the drug or drugs dispensed.				
4	(8) The quantity of the drug or drugs dispensed.				
5	(9) The expiration date of the effectiveness of the drug dispensed.				
6 7	(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription				
8	12. Section 4110 of the Code states in part:				
9	(a) No person shall conduct a pharmacy in the State of California unless				
10	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				
11	more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be				
12	transferred				
13	13. Section 4113 of the Code states in part:				
14 15	(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.				
16					
17	(c) The pharmacist-in-charge shall be responsible for a pharmacy's				
18	compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.				
19					
20	14. Section 4169 of the Code states in part:				
21	(a) A person or entity may not do any of the following:				
22	(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at				
23	wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.				
24	• • •				
25	(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or				
26	reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code				
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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...

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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 confidentially of the prescription...

26

18. Section 111330 of the Health and Safety Code states, "Any drug or device is

27 misbranded if its labeling is false or misleading in any particular."

1	19. Section 111335 of the Health and Safety Code states, "Any drug or device is			
2	misbranded if its labeling or packaging does not conform to the requirements of Chapter 4			
3	(commencing with Section 110290)."			
4	20. Section 111340 of the Health and Safety Code states:			
5	Any drug or device is misbranded unless it bears a label containing all of the following information:			
6 7	(a) The name and place of business of the manufacturer, packer, or distributor.			
8	(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.			
9 10 11	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.			
12	21. Section 111440 of the Health and Safety Code states, "It is unlawful for any person to			
13	manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."			
14	22. Section 111445 of the Health and Safety Code states: "It is unlawful for any person to			
15	misbrand any drug or device.			
16	23. Title 16, California Code of Regulations ("CCR"), section 1735 states in part:			
17 18	(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:			
19	(1) Altering the dosage form or delivery system of a drug			
20	(2) Altering the strength of a drug			
21	(3) Combining components or active ingredients			
22	(4) Preparing a drug product from chemicals or bulk drug substances			
23				
24	24. Title 16, CCR, section 1735.4 states:			
25 26	(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).			
27 28	(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.			
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1)	
1 2 3	(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.	
4	25. Title 16, CCR, section 1735.2 states in part:	
5		
6	(h) Every compounded drug product shall be given an expiration date	
7	representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used.	
8	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	
9 compounded drug product, unless a longer date is supported by stability studi 9 of finished drugs or compounded drug products using the same components a		
10	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.	
11		
12	26. Title 16, CCR, section 1735.5 states in part:	
13	1) I I I I I I I I I I I I I I I I I I I	
14	(c) The policy and procedure manual shall include the following	
15		
16 17	(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.	
18		
19	27. Title 16, CCR, section 1761 states in part:	
20	(a) No pharmacist shall compound or dispense any prescription which	
21	contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact	
22	the prescriber to obtain the information needed to validate the prescription.	
23		
24	COST RECOVERY	
25	28. Section 125.3 of the Code states, in pertinent part, that the Board may request the	
26	administrative law judge to direct a licentiate found to have committed a violation or violations of	
27	the licensing act to pay a sum not to exceed the reasonable costs of the investigation and	
28	enforcement of the case.	
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DRUGS

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

30. <u>Valium/Flexeril/lidocaine suppository</u> 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.

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RELEANA® PRESCRIPTIONS

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

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

On or about August 20, 2010, a prescription was faxed to CPCC for J.S. for sixty 2133. vaginal suppositories of Valium/Flexeril/lidocaine. The prescription appeared to be signed by 22 S.S., a physician's assistant. The prescription showed it was faxed from a fax machine with the 23 name and telephone number of J.S. to CPCC. CPCC filled the prescription on the same day 24 under prescription number RX 652991. CPCC dispensed twelve suppositories of a compounded 25 medication containing "cyclo/diaz/lido" (cyclobenzaprine/diazepam/lidocaine). A duplicate label 26 provided by Respondent Schapiro showed the drug dispensed was "cyclo/diaz/lido" 10/5/62.5 mg 27 suppository and the prescriber was identified as Dr. M.C., not S.S. 28

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

35. During the inspection of CPCC on January 11, 2011, Respondent Schapiro explained 5 that CPCC reached an exclusive agreement with Millenium Medical Spa ("Millenium") to 6 compound Releana®. Millenium was located in Newport Beach, California and was not licensed 7 with the Board as a pharmacy or wholesaler in California. Millenium held the patent for 8 Releana®, a medication containing the human chorionic gonadotropin ("HCG") as an active 9 ingredient. HCG formulations are used to facilitate weight loss and body contouring. According 10 to Respondent Schapiro, Millenium was responsible for marketing Releana® and receiving orders 11 from physicians throughout the country for Respondent CPCC to fill. Millenium processed the 12 orders and invoiced the physicians. Millenium then e-mailed the order form and a "Prescription 13 Fill-in Form" to CPCC. The Prescription Fill-in Form contained prescriptions written for each 14 patient and is further described in paragraph 34(c), below. 15

36. According to Respondent Schapiro, after CPCC received a prescription for Releana® 16 by e-mail, CPCC processed the prescription, compounded the Releana® vehicle, which is a 17 proprietary formula, and packaged the HCG in a separate container. CPCC dispensed the 18 medication in a Ziploc bag with a prescription label with the patient's name, prescription number, 19 the instruction to "Use as directed by physician," the prescribing physician, the date dispensed 20 and the expiration date. Releana® was dispensed in the form of a small vial containing the HCG 21 powder and a larger bottle containing the Releana® vehicle, a buffered solution. The medication 22 was shipped to the prescribing physician's office where the medication was mixed by the 23 physician and the larger container was dispensed to the patient. Millenium paid CPCC for all 24 materials and dispensing fees. 25

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

Washington. Respondent CPCC compounded the medication for dispensing to physicians in 1 these states. 2 38. On March 8, 2011, Board inspectors conducted further investigation of CPCC's 3 practice regarding dispensing Releana®. The process by which Releana® was ordered was as 4 follows: 5 The physician ordered Releana® from Millenium. The order form was faxed to 6 a. Millenium along with the prescriptions for Releana® written on a prescription form with the 7 Releana® logo. 8 The order was processed by Millenium. A packing slip was generated with the b. 9 quantity purchased, the payment method (credit card name) and the amount due from the 10 prescriber. 11 Millenium then e-mailed the following documents to CPCC: c. 12 i) the packing slip with Releana®'s logo for the quantity ordered and addressed to 13 the physician; 14 ii) an order form with the name, address and telephone number of the physician, the 15 description of the drug ("human chorionic gonadotropin proprietary formula") and the 16 quantity ordered; and, 17 iii) a Prescription Fill-in Form with the prescriber's information and two columns of 18 five boxes to fill in the patient's name, address, telephone number, the pre-printed 19 description of the drugs as "Human Chorionic Gonadotropin proprietary formula" and 20 quantity to either select from "[1], [2], or [3]" or to fill in. The prescription form did not 21 state the date each prescription was written nor the strength of the drug. 22 CPCC's Drug Recall Report for Releana® showed that CPCC dispensed 5958 39. 23 prescriptions for Releana® from October 1, 2010 to March 8, 2011. Thirty patients from the 24 Drug Recall Report were randomly selected and their Patient Drug Histories from March 8, 2010 25 to March 8, 2011 and prescriptions for Releana® were reviewed by Board inspectors. 26The Drug Histories and Releana® prescriptions for the following patients were 40. 27 reviewed: 28 11

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
<u>M.E.</u>	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
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dispensed for this patient. However, a sample Releana® prescription was not provided to the
 Board inspectors. A prescription for testosterone was provided instead.

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

10 41. A review of the original prescriptions revealed that the Releana® prescriptions for 11 each patient were cut out from the prescription form sent by Millenium to CPCC and affixed to a 12 blank telephone prescription pad. A date was stamped on the prescription pads that appeared to 13 be the date the prescriptions were filled. The prescriptions contained the name and address of the 14 patient, the pre-printed drug name "human chorionic gonadotropin proprietary formula" and the 15 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 16 17 indicating the pharmacist verified the prescriptions with the physicians since the prescriptions 18 were electronically received from Millenium instead of from the prescribing physicians. Many of 19 the prescribing physicians were located out of the state of California.

20 42. Affixed to the prescriptions were the prescription backer labels. The backer labels 21 indicated the prescription number assigned, the patient's name, the physician's name, the drug 22 dispensed (Releana - Chorionic Gonadotropin), the quantity, the instruction "Use as Directed by 23 Physician," and notations with CPCC's compounding lot number for the product dispensed and 24 the pharmacist's initials. The prescription backer label did not state the concentration, volume or 25 weight of the active ingredient nor the quantity of the drug dispensed. Prescriptions labels that 26were duplicates of the prescription labels on the drug containers were also obtained. The 27duplicate prescription labels did not state the concentration, volume or weight of the active ingredient nor the quantity of the drug dispensed. 28

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1	FIRST CAUSE FOR DISCIPLINE	
2	AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER	
3	AND DAVID JOSEPH SCHAPIRO	
4	(Violation of Pharmacy Law – Failure to Ensure Integrity of Prescription)	
5	43. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section	
6	4301, subdivisions (j) and (o), for violating Code section 4071 and Health and Safety Code	
7	section 11164 in that Respondents failed to ensure the security, integrity and/or authority of J.S.'s	
8	prescription by failing to verify the prescription with the prescribing physician, as more fully set	
9	forth in paragraphs 29 – 30, which are incorporated by this reference as though set forth in full	
10	herein.	
11	SECOND CAUSE FOR DISCIPLINE	
12	AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER	
13	AND DAVID JOSEPH SCHAPIRO	
14	(Violation of Pharmacy Law - Erroneous and Uncertain Prescriptions)	
15	44. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section	
16	4301, subdivisions (j) and (o), for violating Code section 4040; title 16, CCR, section 1761; and,	
17	Health and Safety Code section 11164. Respondents compounded and/or dispensed prescriptions	
18	for Releana® containing significant errors, omissions, irregularities and/or uncertainties as more	
19	fully set forth in paragraphs 29 – 38, which are incorporated by this reference as though set forth	
20	in full herein, and as follows:	
21	a. The prescriptions for Releana® did not specify the quantity to dispense, the directions	
22	for use and the date the prescription was issued.	
23	b. The electronically transmitted prescriptions for Releana® were not valid in that the	
24	prescriptions were received by CPCC from Millenium instead of the prescriber and were not	
25	verified with the prescribing physician by the CPCC.	
26	c. The electronically transmitted prescriptions for Releana® that were produced into a	
27	hard copy did not bear the date the prescription was transcribed or the signature of the	
28	transcribing pharmacist.	
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1	d. The electronically transmitted prescriptions for Releana® did not have the name of	
2	the person at the prescriber's office who transmitted the prescriptions.	
3	THIRD CAUSE FOR DISCIPLINE	
4	AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER	
5 AND DAVID JOSEPH SCHAPIRO		
6 (Selling to Unlicensed Entity)		
7	45. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section	
8	4301, subdivision (o) for violation of section 4169, subdivision (a)(1), for selling dangerous drugs	
9	to an entity not licensed by the Board. Respondents compounded and sold Releana® to	
10	Millenium, an entity not licensed by the Board as a pharmacy or wholesaler in California, as is	
11	more fully set forth in paragraphs $29 - 38$, which are incorporated by this reference as though set	
12	forth in full herein.	
13	FOURTH CAUSE FOR DISCIPLINE	
14	AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER	
15	AND DAVID JOSEPH SCHAPIRO	
16	(Selling Misbranded Drugs)	
17	46. Respondents CPCC and Schapiro are subject to discipline pursuant to Code sections	
18	4301, subdivisions (j) and (o) for violation of section 4169, subdivision (a)(3), and Health and	
19	Safety Code sections 11130, 111440 and 11340, for selling, delivering, transferring, holding or	
20	offering for sale, any drug that Respondents knew or should reasonably have known were	
21	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	
22	manufacturer, packer or distributor and they did not specify the quantity of the contents of each of	
22 23	manufactures, packed of distribution and they did not specify the quantity of the contents of each of	
23		
23 24	the two containers sold in terms of weight or measure, as is more fully set forth in paragraphs 29-	
23 24 25	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.	
23 24 25 26	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. ///	

1	FIFTH CAUSE FOR DISCIPLINE
2	AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER
3	AND DAVID JOSEPH SCHAPIRO
4	(Dispensing Incorrectly Labeled Prescriptions)
5	47. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section
6	4301, subdivision (o) for violation of section 4076, subdivision (a)(7) and (8) and title 16, CCR,
7	1735.4, for dispensing incorrectly labeled Releana® prescriptions in that Respondents dispensed
8	Releana® with prescription labels that did not state the concentration or strength of the active
9	ingredient nor the quantity of the drug dispensed, either in volume, weight or numerical count, as
10	is more fully set forth in paragraphs $29 - 38$, which are incorporated by this reference as though
11	set forth in full herein.
12	SIXTH CAUSE FOR DISCIPLINE
13	AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER
14	AND DAVID JOSEPH SCHAPIRO
15	(Aiding or Abetting Millenium in Sale of Controlled Substances)
16	48. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section
17	4301, subdivision (o) for assisting in or abetting the violation of Code section 4110 by Millenium,
18	in that Millenium sold Releana® to physicians in California, among other states, without having a
19	license as a pharmacy or wholesaler in the State of California, as more fully set forth in
20	paragraphs $29 - 38$ and incorporated by this reference as though set forth in full herein.
21	COMPOUNDED CARBOXYMETHYLCELLULOSE 0.2%
22	49. On January 28, 2015, an annual renewal sterile compounding inspection was
23	conducted at Respondent pharmacy. As part of the inspection, the compounding record for
24	prescription #719944 (Rx #719944) made on January 15, 2015 was reviewed. The original
25	compounding records with integrated master formula for compounding carboxymethulcellulose
26	0.2% preservative free eye drops were reviewed. The pharmacy's policies and procedures for
27	cleaning the autoclave to compound Rx #719944 and the convection oven next to the autoclave
28	were requested but were not available for review during the inspection.
	16
	First Amended Accusation

1	50. Sodium carboxymethulcellulose ("CMC") powder, lot # 14C03-U02-017876 was the			
2	active ingredient used to compound Rx #719944. The compounding record for			
3	carboxymethulcellulose 0.2% erroneously stated that the expiration date of CMC powder, lot #			
4	14C03-U02-017876, was January 15, 2016, when the correct expiration date was January 15,			
5	2015.			
6	51. The expiration date assigned to the compounded drug Rx #719944 was March 1,			
7	2015, 45 days after the expiration of CMC powder, which was the active ingredient used to			
8	compound Rx #719944.			
9	SEVENTH CAUSE FOR DISCIPLINE			
10	AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER			
11	AND DAVID JOSEPH SCHAPIRO			
12	(No Policy and Procedures for Autoclave and Convection Oven)			
13	52. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section			
14	4301, subdivision (o) in conjunction with 16, title CCR, section 1735.5(a) for failing to maintain			
15	a written policy and procedure manual that includes the procedures for maintaining, storing,			
16	calibrating, cleaning, and disinfecting the autoclave and convection oven, equipment used in			
17	compounding, as more fully set forth in paragraph 49 above and which is incorporated by this			
18	reference as though set forth in full herein.			
19	EIGHTH CAUSE FOR DISCIPLINE			
20	AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER			
21	AND DAVID JOSEPH SCHAPIRO			
22	(Erroneous Expiration Date Assigned)			
23	53. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section			
24	4301, subdivision (o) in conjunction with 16, title CCR, section 1735.2(h), for assigning an			
25	erroneous expiration date to Rx #719944 that exceeded the shortest expiration date of any			
26	component in the compounded drug product, as more fully set forth in paragraphs 49-51 above			
27	and which are incorporated by this reference as though set forth in full herein.			
28				
	17 First Amended Accusation			
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1	ADVERSE EVENT REPORT
2	54. On April 1, 2015, the Board was notified of an adverse event pertaining to an Avastin
3	syringe compounded by Respondents. On July and November, 2014, O.B. received Avastin
4	injections in her eye at her doctor's office. The Avastin injection was a compounded sterile
5	product obtained by O.B.'s physician from Respondent. It was used to treat wet age-related
6	macular degeneration.
7	55. On February 2, 2015, O.B. received another Avastin injection compounded by
8	Respondents (lot number B120714). On March 4, 2015, O.B. notified her doctor that she had an
9	eye infection. On March 6, 2015, O.B.'s doctor called Respondents about O.B.'s eye infection
10	and her use of Avastin.
11	56. On March 16, 2015, O.B.'s doctor's office notified Respondents that a culture of the
12	patient was done and the results were negative.
13	NINTH CAUSE FOR DISCIPLINE
14	AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER
15	AND DAVID JOSEPH SCHAPIRO
16	(Failure to Report Adverse Event to Board Within 12 Hours)
17	57. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section
18	4301, subdivision (0) in conjunction with Code section 4127.1(f) in that Respondents failed to
19	report the adverse event regarding O.B. to the Board within 12 hours, as more fully set forth in
20	paragraphs 54-56 above and which are incorporated by this reference as though set forth in full
21	herein.
22	DISCIPLINARY CONSIDERATIONS
23	58. To determine the degree of discipline, if any, to be imposed on Respondents,
24	Complainant alleges:
25	a. On or about August 22, 2014, Citation and Fine Number CI 2014 62109 was issued
26	against California Pharmacy and Compounding Center, Pharmacy Permit No. PHY 49828 for
27	violation of Code section 4169(a)(1), purchasing, trading, selling or transferring dangerous drugs
28	to unlicensed person or entity; and,
	18
1	First Amended Accusation

1	b. On or about August 22, 2014, Citation and Fine Number CI 2014 62118 was issued		
2	against David Joseph Shapiro, License No. RPH 26704 for violation of Code section 4169(a)(1),		
3	purchasing, trading, selling or transferring dangerous drugs to unlicensed person or entity.		
4	PRAYER		
5	WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,		
6	and that following the hearing, the Board of Pharmacy issue a decision:		
7	1. Revoking or suspending Pharmacy Permit Number PHY 49828 issued to California		
8	Pharmacy and Compounding Center;		
9	2. Revoking or suspending Sterile Compounding License Number LSC 99542 issued to		
10	California Pharmacy and Compounding Center;		
11	3. Revoking or suspending Pharmacist License Number RPH 26704 issued to David		
12	Joseph Schapiro;		
13	4. Ordering California Pharmacy and Compounding Center to pay the Board of		
14	Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to		
15	Business and Professions Code section 125.3;		
16	5. Ordering David Joseph Schapiro to pay the Board of Pharmacy the reasonable costs		
17	of the investigation and enforcement of this case, pursuant to Business and Professions Code		
18	section 125.3; and,		
19	6. Taking such other and further action as deemed necessary and proper.		
20	aboli (). N/1/		
21	DATED: 8/27/15 (haina Herold		
22	Executive Officer Board of Pharmacy		
23	Department of Consumer Affairs State of California		
24	Complainant		
25	SD2013805160/81105755.doc		
26			
27			
28			
	19 First Amended Accusation		

1	1 KAMALA D. HARRIS						
2		Attorney General of California					
3	Supervising Deputy Attorney General MARICHELLE S. TAHIMIC	Supervising Deputy Attorney General					
4		Deputy Attorney General					
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10	0 DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA						
11	1 In the Matter of the Accusation Against: Case No. 4628						
12	2 CALIFORNIA PHARMACY AND						
13		· · ·					
14							
15	5 Pharmacy Permit No. PHY 49828 Sterile Compounding License No. LSC						
16	6 99542						
17	and						
18	B DAVID JOSEPH SCHAPIRO 14501 Larch Avenue 14501 Larch Avenue						
19	19 Irvine, CA 92606						
20	20 Pharmacist License No. RPH 26704						
21_	21						
22		· · · · ·					
23							
24	PARTIES						
25	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity						
26	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.						
27	2. On or about April 1, 2009, the Board of Pharmacy issued Pharmacy Permit Number						
28		PHY 49828 to California Pharmacy and Compounding Center (Respondent). The Pharmacy					
	1	Accusation					
	11						

1	Permit was in full force and effect at all times relevant to the charges brought herein and will	
2	expire on April 1, 2014, unless renewed.	
3	3. On or about April 2, 2009, the Board of Pharmacy issued Sterile Compounding	
4	License Number LSC 99542 to California Pharmacy and Compounding Center (Respondent).	
5	The Sterile Compounding License was in full force and effect at all times relevant to the charges	
6	brought herein and will expire on April 1, 2014, unless renewed.	
7	4. On or about July 16, 1970, the Board of Pharmacy issued Pharmacist License	
8	Number RPH 26704 to David Joseph Schapiro (Respondent). The Pharmacist License was in full	
9	force and effect at all times relevant to the charges brought herein and will expire on July 31,	
10	2013, unless renewed. Respondent Schapiro was the Pharmacist-In-Charge ("PIC") of CPCC and	
11	has been the PIC since April 1, 2009.	
12	JURISDICTION	
13	5. This Accusation is brought before the Board of Pharmacy (Board), Department of	
14	Consumer Affairs, under the authority of the following laws. All section references are to the	
15	Business and Professions Code unless otherwise indicated.	
16	6. Section 4300 of the Code states:	
17	(a) Every license issued may be suspended or revoked.	
18 19	(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:	
20	(1) Suspending judgment.	
21	(1) Suspending Judgment. (2) Placing him or her upon probation.	
22	(3) Suspending his or her right to practice for a period not exceeding one	
22	year.	
24	(4) Revoking his or her license.	
25	(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.	
26		
27	(e) The proceedings under this article shall be conducted in accordance with	
28	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	í
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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.

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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 ," "Rx only," or words of this device to sale by or on the order of a 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." Section 4040 of the Code states in part: 9. (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 24 classification, and his or her federal registry number, if a controlled 25 substance is prescribed. (E) A legible, clear notice of the condition or purpose for which the 26 drug is being prescribed, if requested by the patient or patients. 27 (F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or 28

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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.

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(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

		•
1	other means of identifying the prescription.	
1	(7) The strength of the drug or drugs dispensed.	
2	(8) The quantity of the drug or drugs dispensed.	
3	(9) The expiration date of the effectiveness of the drug dispensed.	
4 5	(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription	
6	12. Section 4110 of the Code states in part:	-
7	(a) No person shall conduct a pharmacy in the State of California unless	
8	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	
9	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,	
10	by regulation, determine the circumstances under which a license may be transferred	
11	13. Section 4113 of the Code states in part:	
12	(a) Every pharmacy shall designate a pharmacist-in-charge and, within 30	
13	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.	
14		
15	(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the	
16	practice of pharmacy.	
17		
18	14. Section 4169 of the Code states in part:	
19	(a) A person or entity may not do any of the following:	
20	(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	
21 -	wholesaler or pharmacy.	
22	· · · · · · · · · · · · · · · · · · ·	
23	(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335	
24	of the Health and Safety Code	
25	15. Section 4301 of the Code states in part:	
26	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	
27	misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:	
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(j) The violation of any of the statutes of this state, 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

17 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

19 misbranded if its labeling or packaging does not conform to the requirements of Chapter 4

20 (commencing with Section 110290)."

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<u>19. Section 111340 of the Health and Safety Code states:</u>

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.

1	20. Section 111440 of the Health and Safety Code states, 'It is unlawful for any person to				
2	manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."				
3	21. Section 111445 of the Health and Safety Code states: "It is unlawful for any person to				
4	misbrand any drug or device.				
5	22. Title 16, California Code of Regulations ("CCR"), section 1735 states in part:				
6 7	(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:				
8	(1) Altering the dosage form or delivery system of a drug				
9	(2) Altering the strength of a drug				
10	(3) Combining components or active ingredients				
11	(4) Preparing a drug product from chemicals or bulk drug substances				
12	••••				
13	23. Title 16, CCR, section 1735.4 states:				
14	(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).				
15					
16 17	(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.				
18	(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,				
19 20	and expiration date.				
	24				
22	(a) No pharmacist shall compound or dispense any prescription which				
23	contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact				
24	the prescriber to obtain the information needed to validate the prescription.				
25					
26	COST RECOVERY				
27	25. Section 125.3 of the Code states, in pertinent part, that the Board may request the				
28	administrative law judge to direct a licentiate found to have committed a violation or violations of				
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	Accusation				

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

DRUGS

26. <u>Releana®</u>, a brand name for human chorionic gonadotropin is a Schedule III 4 controlled substance pursuant to Health and Safety Code section 11056(f)(32) and is a dangerous 5 drug pursuant to Business and Professions Code section 4022.

Valium/Flexeril/lidocaine suppository is a compounded product containing a 27. 7 combination of the following ingredients: cyclobenzaprine (Flexeril), diazepam (Valium) and 8 lidocaine. It is a Schedule IV controlled substance as designated by Health and Safety Code 9 Section 11057(d)(9), and is a dangerous drug pursuant to Business and Professions Code section 10 4022. It is used as a muscle relaxant. 11

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FACTS

At all times mentioned herein, Respondent Schapiro was the PIC of Respondent 28. 13 California Pharmacy and Compounding Center (hereinafter "CPCC"). On or about November 4, 14 2010, the Board received a telephone complaint from J.S. alleging CPCC filled a prescription 15 "without the dosage." On December 14, 2010, the Board received an anonymous complaint that 16 17 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 18 "Releana." 19

29. On or about January 11, 2011, an inspector for the Board conducted an inspection of 20 CPCC following the receipt of these complaints concerning the pharmacy, which is further 21 described below. 22

On or about August 20, 2010, a prescription was faxed to CPCC for J.S. for sixty 23 30. vaginal suppositories of Valium/Flexeril/lidocaine. The prescription appeared to be signed by 24 S.S., a physician's assistant. The prescription showed it was faxed from a fax machine with the 25 name and telephone number of J.S. to CPCC. CPCC filled the prescription on the same day 26 under prescription number RX 652991. CPCC dispensed twelve suppositories of a compounded 27 medication containing "cyclo/diaz/lido" (cyclobenzaprine/diazepam/lidocaine). A duplicate label 28

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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.

3 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 7 that CPCC reached an exclusive agreement with Millenium Medical Spa ("Millenium") to 8 compound Releana®. Millenium was located in Newport Beach, California and was not licensed 9 with the Board as a pharmacy or wholesaler in California. Millenium held the patent for 10 Releana®, a medication containing the human chorionic gonadotropin ("HCG") as an active 11 ingredient. HCG formulations are used to facilitate weight loss and body contouring. According 12 to Respondent Schapiro, Millenium was responsible for marketing Releana® and receiving orders 13 from physicians throughout the country for Respondent CPCC to fill. Millenium processed the 14 orders and invoiced the physicians. Millenium then e-mailed the order form and a "Prescription 15 Fill-in Form" to CPCC. The Prescription Fill-in Form contained prescriptions written for each 16 patient and is further described in paragraph 34(c), below. 17

According to Respondent Schapiro, after CPCC received a prescription for Releana® 33. 18 by e-mail, CPCC processed the prescription, compounded the Releana® vehicle, which is a 19 proprietary formula, and packaged the HCG in a separate container. CPCC dispensed the 20 medication in a Ziploc bag with a prescription label with the patient's name, prescription number, -21 the instruction to "Use as directed by physician," the prescribing physician, the date dispensed 22 and the expiration date. Releana® was dispensed in the form of a small vial containing the HCG 23 powder and a larger bottle containing the Releana® vehicle, a buffered solution. The medication 24 was shipped to the prescribing physician's office where the medication was mixed by the 25 physician and the larger container was dispensed to the patient. Millenium paid CPCC for all 26 materials and dispensing fees. 27

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34. In addition to physicians in California, Millenium sold Releana® to physicians in 1 Alabama, Arizona, Florida, Georgia, Hawaii, Iowa, Illinois, Indiana, Maryland, Missouri, 2 Mississippi, Nebraska, Nevada, New York, Ohio, Oklahoma, South Carolina, Texas, Virginia and 3 Washington. Respondent CPCC compounded the medication for dispensing to physicians in 4 these states. 5

35. On March 8, 2011, Board inspectors conducted further investigation of CPCC's 6 practice regarding dispensing Releana[®]. The process by which Releana[®] was ordered was as 7 follows: 8

9 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 10 Releana® logo. 11

The order was processed by Millenium. A packing slip was generated with the b. 12 quantity purchased, the payment method (credit card name) and the amount due from the 13 prescriber. 14

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

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i) the packing slip with Releana®'s logo for the quantity ordered and addressed to 16 the physician;

ii) an order form with the name, address and telephone number of the physician, the 18 description of the drug ("human chorionic gonadotropin proprietary formula") and the 19 quantity ordered; and, 20

iii) a Prescription Fill-in Form with the prescriber's information and two columns of 21five boxes to fill in the patient's name, address, telephone number, the pre-printed 22 description of the drugs as "Human Chorionic Gonadotropin proprietary formula" and 23 quantity to either select from "[1], [2], or [3]" or to fill in. The prescription form did not 24 state the date each prescription was written nor the strength of the drug. 25

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

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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:

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

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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.

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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

14 38. A review of the original prescriptions revealed that the Releana® prescriptions for 15 each patient were cut out from the prescription form sent by Millenium to CPCC and affixed to a 16 blank telephone prescription pad. A date was stamped on the prescription pads that appeared to 17 be the date the prescriptions were filled. The prescriptions contained the name and address of the 18 patient, the pre-printed drug name "human chorionic gonadotropin proprietary formula" and the 19 provider's signature. The prescriptions did not have the strength of HCG and the quantity 20 prescribed was specified in units of "1", "2" or "3." There were no notations on the prescriptions 21 indicating the pharmacist verified the prescriptions with the physicians since the prescriptions. 22 were electronically received from Millenium instead of from the prescribing physicians. Many of 23 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

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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

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(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.

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1	b. The electronically transmitted prescriptions for Releana® were not valid in that the
2	prescriptions were received by CPCC from Millenium instead of the prescriber and were not
3	verified with the prescribing physician by the CPCC.
4	c. The electronically transmitted prescriptions for Releana® that were produced into a
5	hard copy did not bear the date the prescription was transcribed or the signature of the
6	transcribing pharmacist.
7	d. The electronically transmitted prescriptions for Releana® did not have the name of
8	the person at the prescriber's office who transmitted the prescriptions.
9	THIRD CAUSE FOR DISCIPLINE
10	AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER
11	AND DAVID JOSEPH SCHAPIRO
12	(Selling to Unlicensed Entity)
13	42. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section
14	4301, subdivision (o) for violation of section 4169, subdivision (a)(1), for selling dangerous drugs
15	to an entity not licensed by the Board. Respondents compounded and sold Releana ${ m I\!R}$ to
16	Millenium, an entity not licensed by the Board as a pharmacy or wholesaler in California, as is
17	more fully set forth in paragraphs $29 - 38$, which are incorporated by this reference as though set
18	forth in full herein.
19	FOURTH CAUSE FOR DISCIPLINE
20	AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER
-21-	AND DAVID JOSEPH SCHAPIRO
22	(Selling Misbranded Drugs)
23	43. Respondents CPCC and Schapiro are subject to discipline pursuant to Code sections
24	4301, subdivisions (j) and (o) for violation of section 4169, subdivision (a)(3), and Health and
25	Safety Code sections 11130, 111440 and 11340, for selling, delivering, transferring, holding or
26	offering for sale, any drug that Respondents knew or should reasonably have known were
27	misbranded. The Releana® drugs were misbranded in that the label affixed to each individual
28	container of Releana® powder and Releana® vehicle, did not specify the name and address of the
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	Accusation

1	manufacturer, packer or distributor and they did not specify the quantity of the contents of each of		
2	the two containers sold in terms of weight or measure, as is more fully set forth in paragraphs 29-		
3	38, which are incorporated by this reference as though set forth in full herein.		
4	FIFTH CAUSE FOR DISCIPLINE		
5	AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER		
6	AND DAVID JOSEPH SCHAPIRO		
7	(Dispensing Incorrectly Labeled Prescriptions)		
8	44. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section		
9	4301, subdivision (o) for violation of section 4076, subdivision (a)(7) and (8) and title 16, CCR,		
10	1735.4, for dispensing incorrectly labeled Releana® prescriptions in that Respondents dispensed		
11	Releana® with prescription labels that did not state the concentration or strength of the active		
12	ingredient nor the quantity of the drug dispensed, either in volume, weight or numerical count, as		
13	is more fully set forth in paragraphs $29 - 38$, which are incorporated by this reference as though		
14	set forth in full herein.		
15	SIXTH CAUSE FOR DISCIPLINE		
16	AGAINST CALIFORNIA PHARMACY AND COMPOUNDING CENTER		
17	AND DAVID JOSEPH SCHAPIRO		
18	(Aiding or Abetting Millenium in Sale of Controlled Substances)		
19	45. Respondents CPCC and Schapiro are subject to discipline pursuant to Code section		
20	4301, subdivision (o) for assisting in or abetting the violation of Code section 4110 by Millenium,		
21	in that Millenium sold Releana® to physicians in California, among other states, without having a		
22	license as a pharmacy or wholesaler in the State of California, as more fully set forth in		
23	paragraphs $29 - 38$ and incorporated by this reference as though set forth in full herein.		
24	PRAYER		
25	WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,		
26	and that following the hearing, the Board of Pharmacy issue a decision:		
27	1. Revoking or suspending Pharmacy Permit Number PHY 49828 issued to California		
28	Pharmacy and Compounding Center;		
	15		
	Accusation		

12. Revoking or suspending Sterile Compounding License Number LSC 99542 issued to2California Pharmacy and Compounding Center;

3 3. Revoking or suspending Pharmacist License Number RPH 26704 issued to David
4 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;

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

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

12 DATED 13 14

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IRGINIA ROLD

Executive Officer Board of Pharmacy Department of Consumer Affairs State of California *Complainant*

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