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

In the Matter of the Second Amended Accusation Against: **KOHANA PHARMACY AND CENTER FOR REGENERATIVE MEDICINE, INC. DBA KOHANA PHARMACY AND CENTER FOR REGENERATIVE MEDICINE, ROBERT DENIS QUINN, OWNER** 181 Tank Farm Rd., #120 San Luis Obispo, CA 93401 **Pharmacy Permit No. PHY 50264,** **ROBERT DENIS QUINN** 7475 Balboa Road Atascadero, CA 93422 **Pharmacist License No. RPH 32154,** **NATALIYA McELROY MILLER** 522 Playa Circle Paso Robles, CA 93446 **Pharmacist License No. RPH 70014** and **ANTHONY SINCONIS,** PO Box 75 Avila Beach, CA 93424 **Pharmacist License No. RPH 71144** Respondents.	Case No. 5556 **SECOND AMENDED ACCUSATION**

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 20, 2010, the Board of Pharmacy issued Pharmacy Permit Number PHY 50264 to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine (Respondent Pharmacy). Pursuant to the Board's records, both Alan James Martin and Robert Denis Quinn are and have been a director and 50% shareholder of Respondent Pharmacy from April 20, 2010 to April 1, 2015. Robert Denis Quinn is and has been the President, 100% shareholder from April 1, 2015 to the present. Alan James Martin, Pharmacist License No. RPH 37337[1] (Pharmacist Martin) was the Pharmacist-in-Charge of Respondent Pharmacy from April 20, 2010 to October 16, 2013. Respondent Robert Denis Quinn is and has been the Pharmacist-in-Charge of Respondent Pharmacy from November 16, 2013 to the present. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2018, unless renewed.

3. On or about May 26, 2010, the Board issued Sterile Compounding License Number LSC 99609 to Respondent Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine (Respondent Pharmacy). The Sterile Compounding License expired on April 1, 2017, and was not been renewed. Respondent Pharmacy voluntarily surrendered the Sterile Compounding License effective August 24, 2017.

4. On or about August 3, 1978, the Board of Pharmacy issued Pharmacist License Number RPH 32154 to Robert Denis Quinn (Respondent Quinn). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2018, unless renewed.

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[1] Alan James Martin entered into a stipulated settlement of Accusation No. 5556, which was adopted by the Board, effective May 19, 2017.

5. On or about October 11, 2013, the Board of Pharmacy issued Pharmacist License Number RPH 70014 to Nataliya McElroy Miller (Respondent Miller). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2019, unless renewed.

6. On or about August 26, 2014, the Board of Pharmacy issued Pharmacist License Number RPH 71144 to Anthony Sinconis (Respondent Sinconis). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2017, unless renewed.

JURISDICTION

7. 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.

8. Section 4300 provides in pertinent part, that every license issued by the Board is subject to discipline, including suspension or revocation.

9. 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."

10. Section 4113, subdivision (c), states that "[t]he 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."

11. 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."

12. Section 4033 of the Code states, in part:

"(a)(1) 'Manufacturer' means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer."

13. 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 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."

14. Section 4306.5 of the Code states, in part:

"Unprofessional conduct for a pharmacist may include any of the following:

"(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

"(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services."

15. Section 4307, subdivision (a), of the Code states:

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

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

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

(b) Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

16. Section 4081 of the Code states, in part:

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

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

REGULATORY PROVISIONS

17. California Code of Regulations, title 16, section 1770, states:

"For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare."

18. California Code of Regulations 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."

19. California Code of Regulations, title 16, section 1735.2, states, in part:

"(a) Except as specified in (b) and (c), no drug preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

. . .

"(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.
(2) Equipment to be used.
(3) Expiration dating requirements.
(4) Inactive ingredients to be used.
(5) Process and/or procedure used to prepare the drug.
(6) Quality reviews required at each step in preparation of the drug.
(7) Post-compounding process or procedures required, if any.

. . .

"(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

"(g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.\

...

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

...

(3) Extension of a beyond use date is only allowable when supported by the following:
(A) Method Suitability Test,
(B) Container Closure Integrity Test, and C) Stability Studies.
(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation."

20. California Code of Regulations, title 16, section 1735.3, states:

"(a) For each compounded drug product, the pharmacy records shall include:
(1) The master formula record.
(2) The date the drug product was compounded.
(3) The identity of the pharmacy personnel who compounded the drug product.
(4) The identity of the pharmacist reviewing the final drug product.
(5) The quantity of each component used in compounding the drug product.
(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.

Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia--National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

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

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

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

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

"(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.

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

21. California Code of Regulations, title 16, section 1735.5, states:

"(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

"(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

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

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.

(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.

(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.

(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products."

(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products."

22. California Code of Regulations, title 16, section 1735.6, subdivision (b), states:

"(b) Any equipment used to compound drug preparations shall be stored, used, maintained, and cleaned in accordance with manufacturers' specifications."

23. California Code of Regulations, title 16, sections 1735.8, subdivision (b), states:

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

24. California Code of Regulations, title 16, section 1751.1(a), states:

"(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber."

25. California Code of Regulations, title 16, section 1751.4 subdivision (d)(1)

"(d) Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.

(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters."

26. California Code of Regulations, title 16, section 1751.6 states, in part:

"(e) Pharmacies that compound sterile drug preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

(C) Sterile preparation compounding documentation.

(D) Quality assurance procedures.

(E) Aseptic preparation procedures.

(F) Proper hand hygiene, gowning and gloving technique.

(G) General conduct in the controlled area (aseptic area practices).

(H) Cleaning, sanitizing, and maintaining of the equipment and the controlled area.

(I) Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.

(J) Container, equipment, and closure system selection.

(2) Each person engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs

must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years."

27. California Code of Regulations, title 16, section 1761(a),

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

COST RECOVERY

28. Section 125.3 of the Code provides, 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, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

AVASTIN

29. Avastin (bevacizumab) is a dangerous drug pursuant to Section 4022. It is used to treat various cancers. It is usually given as an infusion. Avastin is restricted for purchase to hospital, federal accounts, physician's offices, and authorized specialty pharmacies. Avastin does not contain any preservatives, and, therefore, is meant for immediate one time use. Any unused portions left in a vial of Avastin should be discarded. Diluted Avastin solutions may be stored at 2–8°C (36–46°F) for up to 8 hours. Avastin is available in a 100mg/4ml (also referred to as 25mg/ml 4ml) single use vial and a 400mg/16ml single use vial.

30. Avastin has an off label use in the treatment of macular degeneration. Avastin is commercially available in a much larger quantity vial than is needed for a single dose administration in the treatment of eye disease. Generally, the 4ml vial is used to produce between 50 to 80 doses. Dividing a vial of Avastin into numerous tiny doses for injection into the eye introduces the risk of bacterial contamination, which may cause severe eye infections and

blindness. Pharmacies compounding Avastin must adhere to the sterile techniques and standards outlined in USP Chapter 797.[2]

31. The Federal Food and Drug Administration (FDA) has approved Lucentis (ranibizumab), a similar product on the market, for treatment of macular degeneration. It is supplied as a single ophthalmic dose. There is a significant price difference between Lucentis and Avastin. Lucentis cost approximately $2,000 per dose compared to Avastin's cost of approximately $30 to $50 per dose once compounded.

FACTUAL SUMMARY

32. On or about February 19, 2013, French Hospital Medical Center (French Hospital), located at 1911 Johnson Avenue, San Luis Obispo, California, notified the Board that employees of French Hospital, one of which was Pharmacist Martin's wife, were ordering Avastin through the French Hospital Pharmacy and reselling it to Respondent Pharmacy and Center for Regenerative Medicine (Respondent Pharmacy). Respondent Pharmacy paid in cash for the Avastin. According to French Hospital, there were 12 orders of Avastin placed and received on Respondent Pharmacy's behalf over the course of 15 months (November 2011 through January 15, 2013). None of these 12 orders were needed or used by French Hospital patients and there was no on-hand inventory of Avastin. French Hospital did not maintain any accounting records of Respondent Pharmacy's Avastin orders and payments. French Hospital tracked the orders through the hospital's vendors. French Hospital did not provide Respondent Pharmacy with any invoices for the Avastin and Respondent Pharmacy did not provide any receipts for its payments. There was no paper documentation that showed how much Respondent Pharmacy paid for each order or for which orders payments had been received.

[2] USP Chapter 797 "provides procedures and requirements for compounding sterile preparations. General Chapter 797 describes conditions and practices to prevent harm to patients that could result from microbial contamination, excessive bacterial endotoxins, variability in intended strength, unintended chemical and physical contaminants, and ingredients of inappropriate quality in compounded sterile preparations." ("USP–NF General Chapters for Compounding." *USP NF Compounding General Chapters*. N.p., n.d. Web. 30 Oct. 2015.)

33. The Board's investigation revealed that from November 2011 through January 15, 2013, Respondent Pharmacy purchased 19 to 21 vials of Avastin 25mg/ml 4ml[3] from French Hospital, and that records of purchase and sale were not maintained.[4]

34. The Board's investigation also revealed that from August 15, 2011, through February 12, 2013, 1997 syringes of Avastin were dispensed by Respondent Pharmacy.[5] Respondent Pharmacy compounded the 1997 non-patient specific doses of Avastin for off label ophthalmic use and sold it to a few physicians' offices to treat patients with macular degeneration. Pharmacist Martin and Respondent Quinn were responsible for compounding the Avastin ophthalmic preparations. Of the 1997 doses, Pharmacist Martin was responsible for at least 1917 doses and Respondent Quinn was responsible for at least 80 doses. During this period, Pharmacist Martin was the pharmacist-in-charge of Respondent Pharmacy. Respondent Pharmacy was not licensed as a drug manufacturer.

35. Respondent Pharmacy did not maintain any compounding records or any documentation on sterility testing or beyond use dating (expiration date).

36. The dose dispensed by Respondent Pharmacy was 0.05 ml =1.25mg Avastin. Each vial of 100mg/4ml should yield 80 doses. The product was transferred into 1ml tuberculin syringes. This altered the dosage form and delivery system from intravenous (IV) to intra-ocular injection.

37. Respondent Quinn stated that Respondent Pharmacy usually used one vial of Avastin per prescription, but when there was any product remaining, the remainder was put into the pharmacy's refrigerator with an expiration date of 30 days. If that product was used for a prescription, Respondent Pharmacy would base the expiration of that product off of the 30 days.

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[3] The invoices from French Hospital's vendors refer to the vials purchased as Avastin 25mg/ml 4ml or Avastin 100mg/4ml. Each ml of concentrate contains 25mg of Avastin. Each 4ml vial contains 100mg of Avastin.

[4] Respondent Pharmacy's records showed it purchased 19 vials of 4ml Avastin for a purchase amount of approximately $11,823.32. French Hospital stated they sold 21 vials of 4ml Avastin to Respondent Pharmacy for the amount of $12,058.88. There was a discrepancy of 2 vials and $1,235.56. The discrepancy could not be explained due to the incomplete record keeping on the part of both Respondent Pharmacy and French Hospital.

[5] Prior to purchasing Avastin from French Hospital, the prescribing physicians provided Respondent Pharmacy with Avastin to compound into syringes.

The Board's inspector determined that there was no vial of Avastin that was completely dispensed by Respondent Pharmacy prior to the purchase of the next vial. The time between the first dose compounded from a vial and the last dose compounded from the same vial was greater than 8 hours, which was the time the manufacturer stated the diluted medication should be discarded. The shortest amount of time noted for an open vial being used for compounding at Respondent Pharmacy was approximately 11 days.

FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Acquisition)

38. Respondent Pharmacy is subject to disciplinary action under section 4301, subdivisions (j) and (o), on the grounds of unprofessional conduct, in that they failed to comply with section 4081, subdivision (a), by failing to maintain records of acquisition of dangerous drugs. Specifically, between November 2011 and January 15, 2013, while Pharmacist Martin was working as the pharmacist-in-charge, Respondent Pharmacy purchased between 19 and 21 vials of Avastin 25mg/ml 4ml, from French Hospital and failed to maintain records of purchase. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 32 through 37, as if set forth in full herein.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Required Compounding Records)

39. Respondents Pharmacy and Quinn are subject to disciplinary action under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1735.3, subdivisions (a) and (b). Specifically, between August 15, 2011, through February 12, 2013, while Pharmacist Martin was working as the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vials to compound Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondent Pharmacy compounded 1997 doses of Avastin. Respondent Quinn was responsible for at least 80 doses. Respondents did not maintain compounding records. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 32 through 37, as if set forth in full herein.

THIRD CAUSE FOR DISCIPLINE

(Failure to Comply with Sterile Injectable Recordkeeping Requirements)

40. Respondents Pharmacy and Quinn are subject to disciplinary action under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1751.1, subdivision (a), by failing to keep the required records for sterile injectable products. Specifically, from August 15, 2011, to February 12, 2013, while Pharmacist Martin was working as the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vial to compound Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondents compounded 1997 doses and failed to maintain records indicating the name, lot number, amount, and date on which the products were provided to a prescriber. Respondent Quinn was responsible for at least 80 doses. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 32 through 37, as if set forth in full herein.

FOURTH CAUSE FOR DISCIPLINE

(Acting as a Drug Manufacturer without a Permit)

41. Respondents Pharmacy and Quinn are subject to disciplinary action under section 4301, subdivisions (j) and (o), on the grounds of unprofessional conduct, in conjunction with Section 4033, subdivision (a)(1), for acting as a drug manufacturer without a permit. Specifically, from August 15, 2011 to February 12, 2013, while Pharmacist Martin was working as the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vials to compound 1997 Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondent Quinn was responsible for at least 80 doses. The product was transferred into 1ml tuberculin syringes, which changed the dosage form and delivery system from intravenous (IV) to intra-ocular injection. Respondents then sold the 1997 non-patient specific doses to physicians' offices to use on their patients. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 32 through 37, as if set forth in full herein.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Comply with Compounding Limitations and Requirements)

42. Respondents Pharmacy and Quinn are subject to disciplinary action under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1735.2, subdivisions (d),(f), and (g), for compounding without adhering to compounding limitations and requirements. Specifically, from August 15, 2011 to February 12, 2013, while Pharmacist Martin was working as the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vials to compound Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondent Pharmacy compounded 1997 doses and failed to maintain a written master formula, ensure integrity, potency, quality and labeled strength of the product, and used drug products in compounding that had exceeded the manufacturer and USP 797 beyond use dating. Respondent Quinn was responsible for at least 80 doses. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 32 through 37, as if set forth in full herein.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Comply with the Required Compounding Policies and Procedures)

43. Respondents Pharmacy and Quinn are subject to disciplinary action under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1735.5, subdivision (c), which requires that a pharmacy's policy and procedure manual include the following: "(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products." Specifically, from August 15, 2011 to February 12,2013, while Pharmacist Martin was working as the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vial to compound Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondent Pharmacy compounded 1997 doses and failed to document the methodology used to establish a beyond use date that exceeded the manufacturer's and USP 797 guidelines. Respondent Quinn was responsible for at least 80 doses. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 32 through 37, as if set forth in full herein.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Exercise Professional Judgment)

44. Respondent Quinn is subject to discipline pursuant to Code section 4301, subdivisions (j) and (o), on the grounds of unprofessional conduct, in that he failed to exercise professional judgment, in violation of Code section 4306.5, subdivision (a). Specifically, from August 15, 2011 to February 12, 2013, Pharmacist Martin and Respondent Quinn used Avastin 25mg/ml 4ml vials to compound Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. They failed to follow USP 797 guidelines and failed to establish the beyond use date (expiration date) for a preservative-free single dose vial used in the compounding of Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. The beyond use date of 30 days given to the ophthalmic compounded Avastin 0.05ml syringes exceeded the manufacturers beyond use date and exceeded USP 797 guidelines. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 32 through 37, as if set forth in full herein.

EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

45. Respondent Quinn is subject to disciplinary action under section 4301 for unprofessional conduct. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 32 through 44, as if set forth in full herein.

MARCH 2017 INSPECTION

46. On or about March 13, 2017, and March 14, 2017, a Board inspector performed an annual inspection of Respondent's facilities, which revealed the following:

47. Respondent Pharmacy was performing "high risk" non-sterile to sterile compounding and was generally compounding TriMix (an injectable prescription medication used to treat erectile dysfunction), other injections, and a large volume of eye drops. Respondent was compounding prednisolone phosphate 1% / moxifloxacin HCL 0.5% / bromfenac sodium 0.09% (Steroid / Anti-Infective / NSAID) and prednisolone sodium phosphate 1% / moxifloxacin HCL 0.5% (Steroid /Anti-Infective) combination eye drops. These eye drops are instilled into a

patient's eye before and after eye surgery. Sterility of these eye drops is critical for the patient's health and eyesight.

48. Respondent Pharmacy used a filter for end product sterilization (for eye drops) that was not made to be a sterilizing grade filter. ThermoScientific, the product manufacturer, states in the product information: "Filter Assembly [is] not intended as a final sterilization filter".

49. Respondent Pharmacy placed extended "beyond use date" or BUD[6] on compounded eye drops without performing the required tests such as method suitability, container closure integrity, or stability studies to support such extended BUD. Respondent Pharmacy specifically compounded small lots of ophthalmic solution for extended BUD testing that were compounded using a *sterilization grade filter*, and then placed the extended BUDs from the testing of these lots to much larger lots of compounded ophthalmic solution that were compounded using a *non-sterilizing filter* and used additional compounding steps. These tested and untested batches were not identical in specific and essential compounding steps.

50. During the Board's investigation, Respondent Pharmacy was unable to provide the Board with documentation demonstrating that its sterile compounding staff possesses the necessary knowledge and skill to perform their assigned tasks properly. Respondent did not have a comprehensive written program of sterile compounding training for employees, what and how they would be trained on all required subjects, and documentation after the training was completed.

51. Respondent Pharmacy failed to have each person engaged in sterile compounding successfully complete the required skills training and failed to have pharmacy personnel in the supervision of sterile compounding be qualified to do so.

52. Respondent Pharmacy's employees were not aware of daily cleaning requirements and did not understand the reason for daily cleaning, the use of a sterilization grade filter to sterilize a solution from non-sterile ingredients, and the testing required to ensure appropriateness of an extended BUD.

[6] Compounded drugs have a "beyond use date" or BUD after which the drug should not be used, stored, or administered (expiration date).

NINTH CAUSE FOR DISCIPLINE

(Failure to follow manufacturer's instructions)

53. Respondents Pharmacy, Quinn, and Sinconis are subject to disciplinary action under section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.6, subdivision (b), by failing to ensure equipment used to compound drug preparations was in accordance with manufacturer's specifications. Specifically, Respondent Pharmacy used a Thermo Fisher Filter Assembly, product number SH00055-I, as the sterilization method to prepare a sterile compound from one or more non-sterile ingredients. The product page for the Thermo Fisher Filter Assembly stated "Filter Assembly is not intended as a final sterilization filter." Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 46 through 52, as if set forth in full herein.

TENTH CAUSE FOR DISCIPLINE

(Failure to Perform the Tests Required for Extended Beyond Use Date)

54. Respondents Pharmacy, Quinn, and Sinconis are subject to disciplinary action under section 4301, subdivision (o), for violating California Code of Regulations Section 1735.2, subdivision (i)(3), by failing to ensure the required valid testing was completed prior to dispensing of compounded preparations with extended beyond use dates. Specifically, Respondent Pharmacy dispensed ophthalmic preparations, compounded from one or more non-sterile ingredients, with extended beyond use dates that were not supported by required testing. Lot # 02152017@9 was given a beyond use date of 180 days based on data from testing lot # 05062015@26. Respondent Pharmacy could not provide data to support the required Method Suitability Test, Container Closure Integrity Test and Stability Studies for lot # 02152017@9. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 46 through 52, as if set forth in full herein.

ELEVENTH CAUSE FOR DISCIPLINE

(Using Invalid Extended Beyond Date)

55. Respondents Pharmacy, Quinn, and Sinconis are subject to disciplinary action under section 4301, subdivision (o), for violating California Code of Regulations Section 1735.2

subdivision (i)(4), by using extended beyond date that was invalid for current compounding process. Specifically, Respondent Pharmacy used compounded preparation lot # 12152016@13 (compounded from one or more non-sterile ingredients) for testing to establish the extended beyond use date applied to lot # 02132017@1, which was not identical in specific and essential compounding steps. Respondent Pharmacy used compounded preparation lot # 05062015@26 (compounded from one or more non-sterile ingredients) for extended beyond use dating for lot # 02152017@9, which was not identical in specific and essential compounding steps. Respondent Pharmacy compounded a preparation for testing for extended beyond use date. The extended beyond use date was assigned to a current compounded preparation (compounded from one or more non-sterile ingredients) which did not utilize the same essential compounding processes. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 46 through 52, as if set forth in full herein.

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Clean ISO 5 Surfaces Daily)

56. Respondents Pharmacy, Quinn, and Sinconis are subject to disciplinary action under section 4301, subdivision (o), for violating California Code of Regulations Section 1751.4, subdivision (d)(1) by failing to clean daily the sterile compounding area, particularly the ISO Class 5 surfaces. Specifically, on March 13, 2017, and March 14, 2017, a Licensed Sterile Compounding renewal inspection revealed that Respondent Pharmacy performed sterile compounding only once or twice a week and the compounding days were the only days the sterile compounding area, including ISO 5 area, were cleaned. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 46 through 52, as if set forth in full herein.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Adequately Train Sterile Compounding Staff)

57. Respondents Pharmacy, Quinn, and Miller are subject to disciplinary action under section 4301, subdivision (o), for violating California Code of Regulations Section 1751.6 subdivision (e)(1) and (e)(2) and California Code of Regulations Sections 1735.8, subdivision (b),

by failing to adequately train sterile compounding staff. Specifically, Respondent Pharmacy failed to have a written program addressing all the required training for sterile compounding and documenting the training and failed to have pharmacy personnel in the supervision of sterile compounding be qualified to do so. Respondent Miller had no documented training on aseptic techniques and aseptic area practices, yet she was the pharmacist directly responsible for verifying the sterile compounding training of Respondent Sinconis, the main compuonding pharmacist at the pharmacy. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 46 through 52, as if set forth in full herein.

FOURTEENTH CAUSE FOR DISCIPLINE

(Unlicensed Activity: Acting as a Manufacturer)

58. Respondents Pharmacy, Quinn, and Miller are subject to disciplinary action under section 4033, subdivision (a)(1), and California Code of Regulations Section 1735.2 subdivision (a), by acting as a manufacturer in preparation of compounded ophthalmic solutions for dispensing to physician offices under the pretense of patient specific prescriptions. Specifically Respondent Pharmacy dispensed ophthalmic solutions pursuant to prescriptions which did not contain all of the required elements of a valid prescription, such as individual patient addresses or patient directions. Prescriptions were dispensed in amounts greater than a reasonable quantity for a specific patient, such as: Rx# 127104 dispensed to K.S. for 30ml on March 1, 2017, and March 7, 2017. The ophthalmic solution compounded preparations were labeled with and placed in an individual box that resembled a professionally manufactured product. Respondent Pharmacy had a preprinted prescription form with ophthalmic drops listed. Respondent Pharmacy's pre-printed prescription form had a number resembling a FDA issued National Drug Code listed in front of each type of ophthalmic solution; such as found with Rx #127106, Rx# 127104, and Rx# 127335. Respondent Pharmacy prepared large volume batches of the ophthalmic solution combination prednisolone sodium1%/moxifloxacin HCL 0.5%/bromfenac sodium 0.09%: 648 containers on February 13, 2017, and 552 containers on February 27, 2017; and 276 containers of prednisolone sodium 1%/moxifloxacin 0.5% on February 15, 2017. When recalling 121 containers of ophthalmic solution, Respondent Pharmacy only contacted 6 individual patients and prescribers

were contacted to return the remaining 115 dispenses. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 46 through 52, as if set forth in full herein.

FIFTEENTH CAUSE FOR DISCIPLINE

(Erroneous or Uncertain Prescriptions)

59. Respondents Pharmacy, Quinn, and Miller are subject to disciplinary action under section 4301, subdivision (o), for violating California Code of Regulations Section 1761(a), by dispensing dangerous drugs without first contacting the prescribers to obtain the needed information on uncertain, ambitious, and irregular prescriptions. Specifically, Respondent Pharmacy dispensed ophthalmic solutions pursuant to prescriptions which did not contain all of the required elements of a valid prescription, such as individual patient addresses or patient directions. Prescriptions were dispensed in amounts greater than a reasonable quantity for a specific patient, such as: Rx# 127104 dispensed to K.S. for 30ml on March 1, 2017, and March 7, 2017. The ophthalmic solution compounded preparations were labeled and placed in an individual box that resembled a professionally manufactured product. Respondent Pharmacy had a preprinted prescription form with ophthalmic drops listed. Respondent Pharmacy's pre-printed prescription form had a number resembling a FDA issued National Drug Code listed in front of each type of ophthalmic solution; such as found with Rx #127106, Rx# 127104, and Rx# 127335. Respondent Pharmacy prepared large volume batches of the ophthalmic solution combination prednisolone sodium1%/moxifloxacin HCL 0.5%/bromfenac sodium 0.09%: 648 containers on 2/13/17 and 552 containers on 2/27/17; and 276 containers of prednisolone sodium 1%/moxifloxacin 0.5% on 2/15/17. When recalling 121 containers of ophthalmic solution, Respondent Pharmacy only contacted 6 individual patients, and prescribers were contacted to return the remaining 115 dispenses. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 46 through 58, as if set forth in full herein.

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SIXTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

60. Respondents are subject to disciplinary action under section 4301 for unprofessional conduct. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 32 through 59, as if set forth in full herein.

DISCIPLINARY CONSIDERATIONS

61. To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy, Complainant alleges the following:

Respondent Pharmacy

62. On or about February 18, 2014, in a prior action, the Board issued Citation Number CI 2012 57004 to Kohana Pharmacy and Center for Regenerative Medicine, PHY 50264 for violating California Code of Regulations, title 16, section 1717.3, subdivision (b) (dispensing a controlled substance pursuant to a preprinted multiple check-off prescription blank) and fined $2,000. Specifically, from a date unknown through July 31, 2013, Respondent Pharmacy filled 1087 prescription orders containing ketamine, a controlled substance, pursuant to a preprinted, multiple check-off prescription blank. That Citation is now final and is incorporated by reference as if fully set forth.

OTHER MATTERS

63. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50264 issued to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center For Regenerative Medicine, Kohana Pharmacy and Center For Regenerative Medicine, Inc. shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50264 is placed on probation or until Pharmacy Permit Number PHY 50264 is reinstated if it is revoked.

64. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50264 issued to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center For Regenerative Medicine while Robert Denis Quinn has been an

officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Robert Denis Quinn shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50264 is placed on probation or until Pharmacy Permit Number PHY 50264 is reinstated if it is revoked.

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 50264, issued to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine;

2. Revoking or suspending Pharmacist License Number RPH 32154, issued to Robert Denis Quinn;

3. Revoking or suspending Pharmacist License Number RPH 70014 issued to Nataliya McElroy Miller;

4. Revoking or suspending Pharmacist License Number RPH 71144 issued to Anthony Sinconis;

5. Prohibiting Kohana Pharmacy and Center for Regenerative Medicine, Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49140 is placed on probation or until Pharmacy Permit Number PHY 49140 is reinstated if Pharmacy Permit Number 49140 issued to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine is revoked;

6. Prohibiting Robert Denis Quinn from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49140 is placed on probation or until Pharmacy Permit Number PHY 49140 is reinstated if Pharmacy Permit Number PHY 49140 issued to Kohana Pharmacy and Center for

Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine is revoked;

7. Ordering Respondents 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. Taking such other and further action as deemed necessary and proper.

DATED: 3/28/18

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 First Amended Accusation Against: **KOHANA PHARMACY AND CENTER FOR REGENERATIVE MEDICINE, INC. DBA KOHANA PHARMACY AND CENTER FOR REGENERATIVE MEDICINE, ROBERT DENIS QUINN, OWNER** 181 Tank Farm Rd., #120 San Luis Obispo, CA 93401 **Pharmacy Permit No. PHY 50264,** **ROBERT DENIS QUINN** 7475 Balboa Road Atascadero, CA 93422 **Pharmacist License No. RPH 32154,** **NATALIYA McELROY MILLER** 522 Playa Circle Paso Robles, CA 93446 **Pharmacist License No. RPH 70014** and **ANTHONY SINCONIS,** PO Box 75 Avila Beach, CA 93424 **Pharmacist License No. RPH 71144** Respondents.	Case No. 5556 **FIRST AMENDED ACCUSATION**

Complainant alleges:

PARTIES

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

2. On or about April 20, 2010, the Board of Pharmacy issued Pharmacy Permit Number PHY 50264 to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine (Respondent Pharmacy). Pursuant to the Board's records, both Alan James Martin and Robert Denis Quinn are and have been a director and 50% shareholder of Respondent Pharmacy since April 20, 2010. Alan James Martin, Pharmacist License No. RPH 37337[1] (Pharmacist Martin) was the Pharmacist-in-Charge of Respondent Pharmacy from April 20, 2010 to October 16, 2013. Respondent Robert Denis Quinn has been the Pharmacist-in-Charge of Respondent Pharmacy from November 16, 2013 to the present. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2018, unless renewed.

3. On or about May 26, 2010, the Board issued Sterile Compounding License Number LSC 99609 to Respondent Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine (Respondent). The Sterile Compounding License expired on April 1, 2017, and has not been renewed.[2]

4. On or about August 3, 1978, the Board of Pharmacy issued Pharmacist License Number RPH 32154 to Robert Denis Quinn (Respondent Quinn). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2018, unless renewed.

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[1] Alan James Martin entered into a stipulated settlement of Accusation No. 5556, which was adopted by the Board, effective May 19, 2017.

[2] On or about June 14, 2017, Kohana Pharmacy and Center for Regenerative Medicine, Inc. entered into a Stipulated Surrender, in which it surrendered its Sterile Compounding License Number LSC 99609. The Board's decision on the Stipulated Surrender is pending.

5. On or about October 11, 2013, the Board of Pharmacy issued Pharmacist License Number RPH 70014 to Nataliya McElroy Miller (Respondent Miller). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2019, unless renewed.

6. On or about August 26, 2014, the Board of Pharmacy issued Pharmacist License Number RPH 71144 to Anthony Sinconis (Respondent Sinconis). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2017, unless renewed.

JURISDICTION

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

8. Section 4300 provides in pertinent part, that every license issued by the Board is subject to discipline, including suspension or revocation.

9. 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."

10. Section 4113, subdivision (c), states that "[t]he 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."

11. 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."

12. Section 4033 of the Code states, in part:

"(a)(1) 'Manufacturer' means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer."

13. 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 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."

14. Section 4306.5 of the Code states, in part:

"Unprofessional conduct for a pharmacist may include any of the following:

"(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

"(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services."

15. Section 4307, subdivision (a), of the Code states:

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

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

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

(b) Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

16. Section 4081 of the Code states, in part:

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

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

REGULATORY PROVISIONS

17. California Code of Regulations, title 16, section 1770, states:

"For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare."

18. California Code of Regulations 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."

19. California Code of Regulations, title 16, section 1735.2, states, in part:

"(a) Except as specified in (b) and (c), no drug preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

. . .

"(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.
(2) Equipment to be used.
(3) Expiration dating requirements.
(4) Inactive ingredients to be used.
(5) Process and/or procedure used to prepare the drug.
(6) Quality reviews required at each step in preparation of the drug.
(7) Post-compounding process or procedures required, if any.

. . .

"(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

"(g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.\

...

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

...

(3) Extension of a beyond use date is only allowable when supported by the following:
(A) Method Suitability Test,
(B) Container Closure Integrity Test, and C) Stability Studies.

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation."

20. California Code of Regulations, title 16, section 1735.3, states:

"(a) For each compounded drug product, the pharmacy records shall include:
(1) The master formula record.
(2) The date the drug product was compounded.
(3) The identity of the pharmacy personnel who compounded the drug product.
(4) The identity of the pharmacist reviewing the final drug product.
(5) The quantity of each component used in compounding the drug product.
(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.

Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia--National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

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

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

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

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

"(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.

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

21. California Code of Regulations, title 16, section 1735.5, states:

"(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

"(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

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

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.

(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.

(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.

(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products."

(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products."

22. California Code of Regulations, title 16, section 1735.6, subdivision (b), states:

"(b) Any equipment used to compound drug preparations shall be stored, used, maintained, and cleaned in accordance with manufacturers' specifications."

23. California Code of Regulations, title 16, sections 1735.8, subdivision (b), states:

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

24. California Code of Regulations, title 16, section 1751.1(a), states:

"(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber."

25. California Code of Regulations, title 16, section 1751.4 subdivision (d)(1)

"(d) Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.

(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters."

26. California Code of Regulations, title 16, section 1751.6 states, in part:

"(e) Pharmacies that compound sterile drug preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(A) Aseptic technique.
(B) Pharmaceutical calculations and terminology.
(C) Sterile preparation compounding documentation.
(D) Quality assurance procedures.
(E) Aseptic preparation procedures.
(F) Proper hand hygiene, gowning and gloving technique.
(G) General conduct in the controlled area (aseptic area practices).
(H) Cleaning, sanitizing, and maintaining of the equipment and the controlled area.
(I) Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.
(J) Container, equipment, and closure system selection.

(2) Each person engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs

must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years."

27. California Code of Regulations, title 16, section 1761(a),

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

COST RECOVERY

28. Section 125.3 of the Code provides, 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, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

AVASTIN

29. Avastin (bevacizumab) is a dangerous drug pursuant to Section 4022. It is used to treat various cancers. It is usually given as an infusion. Avastin is restricted for purchase to hospital, federal accounts, physician's offices, and authorized specialty pharmacies. Avastin does not contain any preservatives, and, therefore, is meant for immediate one time use. Any unused portions left in a vial of Avastin should be discarded. Diluted Avastin solutions may be stored at 2–8°C (36–46°F) for up to 8 hours. Avastin is available in a 100mg/4ml (also referred to as 25mg/ml 4ml) single use vial and a 400mg/16ml single use vial.

30. Avastin has an off label use in the treatment of macular degeneration. Avastin is commercially available in a much larger quantity vial than is needed for a single dose administration in the treatment of eye disease. Generally, the 4ml vial is used to produce between 50 to 80 doses. Dividing a vial of Avastin into numerous tiny doses for injection into the eye introduces the risk of bacterial contamination, which may cause severe eye infections and

blindness. Pharmacies compounding Avastin must adhere to the sterile techniques and standards outlined in USP Chapter 797.[3]

31. The Federal Food and Drug Administration (FDA) has approved Lucentis (ranibizumab), a similar product on the market, for treatment of macular degeneration. It is supplied as a single ophthalmic dose. There is a significant price difference between Lucentis and Avastin. Lucentis cost approximately $2,000 per dose compared to Avastin's cost of approximately $30 to $50 per dose once compounded.

FACTUAL SUMMARY

32. On or about February 19, 2013, French Hospital Medical Center (French Hospital), located at 1911 Johnson Avenue, San Luis Obispo, California, notified the Board that employees of French Hospital, one of which was Pharmacist Martin's wife, were ordering Avastin through the French Hospital Pharmacy and reselling it to Respondent Pharmacy and Center for Regenerative Medicine (Respondent Pharmacy). Respondent Pharmacy paid in cash for the Avastin. According to French Hospital, there were 12 orders of Avastin placed and received on Respondent Pharmacy's behalf over the course of 15 months (November 2011 through January 15, 2013). None of these 12 orders were needed or used by French Hospital patients and there was no on-hand inventory of Avastin. French Hospital did not maintain any accounting records of Respondent Pharmacy's Avastin orders and payments. French Hospital tracked the orders through the hospital's vendors. French Hospital did not provide Respondent Pharmacy with any invoices for the Avastin and Respondent Pharmacy did not provide any receipts for its payments. There was no paper documentation that showed how much Respondent Pharmacy paid for each order or for which orders payments had been received.

[3] USP Chapter 797 "provides procedures and requirements for compounding sterile preparations. General Chapter 797 describes conditions and practices to prevent harm to patients that could result from microbial contamination, excessive bacterial endotoxins, variability in intended strength, unintended chemical and physical contaminants, and ingredients of inappropriate quality in compounded sterile preparations." ("USP–NF General Chapters for Compounding." *USP NF Compounding General Chapters*. N.p., n.d. Web. 30 Oct. 2015.)

33. The Board's investigation revealed that from November 2011 through January 15, 2013, Respondent Pharmacy purchased 19 to 21 vials of Avastin 25mg/ml 4ml[4] from French Hospital, and that records of purchase and sale were not maintained.[5]

34. The Board's investigation also revealed that from August 15, 2011, through February 12, 2013, 1997 syringes of Avastin were dispensed by Respondent Pharmacy.[6] Respondent Pharmacy compounded the 1997 non-patient specific doses of Avastin for off label ophthalmic use and sold it to a few physicians' offices to treat patients with macular degeneration. Pharmacist Martin and Respondent Quinn were responsible for compounding the Avastin ophthalmic preparations. Of the 1997 doses, Pharmacist Martin was responsible for at least 1917 doses and Respondent Quinn was responsible for at least 80 doses. During this period, Pharmacist Martin was the pharmacist-in-charge of Respondent Pharmacy. Respondent Pharmacy was not licensed as a drug manufacturer.

35. Respondent Pharmacy did not maintain any compounding records or any documentation on sterility testing or beyond use dating (expiration date).

36. The dose dispensed by Respondent Pharmacy was 0.05 ml =1.25mg Avastin. Each vial of 100mg/4ml should yield 80 doses. The product was transferred into 1ml tuberculin syringes. This altered the dosage form and delivery system from intravenous (IV) to intra-ocular injection.

37. Respondent Quinn stated that Respondent Pharmacy usually used one vial of Avastin per prescription, but when there was any product remaining, the remainder was put into the pharmacy's refrigerator with an expiration date of 30 days. If that product was used for a prescription, Respondent Pharmacy would base the expiration of that product off of the 30 days.

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[4] The invoices from French Hospital's vendors refer to the vials purchased as Avastin 25mg/ml 4ml or Avastin 100mg/4ml. Each ml of concentrate contains 25mg of Avastin. Each 4ml vial contains 100mg of Avastin.

[5] Respondent Pharmacy's records showed it purchased 19 vials of 4ml Avastin for a purchase amount of approximately $11,823.32. French Hospital stated they sold 21 vials of 4ml Avastin to Respondent Pharmacy for the amount of $12,058.88. There was a discrepancy of 2 vials and $1,235.56. The discrepancy could not be explained due to the incomplete record keeping on the part of both Respondent Pharmacy and French Hospital.

[6] Prior to purchasing Avastin from French Hospital, the prescribing physicians provided Respondent Pharmacy with Avastin to compound into syringes.

The Board's inspector determined that there was no vial of Avastin that was completely dispensed by Respondent Pharmacy prior to the purchase of the next vial. The time between the first dose compounded from a vial and the last dose compounded from the same vial was greater than 8 hours, which was the time the manufacturer stated the diluted medication should be discarded. The shortest amount of time noted for an open vial being used for compounding at Respondent Pharmacy was approximately 11 days.

FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Acquisition)

38. Respondent Pharmacy is subject to disciplinary action under section 4301, subdivisions (j) and (o), on the grounds of unprofessional conduct, in that they failed to comply with section 4081, subdivision (a), by failing to maintain records of acquisition of dangerous drugs. Specifically, between November 2011 and January 15, 2013, while Pharmacist Martin was working as the pharmacist-in-charge, Respondent Pharmacy purchased between 19 and 21 vials of Avastin 25mg/ml 4ml, from French Hospital and failed to maintain records of purchase. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 32 through 37, as if set forth in full herein.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Required Compounding Records)

39. Respondents Pharmacy and Quinn are subject to disciplinary action under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1735.3, subdivisions (a) and (b). Specifically, between August 15, 2011, through February 12, 2013, while Pharmacist Martin was working as the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vials to compound Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondent Pharmacy compounded 1997 doses of Avastin. Respondent Quinn was responsible for at least 80 doses. Respondents did not maintain compounding records. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 32 through 37, as if set forth in full herein.

THIRD CAUSE FOR DISCIPLINE

(Failure to Comply with Sterile Injectable Recordkeeping Requirements)

40. Respondents Pharmacy and Quinn are subject to disciplinary action under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1751.1, subdivision (a), by failing to keep the required records for sterile injectable products. Specifically, from August 15, 2011, to February 12, 2013, while Pharmacist Martin was working as the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vial to compound Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondents compounded 1997 doses and failed to maintain records indicating the name, lot number, amount, and date on which the products were provided to a prescriber. Respondent Quinn was responsible for at least 80 doses. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 32 through 37, as if set forth in full herein.

FOURTH CAUSE FOR DISCIPLINE

(Acting as a Drug Manufacturer without a Permit)

41. Respondents Pharmacy and Quinn are subject to disciplinary action under section 4301, subdivisions (j) and (o), on the grounds of unprofessional conduct, in conjunction with Section 4033, subdivision (a)(1), for acting as a drug manufacturer without a permit. Specifically, from August 15, 2011 to February 12, 2013, while Pharmacist Martin was working as the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vials to compound 1997 Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondent Quinn was responsible for at least 80 doses. The product was transferred into 1ml tuberculin syringes, which changed the dosage form and delivery system from intravenous (IV) to intra-ocular injection. Respondents then sold the 1997 non-patient specific doses to physicians' offices to use on their patients. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 32 through 37, as if set forth in full herein.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Comply with Compounding Limitations and Requirements)

42. Respondents Pharmacy and Quinn are subject to disciplinary action under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1735.2, subdivisions (d),(f), and (g), for compounding without adhering to compounding limitations and requirements. Specifically, from August 15, 2011 to February 12, 2013, while Pharmacist Martin was working as the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vials to compound Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondent Pharmacy compounded 1997 doses and failed to maintain a written master formula, ensure integrity, potency, quality and labeled strength of the product, and used drug products in compounding that had exceeded the manufacturer and USP 797 beyond use dating. Respondent Quinn was responsible for at least 80 doses. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 32 through 37, as if set forth in full herein.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Comply with the Required Compounding Policies and Procedures)

43. Respondents Pharmacy and Quinn are subject to disciplinary action under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1735.5, subdivision (c), which requires that a pharmacy's policy and procedure manual include the following: "(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products." Specifically, from August 15, 2011 to February 12,2013, while Pharmacist Martin was working as the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vial to compound Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondent Pharmacy compounded 1997 doses and failed to document the methodology used to establish a beyond use date that exceeded the manufacturer's and USP 797 guidelines. Respondent Quinn was responsible for at least 80 doses. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 32 through 37, as if set forth in full herein.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Exercise Professional Judgment)

44. Respondent Quinn is subject to discipline pursuant to Code section 4301, subdivisions (j) and (o), on the grounds of unprofessional conduct, in that he failed to exercise professional judgment, in violation of Code section 4306.5, subdivision (a). Specifically, from August 15, 2011 to February 12, 2013, Pharmacist Martin and Respondent Quinn used Avastin 25mg/ml 4ml vials to compound Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. They failed to follow USP 797 guidelines and failed to establish the beyond use date (expiration date) for a preservative-free single dose vial used in the compounding of Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. The beyond use date of 30 days given to the ophthalmic compounded Avastin 0.05ml syringes exceeded the manufacturers beyond use date and exceeded USP 797 guidelines. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 32 through 37, as if set forth in full herein.

EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

45. Respondent Quinn is subject to disciplinary action under section 4301 for unprofessional conduct. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 32 through 44, as if set forth in full herein.

MARCH 2017 INSPECTION

46. On or about March 13, 2017, and March 14, 2017, a Board inspector performed an annual inspection of Respondent's facilities, which revealed the following:

47. Respondent Pharmacy was performing "high risk" non-sterile to sterile compounding and was generally compounding TriMix (an injectable prescription medication used to treat erectile dysfunction), other injections, and a large volume of eye drops. Respondent was compounding prednisolone phosphate 1% / moxifloxacin HCL 0.5% / bromfenac sodium 0.09% (Steroid / Anti-Infective / NSAID) and prednisolone sodium phosphate 1% / moxifloxacin HCL 0.5% (Steroid /Anti-Infective) combination eye drops. These eye drops are instilled into a

patient's eye before and after eye surgery. Sterility of these eye drops is critical for the patient's health and eyesight.

48. Respondent Pharmacy used a filter for end product sterilization (for eye drops) that was not made to be a sterilizing grade filter. ThermoScientific, the product manufacturer, states in the product information: "Filter Assembly [is] not intended as a final sterilization filter".

49. Respondent Pharmacy placed extended "beyond use date" or BUD[7] on compounded eye drops without performing the required tests such as method suitability, container closure integrity, or stability studies to support such extended BUD. Respondent Pharmacy specifically compounded small lots of ophthalmic solution for extended BUD testing that were compounded using a *sterilization grade filter*, and then placed the extended BUDs from the testing of these lots to much larger lots of compounded ophthalmic solution that were compounded using a *non-sterilizing filter* and used additional compounding steps. These tested and untested batches were not identical in specific and essential compounding steps.

50. During the Board's investigation, Respondent Pharmacy was unable to provide the Board with documentation demonstrating that its sterile compounding staff possesses the necessary knowledge and skill to perform their assigned tasks properly. Respondent did not have a comprehensive written program of sterile compounding training for employees, what and how they would be trained on all required subjects, and documentation after the training was completed.

51. Respondent Pharmacy failed to have each person engaged in sterile compounding successfully complete the required skills training and failed to have pharmacy personnel in the supervision of sterile compounding be qualified to do so.

52. Respondent Pharmacy's employees were not aware of daily cleaning requirements and did not understand the reason for daily cleaning, the use of a sterilization grade filter to sterilize a solution from non-sterile ingredients, and the testing required to ensure appropriateness of an extended BUD.

[7] Compounded drugs have a "beyond use date" or BUD after which the drug should not be used, stored, or administered (expiration date).

NINTH CAUSE FOR DISCIPLINE

(Failure to follow manufacturer's instructions)

53. Respondents Pharmacy, Quinn, and Sinconis are subject to disciplinary action under section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.6, subdivision (b), by failing to ensure equipment used to compound drug preparations was in accordance with manufacturer's specifications. Specifically, Respondent Pharmacy used a Thermo Fisher Filter Assembly, product number SH00055-I, as the sterilization method to prepare a sterile compound from one or more non-sterile ingredients. The product page for the Thermo Fisher Filter Assembly stated "Filter Assembly is not intended as a final sterilization filter." Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 46 through 52, as if set forth in full herein.

TENTH CAUSE FOR DISCIPLINE

(Failure to Perform the Tests Required for Extended Beyond Use Date)

54. Respondents Pharmacy, Quinn, and Sinconis are subject to disciplinary action under section 4301, subdivision (o), for violating California Code of Regulations Section 1735.2, subdivision (i)(3), by failing to ensure the required valid testing was completed prior to dispensing of compounded preparations with extended beyond use dates. Specifically, Respondent Pharmacy dispensed ophthalmic preparations, compounded from one or more non-sterile ingredients, with extended beyond use dates that were not supported by required testing. Lot # 02152017@9 was given a beyond use date of 180 days based on data from testing lot # 05062015@26. Respondent Pharmacy could not provide data to support the required Method Suitability Test, Container Closure Integrity Test and Stability Studies for lot # 02152017@9. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 46 through 52, as if set forth in full herein.

ELEVENTH CAUSE FOR DISCIPLINE

(Using Invalid Extended Beyond Date)

55. Respondents Pharmacy, Quinn, and Sinconis are subject to disciplinary action under section 4301, subdivision (o), for violating California Code of Regulations Section 1735.2

subdivision (i)(4), by using extended beyond date that was invalid for current compounding process. Specifically, Respondent Pharmacy used compounded preparation lot # 12152016@13 (compounded from one or more non-sterile ingredients) for testing to establish the extended beyond use date applied to lot # 02132017@1, which was not identical in specific and essential compounding steps. Respondent Pharmacy used compounded preparation lot # 05062015@26 (compounded from one or more non-sterile ingredients) for extended beyond use dating for lot # 02152017@9, which was not identical in specific and essential compounding steps. Respondent Pharmacy compounded a preparation for testing for extended beyond use date. The extended beyond use date was assigned to a current compounded preparation (compounded from one or more non-sterile ingredients) which did not utilize the same essential compounding processes. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 46 through 52, as if set forth in full herein.

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Clean ISO 5 Surfaces Daily)

56. Respondents Pharmacy, Quinn, and Sinconis are subject to disciplinary action under section 4301, subdivision (o), for violating California Code of Regulations Section 1751.4, subdivision (d)(1) by failing to clean daily the sterile compounding area, particularly the ISO Class 5 surfaces. Specifically, on March 13, 2017, and March 14, 2017, a Licensed Sterile Compounding renewal inspection revealed that Respondent Pharmacy performed sterile compounding only once or twice a week and the compounding days were the only days the sterile compounding area, including ISO 5 area, were cleaned. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 46 through 52, as if set forth in full herein.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Adequately Train Sterile Compounding Staff)

57. Respondents Pharmacy, Quinn, and Miller are subject to disciplinary action under section 4301, subdivision (o), for violating California Code of Regulations Section 1751.6 subdivision (e)(1) and (e)(2) and California Code of Regulations Sections 1735.8, subdivision (b),

by failing to adequately train sterile compounding staff. Specifically, Respondent Pharmacy failed to have a written program addressing all the required training for sterile compounding and documenting the training and failed to have pharmacy personnel in the supervision of sterile compounding be qualified to do so. Respondent Miller had no documented training on aseptic techniques and aseptic area practices, yet she was the pharmacist directly responsible for verifying the sterile compounding training of Respondent Sinconis, the main compuonding pharmacist at the pharmacy. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 46 through 52, as if set forth in full herein.

FOURTEENTH CAUSE FOR DISCIPLINE

(Unlicensed Activity: Acting as a Manufacturer)

58. Respondents Pharmacy, Quinn, and Miller are subject to disciplinary action under section 4033, subdivision (a)(1), and California Code of Regulations Section 1735.2 subdivision (a), by acting as a manufacturer in preparation of compounded ophthalmic solutions for dispensing to physician offices under the pretense of patient specific prescriptions. Specifically Respondent Pharmacy dispensed ophthalmic solutions pursuant to prescriptions which did not contain all of the required elements of a valid prescription, such as individual patient addresses or patient directions. Prescriptions were dispensed in amounts greater than a reasonable quantity for a specific patient, such as: Rx# 127104 dispensed to K.S. for 30ml on March 1, 2017, and March 7, 2017. The ophthalmic solution compounded preparations were labeled with and placed in an individual box that resembled a professionally manufactured product. Respondent Pharmacy had a preprinted prescription form with ophthalmic drops listed. Respondent Pharmacy's pre-printed prescription form had a number resembling a FDA issued National Drug Code listed in front of each type of ophthalmic solution; such as found with Rx #127106, Rx# 127104, and Rx# 127335. Respondent Pharmacy prepared large volume batches of the ophthalmic solution combination prednisolone sodium1%/moxifloxacin HCL 0.5%/bromfenac sodium 0.09%: 648 containers on February 13, 2017, and 552 containers on February 27, 2017; and 276 containers of prednisolone sodium 1%/moxifloxacin 0.5% on February 15, 2017. When recalling 121 containers of ophthalmic solution, Respondent Pharmacy only contacted 6 individual patients and prescribers

were contacted to return the remaining 115 dispenses. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 46 through 52, as if set forth in full herein.

FIFTEENTH CAUSE FOR DISCIPLINE

(Erroneous or Uncertain Prescriptions)

59. Respondents Pharmacy, Quinn, and Miller are subject to disciplinary action under section 4301, subdivision (o), for violating California Code of Regulations Section 1761(a), by dispensing dangerous drugs without first contacting the prescribers to obtain the needed information on uncertain, ambitious, and irregular prescriptions. Specifically, Respondent Pharmacy dispensed ophthalmic solutions pursuant to prescriptions which did not contain all of the required elements of a valid prescription, such as individual patient addresses or patient directions. Prescriptions were dispensed in amounts greater than a reasonable quantity for a specific patient, such as: Rx# 127104 dispensed to K.S. for 30ml on March 1, 2017, and March 7, 2017. The ophthalmic solution compounded preparations were labeled and placed in an individual box that resembled a professionally manufactured product. Respondent Pharmacy had a preprinted prescription form with ophthalmic drops listed. Respondent Pharmacy's pre-printed prescription form had a number resembling a FDA issued National Drug Code listed in front of each type of ophthalmic solution; such as found with Rx #127106, Rx# 127104, and Rx# 127335. Respondent Pharmacy prepared large volume batches of the ophthalmic solution combination prednisolone sodium1%/moxifloxacin HCL 0.5%/bromfenac sodium 0.09%: 648 containers on 2/13/17 and 552 containers on 2/27/17; and 276 containers of prednisolone sodium 1%/moxifloxacin 0.5% on 2/15/17. When recalling 121 containers of ophthalmic solution, Respondent Pharmacy only contacted 6 individual patients, and prescribers were contacted to return the remaining 115 dispenses. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 46 through 58, as if set forth in full herein.

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SIXTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

60. Respondents are subject to disciplinary action under section 4301 for unprofessional conduct. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 32 through 59, as if set forth in full herein.

DISCIPLINARY CONSIDERATIONS

61. To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy, Complainant alleges the following:

Respondent Pharmacy

62. On or about February 18, 2014, in a prior action, the Board issued Citation Number CI 2012 57004 to Kohana Pharmacy and Center for Regenerative Medicine, PHY 50264 for violating California Code of Regulations, title 16, section 1717.3, subdivision (b) (dispensing a controlled substance pursuant to a preprinted multiple check-off prescription blank) and fined $2,000. Specifically, from a date unknown through July 31, 2013, Respondent Pharmacy filled 1087 prescription orders containing ketamine, a controlled substance, pursuant to a preprinted, multiple check-off prescription blank. That Citation is now final and is incorporated by reference as if fully set forth.

OTHER MATTERS

63. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50264 issued to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center For Regenerative Medicine, Kohana Pharmacy and Center For Regenerative Medicine, Inc. shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50264 is placed on probation or until Pharmacy Permit Number PHY 50264 is reinstated if it is revoked.

64. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50264 issued to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center For Regenerative Medicine while Robert Denis Quinn has been an

officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Robert Denis Quinn shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50264 is placed on probation or until Pharmacy Permit Number PHY 50264 is reinstated if it is revoked.

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 50264, issued to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine;

2. Revoking or suspending Pharmacist License Number RPH 32154, issued to Robert Denis Quinn;

3. Revoking or suspending Pharmacist License Number RPH 70014 issued to Nataliya McElroy Miller;

4. Revoking or suspending Pharmacist License Number RPH 71144 issued to Anthony Sinconis;

5. Prohibiting Kohana Pharmacy and Center for Regenerative Medicine, Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49140 is placed on probation or until Pharmacy Permit Number PHY 49140 is reinstated if Pharmacy Permit Number 49140 issued to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine is revoked;

6. Prohibiting Robert Denis Quinn from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49140 is placed on probation or until Pharmacy Permit Number PHY 49140 is reinstated if Pharmacy Permit Number PHY 49140 issued to Kohana Pharmacy and Center for

Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine is revoked;

7. Ordering Respondents 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. Taking such other and further action as deemed necessary and proper.

DATED: 12/1/17

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:	Case No. 5556
KOHANA PHARMACY AND CENTER FOR REGENERATIVE MEDICINE, INC. DBA KOHANA PHARMACY AND CENTER FOR REGENERATIVE MEDICINE **ALAN JAMES MARTIN AND ROBERT DENIS QUINN, OWNERS** 181 Tank Farm Rd., #120 San Luis Obispo, CA 93401 **Pharmacy Permit No. PHY 50264** **Sterile Compounding License No. LSC 99609,** **ALAN JAMES MARTIN** 3186 Rose Avenue San Luis Obispo, CA 93401 **Pharmacist License No. RPH 37337,** **and** **ROBERT DENIS QUINN** 7475 Balboa Road Atascadero, CA 93422 **Pharmacist License No. RPH 32154** Respondents.	**A C C U S A T I O N**

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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 20, 2010, the Board of Pharmacy issued Pharmacy Permit Number PHY 50264 to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine (Respondent Pharmacy). Both Alan James Martin and Robert Denis Quinn are and have been a director and 50% shareholder of Respondent Pharmacy since April 20, 2010. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2017, unless renewed.

3. On or about May 26, 2010, the Board of Pharmacy issued Sterile Compounding License Number LSC 99609 to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine (Respondent Pharmacy). 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, 2017, unless renewed.

4. On or about August 31, 1982, the Board of Pharmacy issued Pharmacist License Number RPH 37337 to Alan James Martin (Respondent Martin). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2017, unless renewed. Respondent Martin was the Pharmacist-in-Charge of Respondent Pharmacy from April 20, 2010 to October 16, 2013.

5. On or about August 3, 1978, the Board of Pharmacy issued Pharmacist License Number RPH 32154 to Robert Denis Quinn (Respondent Quinn). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2018, unless renewed. Respondent Quinn was the Pharmacist-in-Charge of Respondent Pharmacy from November 16, 2013 to the present.

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JURISDICTION

6. 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.

7. Section 4300 provides in pertinent part, that every license issued by the Board is subject to discipline, including suspension or revocation.

8. 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."

9. Section 4113, subdivision (c), states that "[t]he 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."

10. 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."

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11. Section 4033 of the Code states, in part:

"(a)(1) 'Manufacturer' means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer."

12. 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, or any other state, or of the United States regulating controlled substances and dangerous drugs.

...

"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency."

13. Section 4306.5 of the Code states, in part:

"Unprofessional conduct for a pharmacist may include any of the following:

"(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

"(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services."

14. Section 4307, subdivision (a), of the Code states, in pertinent part:

"Any person who has been denied a license or whose license has been revoked or is under

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

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

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

15. Section 4081 of the Code states, in part:

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

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

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REGULATORY PROVISIONS

16. California Code of Regulations, title 16, section 1770, states:

"For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare."

17. California Code of Regulations 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."

18. California Code of Regulations, title 16, section 1735.2, states, in part:

"(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Expiration dating requirements.

(4) Inactive ingredients to be used.

(5) Process and/or procedure used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

. . .

"(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

"(g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength."

19. California Code of Regulations, title 16, section 1735.3, states:

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

(1) The master formula record.

(2) The date the drug product was compounded.

(3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia--National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

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

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

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

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

"(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.

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

20. California Code of Regulations, title 16, section 1735.5, states:

"(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

"(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

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

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.

(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.

(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.

(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products."

21. California Code of Regulations, title 16, section 1751.1(a), states:

"(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber."

COST RECOVERY

22. Section 125.3 of the Code provides, 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, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

AVASTIN

23. Avastin (bevacizumab) is a dangerous drug pursuant to Section 4022. It is used to treat various cancers. It is usually given as an infusion. Avastin is restricted for purchase to hospital, federal accounts, physician's offices, and authorized specialty pharmacies. Avastin does not contain any preservatives, and, therefore, is meant for immediate one time use. Any unused portions left in a vial of Avastin should be discarded. Diluted Avastin solutions may be stored at 2–8°C (36–46°F) for up to 8 hours. Avastin is available in a 100mg/4ml (also referred to as 25mg/ml 4ml) single use vial and a 400mg/16ml single use vial.

24. Avastin has an off label use in the treatment of macular degeneration. Avastin is commercially available in a much larger quantity vial than is needed for a single dose administration in the treatment of eye disease. Generally, the 4ml vial is used to produce between 50 to 80 doses. Dividing a vial of Avastin into numerous tiny doses for injection into the eye introduces the risk of bacterial contamination, which may cause severe eye infections and blindness. Pharmacies compounding Avastin must adhere to the sterile techniques and standards outlined in USP Chapter 797.[1]

25. The Federal Food and Drug Administration (FDA) has approved Lucentis (ranibizumab), a similar product on the market, for treatment of macular degeneration. It is

[1] USP Chapter 797 "provides procedures and requirements for compounding sterile preparations. General Chapter 797 describes conditions and practices to prevent harm to patients that could result from microbial contamination, excessive bacterial endotoxins, variability in intended strength, unintended chemical and physical contaminants, and ingredients of inappropriate quality in compounded sterile preparations." ("USP–NF General Chapters for Compounding." *USP NF Compounding General Chapters*. N.p., n.d. Web. 30 Oct. 2015.)

supplied as a single ophthalmic dose. There is a significant price difference between Lucentis and Avastin. Lucentis cost approximately $2,000 per dose compared to Avastin's cost of approximately $30 to $50 per dose once compounded.

FACTUAL SUMMARY

26. On or about February 19, 2013, French Hospital Medical Center (French Hospital), located at 1911 Johnson Avenue, San Luis Obispo, California, notified the Board that employees of French Hospital, one of which was Respondent Martin's wife, were ordering Avastin through the French Hospital Pharmacy and reselling it to Respondent Pharmacy and Center for Regenerative Medicine (Respondent Pharmacy). Respondent Pharmacy paid in cash for the Avastin. According to French Hospital, there were 13 orders of Avastin placed and received on Respondent Pharmacy's behalf over the course of 15 months (November 2011 through January 15, 2013). None of these orders were needed or used by French Hospital patients and there was no on-hand inventory of Avastin. French Hospital did not maintain any accounting records of Respondent Pharmacy's Avastin orders and payments. French Hospital tracked the orders through the hospital's vendors. French Hospital did not provide Respondent Pharmacy with any invoices for the Avastin and Respondent Pharmacy did not provide any receipts for its payments. There was no paper documentation that showed how much Respondent Pharmacy paid for each order or for which orders payments had been received.

27. The Board's investigation revealed that from November 2011 through January 15, 2013, Respondent Pharmacy purchased 19 to 21 vials of Avastin 25mg/ml 4ml[2] from French Hospital, and that records of purchase and sale were not maintained.[3]

28. The Board's investigation also revealed that from August 15, 2011, through February 12, 2013, 1997 syringes of Avastin were dispensed by Respondent Pharmacy.[4] Respondent

[2] The invoices from French Hospital's vendors refer to the vials purchased as Avastin 25mg/ml 4ml or Avastin 100mg/4ml. Each ml of concentrate contains 25mg of Avastin. Each 4ml vial contains 100mg of Avastin.

[3] Respondent Pharmacy's records showed it purchased 19 vials of 4ml Avastin for a purchase amount of approximately $11,823.32. French Hospital stated they sold 21 vials of 4ml Avastin to Respondent Pharmacy for the amount of $12,058.88. There was a discrepancy of 2 vials and $1,235.56. The discrepancy could not be explained due to the incomplete record keeping on the part of both Respondent Pharmacy and French Hospital.

Pharmacy compounded the 1997 non-patient specific doses of Avastin for off label ophthalmic use and sold it to a few physicians' offices to treat patients with macular degeneration. Respondent Martin and Respondent Quinn were responsible for compounding the Avastin ophthalmic preparations. Of the 1997 doses, Respondent Martin was responsible for at least 1917 doses and Respondent Quinn was responsible for at least 80 doses. During this period, Respondent Martin was the pharmacist-in-charge of Respondent Pharmacy. Respondent Pharmacy was not licensed as a drug manufacturer.

29. Respondents did not maintain any compounding records or any documentation on sterility testing or beyond use dating (expiration date).

30. The dose dispensed by Respondent Pharmacy was 0.05 ml =1.25mg Avastin. Each vial of 100mg/4ml should yield 80 doses. The product was transferred into 1ml tuberculin syringes. This altered the dosage form and delivery system from intravenous (IV) to intra-ocular injection.

31. Respondent Quinn stated that Respondents usually used one vial of Avastin per prescription, but when there was any product remaining, the remainder was put into the pharmacy's refrigerator with an expiration date of 30 days. If that product was used for a prescription, Respondents would base the expiration of that product off of the 30 days. The Board's inspector determined that there was no vial of Avastin that was completely dispensed by Respondent Pharmacy prior to the purchase of the next vial. The time between the first dose compounded from a vial and the last dose compounded from the same vial was greater than 8 hours, which was the time the manufacturer stated the diluted medication should be discarded when stored at 2-8° C. The shortest amount of time noted for an open vial being used for compounding at Respondent Pharmacy was approximately 11 days.

FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Acquisition)

(...continued)

[4] Prior to purchasing Avastin from French Hospital, the prescribing physicians provided Respondent Pharmacy with Avastin "prescriptions" to compound into syringes for "office use".

32. Respondent Pharmacy and Respondent Martin are subject to disciplinary action under section 4301, subdivisions (j) and (o), on the grounds of unprofessional conduct, in that they failed to comply with section 4081, subdivision (a), by failing to maintain records of acquisition of dangerous drugs. Specifically, between November 2011 and January 15, 2013, while Respondent Martin was working as the pharmacist-in-charge, Respondent Pharmacy purchased between 19 and 21 vials of Avastin 25mg/ml 4ml, from French Hospital and failed to maintain records of purchase. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 26 through 31, as if set forth in full herein.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Required Compounding Records)

33. Respondents are subject to disciplinary action under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1735.3, subdivisions (a) and (b). Specifically, between August 15, 2011, through February 12, 2013, while Respondent Martin was working as the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vials to compound Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondent Pharmacy compounded 1997 doses of Avastin. Respondent Quinn was responsible for at least 80 doses. Respondents did not maintain compounding records. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 26 through 30, as if set forth in full herein.

THIRD CAUSE FOR DISCIPLINE

(Failure to Comply with Sterile Injectable Recordkeeping Requirements)

34. Respondents are subject to disciplinary action under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1751.1, subdivision (a), by failing to keep the required records for sterile injectable products. Specifically from August 15, 2011, to February 12, 2013, while Respondent Martin was working as the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vial to compound Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondents compounded 1997 doses and failed to maintain records indicating the

name, lot number, amount, and date on which the products were provided to a prescriber. Respondent Quinn was responsible for at least 80 doses. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 26 through 30, and 32, as if set forth in full herein.

FOURTH CAUSE FOR DISCIPLINE

(Acting as a Drug Manufacturer without a Permit)

35. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and (o), on the grounds of unprofessional conduct, in conjunction with Section 4033, subdivision (a)(1), for acting as a drug manufacturer without a permit. Specifically, from August 15, 2011 to February 12, 2013, while Respondent Martin was working as the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vials to compound 1997 Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondent Quinn was responsible for at least 80 doses. The product was transferred into 1ml tuberculin syringes, which changed the dosage form and delivery system from intravenous (IV) to intra-ocular injection. Respondents then sold the 1997 non-patient specific doses to physicians' offices to use on their patients. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 26 through 30, as if set forth in full herein.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Comply with Compounding Limitations and Requirements)

36. Respondents are subject to disciplinary action under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1735.2, subdivisions (d),(f), and (g), for compounding without adhering to compounding limitations and requirements. Specifically, from August 15, 2011 to February 12, 2013, while Respondent Martin was working as the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vials to compound Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondent Pharmacy compounded 1997 doses and failed to maintain a written master formula, ensure integrity, potency, quality and labeled strength of the product, and used drug products in compounding that had exceeded the manufacturer and

USP 797 beyond use dating. Respondent Quinn was responsible for at least 80 doses. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 26 through 30, as if set forth in full herein.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Comply with the Required Compounding Policies and Procedures)

37. Respondents are subject to disciplinary action under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1735.5, subdivision (c), which requires that a pharmacy's policy and procedure manual include the following: "(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products." Specifically, from August 15, 2011 to February 12,2013, while Respondent Martin was working as the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vial to compound Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondent Pharmacy compounded 1997 doses and failed to document the methodology used to establish a beyond use date that exceeded the manufacturer's and USP 797 guidelines. Respondent Quinn was responsible for at least 80 doses. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 26 through 30, as if set forth in full herein.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Exercise Professional Judgment)

38. Respondent Martin and Respondent Quinn are subject to discipline pursuant to Code section 4301, subdivisions (j) and (o), on the grounds of unprofessional conduct, in that they failed to exercise professional judgment, in violation of Code section 4306.5, subdivision (a). Specifically from August 15, 2011 to February 12, 2013, Respondent Martin and Respondent Quinn used Avastin 25mg/ml 4ml vials to compound Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. They failed to follow USP 797 guidelines and failed to establish the beyond use date (expiration date) for a preservative-free single dose vial used in the compounding of Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. The beyond use date of 30 days given to the ophthalmic compounded Avastin 0.05ml syringes

exceeded the manufacturers beyond use date and exceeded USP 797 guidelines. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 26 and 36, as if set forth in full herein.

EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

39. Respondent Martin and Respondent Quinn are subject to disciplinary action under section 4301 for unprofessional conduct. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 26 and 37, as if set forth in full herein.

DISCIPLINARY CONSIDERATIONS

40. To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy and Respondent Martin, Complainant alleges the following:

Respondent Pharmacy

41. On or about February 18, 2014, in a prior action, the Board issued Citation Number CI 2012 57004 to Kohana Pharmacy and Center for Regenerative Medicine, PHY 50264 for violating California Code of Regulations, title 16, section 1717.3, subdivision (b) (dispensing a controlled substance pursuant to a preprinted multiple check-off prescription blank) and fined $2,000. Specifically, from a date unknown through July 31, 2013, Respondent Pharmacy filled 1087 prescription orders containing ketamine, a controlled substance, pursuant to a preprinted, multiple check-off prescription blank. That Citation is now final and is incorporated by reference as if fully set forth.

Respondent Martin

42. On or about February 18, 2014, in a prior action, the Board issued Citation Number CI 2013 60038 to Respondent Martin for violating California Code of Regulations, title 16, section 1717.3, subdivision (b) (dispensing a controlled substance pursuant to a preprinted multiple check-off prescription blank) and fined $2000. Specifically, from a date unknown through July 31, 2013, Respondent Martin, while acting as the pharmacist-in-charge of Respondent Pharmacy, filled or caused to be filled 1087 prescription orders containing ketamine,

a controlled substance, pursuant to a preprinted, multiple check-off prescription blank. That Citation is now final and is incorporated by reference as if fully set forth.

43. On or about June 27, 2011, in a prior action, the Board issued Citation Number CI 2010 48685 to Respondent Martin for violating California Code of Regulations, title 16, section 1761, subdivision (a), as it relates to Health and Safety Code, section 11170, which prohibits furnishing erroneous or uncertain prescriptions, to wit, controlled substance prescriptions written by a prescriber for himself, and fined $250. Specifically, on January 7, 2010, Respondent Martin, while working at Healthplus Pharmacy (PHY 43683), located at 948 A Foothill Blvd., San Luis Obispo, CA 93405, furnished 6mls of testosterone 25mg/0.1ml, a schedule III controlled substance, pursuant to a prescription written by Dr. Jeffrey Reinking for himself. That Citation is now final and is incorporated by reference as if fully set forth.

OTHER MATTERS

44. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50264 to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine, Kohana Pharmacy and Center for Regenerative Medicine, Inc. shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50264 is placed on probation or until Pharmacy Permit Number PHY 50264 is reinstated if it is revoked.

45. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50264 to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine while Alan James Martin and/or Robert Denis Quinn have been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Alan James Martin and/or Robert Denis, as applicable, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49140 is placed on probation or until Pharmacy Permit Number PHY 49140 is reinstated if it is revoked.

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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 50264, issued to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine;

2. Revoking or suspending Sterile Compounding License Number LSC 99609, issued to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine;

3. Revoking or suspending Pharmacist License Number RPH 37337, issued to Alan James Martin;

4. Revoking or suspending Pharmacist License Number RPH 32154, issued to Robert Denis Quinn;

5. Prohibiting Kohana Pharmacy and Center for Regenerative Medicine, Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50264 is placed on probation or until Pharmacy Permit Number PHY 50264 is reinstated if Pharmacy Permit Number 50264 issued to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine is revoked;

6. Prohibiting Alan James Martin from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49140 is placed on probation or until Pharmacy Permit Number PHY 50264 is reinstated if Pharmacy Permit Number PHY 50264 issued to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine is revoked;

7. Prohibiting Robert Denis Quinn from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50264 is placed on probation or until Pharmacy Permit Number PHY 50264 is reinstated if Pharmacy Permit Number 50264 issued to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine a is revoked;

8. Ordering Kohana Pharmacy and Center for Regenerative Medicine, Alan James Martin and Robert Denis Quinn 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;

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

DATED: 9/4/16

Virginia Herold

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

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