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

10 In the Matter of the Second Amended
11 Accusation Against:

Case No. 5556

12 **KOHANA PHARMACY AND CENTER**
13 **FOR REGENERATIVE MEDICINE, INC.**
14 **DBA KOHANA PHARMACY AND**
15 **CENTER FOR REGENERATIVE**
16 **MEDICINE, ROBERT DENIS QUINN,**
17 **OWNER**

SECOND AMENDED ACCUSATION

15 181 Tank Farm Rd., #120
San Luis Obispo, CA 93401
16 **Pharmacy Permit No. PHY 50264,**

17 **ROBERT DENIS QUINN**
18 7475 Balboa Road
Atascadero, CA 93422
19 **Pharmacist License No. RPH 32154,**

20 **NATALIYA McELROY MILLER**
21 522 Playa Circle
Paso Robles, CA 93446
22 **Pharmacist License No. RPH 70014**

22 and

23 **ANTHONY SINCONIS,**
24 PO Box 75
Avila Beach, CA 93424
25 **Pharmacist License No. RPH 71144**

26 Respondents.

28

1 Complainant alleges:

2 **PARTIES**

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

6 2. On or about April 20, 2010, the Board of Pharmacy issued Pharmacy Permit Number
7 PHY 50264 to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana
8 Pharmacy and Center for Regenerative Medicine (Respondent Pharmacy). Pursuant to the
9 Board's records, both Alan James Martin and Robert Denis Quinn are and have been a director
10 and 50% shareholder of Respondent Pharmacy from April 20, 2010 to April 1, 2015. Robert
11 Denis Quinn is and has been the President, 100% shareholder from April 1, 2015 to the present.
12 Alan James Martin, Pharmacist License No. RPH 37337¹ (Pharmacist Martin) was the
13 Pharmacist-in-Charge of Respondent Pharmacy from April 20, 2010 to October 16, 2013.
14 Respondent Robert Denis Quinn is and has been the Pharmacist-in-Charge of Respondent
15 Pharmacy from November 16, 2013 to the present. The Pharmacy Permit was in full force and
16 effect at all times relevant to the charges brought herein and will expire on April 1, 2018, unless
17 renewed.

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

23 4. On or about August 3, 1978, the Board of Pharmacy issued Pharmacist License
24 Number RPH 32154 to Robert Denis Quinn (Respondent Quinn). The Pharmacist License was in
25 full force and effect at all times relevant to the charges brought herein and will expire on June 30,
26 2018, unless renewed.

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

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

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

5 13. Section 4301 of the Code states, in part:

6 “The board shall take action against any holder of a license who is guilty of unprofessional
7 conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is
8 not limited to, any of the following:

9

10 (j) The violation of any of the statutes of this state, of any other state, or of the United States
11 regulating controlled substances and dangerous drugs.

12 ...

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

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

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

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

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

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

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

3 (b) Manager, administrator, owner, member, officer, director, associate, partner, or any
4 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.

5 (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.
6 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
7 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
8 shall be in addition to the board's authority to proceed under Section 4339 or any other provision
9 of law.

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

11 "(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
12 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
13 food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital,
institution, or establishment holding a currently valid and unrevoked certificate, license, permit,
14 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
15 Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

16 "(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal
17 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."
18

19 REGULATORY PROVISIONS

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

21 "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
22 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
23 licensee or registrant to perform the functions authorized by his license or registration in a manner
24 consistent with the public health, safety, or welfare."

25 18. California Code of Regulations section 1735 states, in part,

26 "(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:

27 (1) Altering the dosage form or delivery system of a drug."
28

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

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

6 ...
7 “(d) A drug product shall not be compounded until the pharmacy has first prepared a
8 written master formula record that includes at least the following elements:

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

16 ...
17 “(f) The pharmacist performing or supervising compounding is responsible for the
18 integrity, potency, quality, and labeled strength of a compounded drug product until it is
19 dispensed.

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

23 ...
24 (i) Every compounded drug preparation shall be given a beyond use date representing the
25 date or date and time beyond which the compounded drug preparation should not be used, stored,
26 transported or administered, and determined based on the professional judgment of the pharmacist
27 performing or supervising the compounding.

28 ...
29 (3) Extension of a beyond use date is only allowable when supported by the following:

- 30 (A) Method Suitability Test,
- 31 (B) Container Closure Integrity Test, and C) Stability Studies.
- 32 (4) In addition to the requirements of paragraph three (3), the drugs or compounded drug
33 preparations tested and studied shall be identical in ingredients, specific and essential
34 compounding steps, quality reviews, and packaging as the finished drug or compounded drug
35 preparation.”

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

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

- 38 (1) The master formula record.
- 39 (2) The date the drug product was compounded.
- 40 (3) The identity of the pharmacy personnel who compounded the drug product.
- 41 (4) The identity of the pharmacist reviewing the final drug product.
- 42 (5) The quantity of each component used in compounding the drug product.
- 43 (6) The manufacturer, expiration date and lot number of each component. If the
44 manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.

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

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

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

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

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

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

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

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

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

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

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

27 (1) Procedures for notifying staff assigned to compounding duties of any changes in
28 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 22. California Code of Regulations, title 16, section 1735.6, subdivision (b), states:

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

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

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

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

5 “(a) Pharmacies compounding sterile injectable products for future use pursuant to section
6 1735.2 shall, in addition to those records required by section 1735.3, make and keep records
7 indicating the name, lot number, amount, and date on which the products were provided to a
8 prescriber.”

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

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

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

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

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

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

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

24 (2) Each person engaged in sterile compounding must successfully complete practical
25 skills training in aseptic technique and aseptic area practices using models that are comparable to
26 the most complex manipulations to be performed by the individual. Each pharmacist responsible
27 for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the
28 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

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

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

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

8 COST RECOVERY

9 28. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
10 administrative law judge to direct a licentiate found to have committed a violation or violations of
11 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
12 enforcement of the case, with failure of the licentiate to comply subjecting the license to not being
13 renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be
14 included in a stipulated settlement.

15 AVASTIN

16 29. Avastin (bevacizumab) is a dangerous drug pursuant to Section 4022. It is used to
17 treat various cancers. It is usually given as an infusion. Avastin is restricted for purchase to
18 hospital, federal accounts, physician's offices, and authorized specialty pharmacies. Avastin does
19 not contain any preservatives, and, therefore, is meant for immediate one time use. Any unused
20 portions left in a vial of Avastin should be discarded. Diluted Avastin solutions may be stored at
21 2–8°C (36–46°F) for up to 8 hours. Avastin is available in a 100mg/4ml (also referred to as
22 25mg/ml 4ml) single use vial and a 400mg/16ml single use vial.

23 30. Avastin has an off label use in the treatment of macular degeneration. Avastin is
24 commercially available in a much larger quantity vial than is needed for a single dose
25 administration in the treatment of eye disease. Generally, the 4ml vial is used to produce between
26 50 to 80 doses. Dividing a vial of Avastin into numerous tiny doses for injection into the eye
27 introduces the risk of bacterial contamination, which may cause severe eye infections and
28

1 blindness. Pharmacies compounding Avastin must adhere to the sterile techniques and standards
2 outlined in USP Chapter 797.²

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

8 FACTUAL SUMMARY

9 32. On or about February 19, 2013, French Hospital Medical Center (French Hospital),
10 located at 1911 Johnson Avenue, San Luis Obispo, California, notified the Board that employees
11 of French Hospital, one of which was Pharmacist Martin's wife, were ordering Avastin through
12 the French Hospital-Pharmacy and reselling it to Respondent Pharmacy and Center for
13 Regenerative Medicine (Respondent Pharmacy). Respondent Pharmacy paid in cash for the
14 Avastin. According to French Hospital, there were 12 orders of Avastin placed and received on
15 Respondent Pharmacy's behalf over the course of 15 months (November 2011 through January
16 15, 2013). None of these 12 orders were needed or used by French Hospital patients and there
17 was no on-hand inventory of Avastin. French Hospital did not maintain any accounting records
18 of Respondent Pharmacy's Avastin orders and payments. French Hospital tracked the orders
19 through the hospital's vendors. French Hospital did not provide Respondent Pharmacy with any
20 invoices for the Avastin and Respondent Pharmacy did not provide any receipts for its payments.
21 There was no paper documentation that showed how much Respondent Pharmacy paid for each
22 order or for which orders payments had been received.

23
24
25 ² USP Chapter 797 "provides procedures and requirements for compounding sterile
26 preparations. General Chapter 797 describes conditions and practices to prevent harm to patients
27 that could result from microbial contamination, excessive bacterial endotoxins, variability in
28 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.)

1 33. The Board's investigation revealed that from November 2011 through January 15,
2 2013, Respondent Pharmacy purchased 19 to 21 vials of Avastin 25mg/ml 4ml³ from French
3 Hospital, and that records of purchase and sale were not maintained.⁴

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

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

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

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

23 ³ The invoices from French Hospital's vendors refer to the vials purchased as Avastin
24 25mg/ml 4ml or Avastin 100mg/4ml. Each ml of concentrate contains 25mg of Avastin. Each
25 4ml vial contains 100mg of Avastin.

26 ⁴ Respondent Pharmacy's records showed it purchased 19 vials of 4ml Avastin for a
27 purchase amount of approximately \$11,823.32. French Hospital stated they sold 21 vials of 4ml
28 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.

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

7 **FIRST CAUSE FOR DISCIPLINE**

8 **(Failure to Maintain Records of Acquisition)**

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

17 **SECOND CAUSE FOR DISCIPLINE**

18 **(Failure to Maintain Required Compounding Records)**

19 39. Respondents Pharmacy and Quinn are subject to disciplinary action under section
20 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply
21 with California Code of Regulations, title 16, section 1735.3, subdivisions (a) and (b).
22 Specifically, between August 15, 2011, through February 12, 2013, while Pharmacist Martin was
23 working as the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vials to
24 compound Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondent
25 Pharmacy compounded 1997 doses of Avastin. Respondent Quinn was responsible for at least 80
26 doses. Respondents did not maintain compounding records. Complainant refers to, and by this
27 reference incorporates, the allegations set forth above in paragraphs 32 through 37, as if set forth
28 in full herein.

1 **THIRD CAUSE FOR DISCIPLINE**

2 **(Failure to Comply with Sterile Injectable Recordkeeping Requirements)**

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

14 **FOURTH CAUSE FOR DISCIPLINE**

15 **(Acting as a Drug Manufacturer without a Permit)**

16 41. Respondents Pharmacy and Quinn are subject to disciplinary action under section
17 4301, subdivisions (j) and (o), on the grounds of unprofessional conduct, in conjunction with
18 Section 4033, subdivision (a)(1), for acting as a drug manufacturer without a permit. Specifically,
19 from August 15, 2011 to February 12, 2013, while Pharmacist Martin was working as the
20 pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vials to compound 1997
21 Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondent Quinn was
22 responsible for at least 80 doses. The product was transferred into 1ml tuberculin syringes, which
23 changed the dosage form and delivery system from intravenous (IV) to intra-ocular injection.
24 Respondents then sold the 1997 non-patient specific doses to physicians' offices to use on their
25 patients. Complainant refers to, and by this reference incorporates, the allegations set forth above
26 in paragraphs 32 through 37, as if set forth in full herein.

1 **FIFTH CAUSE FOR DISCIPLINE**

2 **(Failure to Comply with Compounding Limitations and Requirements)**

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

15 **SIXTH CAUSE FOR DISCIPLINE**

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

17 43. Respondents Pharmacy and Quinn are subject to disciplinary action under section
18 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply
19 with California Code of Regulations, title 16, section 1735.5, subdivision (c), which requires that
20 a pharmacy's policy and procedure manual include the following: "(5) Documentation of the
21 methodology used to determine appropriate expiration dates for compounded drug products."
22 Specifically, from August 15, 2011 to February 12,2013, while Pharmacist Martin was working as
23 the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vial to compound
24 Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondent Pharmacy
25 compounded 1997 doses and failed to document the methodology used to establish a beyond use
26 date that exceeded the manufacturer's and USP 797 guidelines. Respondent Quinn was
27 responsible for at least 80 doses. Complainant refers to, and by this reference incorporates, the
28 allegations set forth above in paragraphs 32 through 37, as if set forth in full herein.

1 **SEVENTH CAUSE FOR DISCIPLINE**

2 **(Failure to Exercise Professional Judgment)**

3 44. Respondent Quinn is subject to discipline pursuant to Code section 4301,
4 subdivisions (j) and (o), on the grounds of unprofessional conduct, in that he failed to exercise
5 professional judgment, in violation of Code section 4306.5, subdivision (a). Specifically, from
6 August 15, 2011 to February 12, 2013, Pharmacist Martin and Respondent Quinn used Avastin
7 25mg/ml 4ml vials to compound Avastin 0.05ml syringes for intravitreal (inside the eye) sterile
8 injection. They failed to follow USP 797 guidelines and failed to establish the beyond use date
9 (expiration date) for a preservative-free single dose vial used in the compounding of Avastin
10 0.05ml syringes for intravitreal (inside the eye) sterile injection. The beyond use date of 30 days
11 given to the ophthalmic compounded Avastin 0.05ml syringes exceeded the manufacturers
12 beyond use date and exceeded USP 797 guidelines. Complainant refers to, and by this reference
13 incorporates, the allegations set forth above in paragraphs 32 through 37, as if set forth in full
14 herein.

15 **EIGHTH CAUSE FOR DISCIPLINE**

16 **(Unprofessional Conduct)**

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

20 **MARCH 2017 INSPECTION**

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

23 47. Respondent Pharmacy was performing "high risk" non-sterile to sterile compounding
24 and was generally compounding TriMix (an injectable prescription medication used to treat
25 erectile dysfunction), other injections, and a large volume of eye drops. Respondent was
26 compounding prednisolone phosphate 1% / moxifloxacin HCL 0.5% / bromfenac sodium 0.09%
27 (Steroid / Anti-Infective / NSAID) and prednisolone sodium phosphate 1% / moxifloxacin HCL
28 0.5% (Steroid /Anti-Infective) combination eye drops. These eye drops are instilled into a

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

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

6 49. Respondent Pharmacy placed extended "beyond use date" or BUD⁶ on compounded
7 eye drops without performing the required tests such as method suitability, container closure
8 integrity, or stability studies to support such extended BUD. Respondent Pharmacy specifically
9 compounded small lots of ophthalmic solution for extended BUD testing that were compounded
10 using a *sterilization grade filter*, and then placed the extended BUDs from the testing of these lots
11 to much larger lots of compounded ophthalmic solution that were compounded using a *non-*
12 *sterilizing filter* and used additional compounding steps. These tested and untested batches were
13 not identical in specific and essential compounding steps.

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

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

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

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

1 **NINTH CAUSE FOR DISCIPLINE**

2 **(Failure to follow manufacturer's instructions)**

3 53. Respondents Pharmacy, Quinn, and Sinconis are subject to disciplinary action under
4 section 4301, subdivision (o), for violating California Code of Regulations, title 16, section
5 1735.6, subdivision (b), by failing to ensure equipment used to compound drug preparations was
6 in accordance with manufacturer's specifications. Specifically, Respondent Pharmacy used a
7 Thermo Fisher Filter Assembly, product number SH00055-I, as the sterilization method to
8 prepare a sterile compound from one or more non-sterile ingredients. The product page for the
9 Thermo Fisher Filter Assembly stated "Filter Assembly is not intended as a final sterilization
10 filter." Complainant refers to, and by this reference incorporates, the allegations set forth above in
11 paragraphs 46 through 52, as if set forth in full herein.

12 **TENTH CAUSE FOR DISCIPLINE**

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

14 54. Respondents Pharmacy, Quinn, and Sinconis are subject to disciplinary action under
15 section 4301, subdivision (o), for violating California Code of Regulations Section 1735.2,
16 subdivision (i)(3), by failing to ensure the required valid testing was completed prior to
17 dispensing of compounded preparations with extended beyond use dates. Specifically,
18 Respondent Pharmacy dispensed ophthalmic preparations, compounded from one or more non-
19 sterile ingredients, with extended beyond use dates that were not supported by required testing.
20 Lot # 02152017@9 was given a beyond use date of 180 days based on data from testing lot #
21 05062015@26. Respondent Pharmacy could not provide data to support the required Method
22 Suitability Test, Container Closure Integrity Test and Stability Studies for lot # 02152017@9.
23 Complainant refers to, and by this reference incorporates, the allegations set forth above in
24 paragraphs 46 through 52, as if set forth in full herein.

25 **ELEVENTH CAUSE FOR DISCIPLINE**

26 **(Using Invalid Extended Beyond Date)**

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

1 subdivision (i)(4), by using extended beyond date that was invalid for current compounding
2 process. Specifically, Respondent Pharmacy used compounded preparation lot # 12152016@13
3 (compounded from one or more non-sterile ingredients) for testing to establish the extended
4 beyond use date applied to lot # 02132017@1, which was not identical in specific and essential
5 compounding steps. Respondent Pharmacy used compounded preparation lot # 05062015@26
6 (compounded from one or more non-sterile ingredients) for extended beyond use dating for lot #
7 02152017@9, which was not identical in specific and essential compounding steps. Respondent
8 Pharmacy compounded a preparation for testing for extended beyond use date. The extended
9 beyond use date was assigned to a current compounded preparation (compounded from one or
10 more non-sterile ingredients) which did not utilize the same essential compounding processes.
11 Complainant refers to, and by this reference incorporates, the allegations set forth above in
12 paragraphs 46 through 52, as if set forth in full herein.

13 **TWELFTH CAUSE FOR DISCIPLINE**

14 **(Failure to Clean ISO 5 Surfaces Daily)**

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

24 **THIRTEENTH CAUSE FOR DISCIPLINE**

25 **(Failure to Adequately Train Sterile Compounding Staff)**

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

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

9 **FOURTEENTH CAUSE FOR DISCIPLINE**

10 **(Unlicensed Activity: Acting as a Manufacturer)**

11 58. Respondents Pharmacy, Quinn, and Miller are subject to disciplinary action under
12 section 4033, subdivision (a)(1), and California Code of Regulations Section 1735.2 subdivision
13 (a), by acting as a manufacturer in preparation of compounded ophthalmic solutions for
14 dispensing to physician offices under the pretense of patient specific prescriptions. Specifically
15 Respondent Pharmacy dispensed ophthalmic solutions pursuant to prescriptions which did not
16 contain all of the required elements of a valid prescription, such as individual patient addresses or
17 patient directions. Prescriptions were dispensed in amounts greater than a reasonable quantity for
18 a specific patient, such as: Rx# 127104 dispensed to K.S. for 30ml on March 1, 2017, and March
19 7, 2017. The ophthalmic solution compounded preparations were labeled with and placed in an
20 individual box that resembled a professionally manufactured product. Respondent Pharmacy had
21 a preprinted prescription form with ophthalmic drops listed. Respondent Pharmacy's pre-printed
22 prescription form had a number resembling a FDA issued National Drug Code listed in front of
23 each type of ophthalmic solution; such as found with Rx #127106, Rx# 127104, and Rx# 127335.
24 Respondent Pharmacy prepared large volume batches of the ophthalmic solution combination
25 prednisolone sodium 1%/moxifloxacin HCL 0.5%/bromfenac sodium 0.09%: 648 containers on
26 February 13, 2017, and 552 containers on February 27, 2017; and 276 containers of prednisolone
27 sodium 1%/moxifloxacin 0.5% on February 15, 2017. When recalling 121 containers of
28 ophthalmic solution, Respondent Pharmacy only contacted 6 individual patients and prescribers

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

4 **FIFTEENTH CAUSE FOR DISCIPLINE**

5 **(Erroneous or Uncertain Prescriptions)**

6 59. Respondents Pharmacy, Quinn, and Miller are subject to disciplinary action under
7 section 4301, subdivision (o), for violating California Code of Regulations Section 1761(a), by
8 dispensing dangerous drugs without first contacting the prescribers to obtain the needed
9 information on uncertain, ambitious, and irregular prescriptions. Specifically, Respondent
10 Pharmacy dispensed ophthalmic solutions pursuant to prescriptions which did not contain all of
11 the required elements of a valid prescription, such as individual patient addresses or patient
12 directions. Prescriptions were dispensed in amounts greater than a reasonable quantity for a
13 specific patient, such as: Rx# 127104 dispensed to K.S. for 30ml on March 1, 2017, and March 7,
14 2017. The ophthalmic solution compounded preparations were labeled and placed in an
15 individual box that resembled a professionally manufactured product. Respondent Pharmacy had
16 a preprinted prescription form with ophthalmic drops listed. Respondent Pharmacy's pre-printed
17 prescription form had a number resembling a FDA issued National Drug Code listed in front of
18 each type of ophthalmic solution; such as found with Rx #127106, Rx# 127104, and Rx# 127335.
19 Respondent Pharmacy prepared large volume batches of the ophthalmic solution combination
20 prednisolone sodium 1%/moxifloxacin HCL 0.5%/bromfenac sodium 0.09%: 648 containers on
21 2/13/17 and 552 containers on 2/27/17; and 276 containers of prednisolone sodium
22 1%/moxifloxacin 0.5% on 2/15/17. When recalling 121 containers of ophthalmic solution,
23 Respondent Pharmacy only contacted 6 individual patients, and prescribers were contacted to
24 return the remaining 115 dispenses. Complainant refers to, and by this reference incorporates, the
25 allegations set forth above in paragraphs 46 through 58, as if set forth in full herein.

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

6 **PRAYER**

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

- 9 1. Revoking or suspending Pharmacy Permit Number PHY 50264, issued to Kohana
10 Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for
11 Regenerative Medicine;
- 12 2. Revoking or suspending Pharmacist License Number RPH 32154, issued to Robert
13 Denis Quinn;
- 14 3. Revoking or suspending Pharmacist License Number RPH 70014 issued to Nataliya
15 McElroy Miller;
- 16 4. Revoking or suspending Pharmacist License Number RPH 71144 issued to Anthony
17 Sinconis;
- 18 5. Prohibiting Kohana Pharmacy and Center for Regenerative Medicine, Inc. from
19 serving as a manager, administrator, owner, member, officer, director, associate, or partner of a
20 licensee for five years if Pharmacy Permit Number PHY 49140 is placed on probation or until
21 Pharmacy Permit Number PHY 49140 is reinstated if Pharmacy Permit Number 49140 issued to
22 Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center
23 for Regenerative Medicine is revoked;
- 24 6. Prohibiting Robert Denis Quinn from serving as a manager, administrator, owner,
25 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
26 Number PHY 49140 is placed on probation or until Pharmacy Permit Number PHY 49140 is
27 reinstated if Pharmacy Permit Number PHY 49140 issued to Kohana Pharmacy and Center for
28


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

3 7. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the
4 investigation and enforcement of this case, pursuant to Business and Professions Code section
5 125.3;

6 8. Taking such other and further action as deemed necessary and proper.
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10 DATED: 3/28/18



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

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Attorneys for Complainant

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

11 In the Matter of the First Amended Accusation
Against:

Case No. 5556

12 **KOHANA PHARMACY AND CENTER**
13 **FOR REGENERATIVE MEDICINE, INC.**
14 **DBA KOHANA PHARMACY AND**
15 **CENTER FOR REGENERATIVE**
16 **MEDICINE, ROBERT DENIS QUINN,**
17 **OWNER**
18 181 Tank Farm Rd., #120
San Luis Obispo, CA 93401
19 **Pharmacy Permit No. PHY 50264,**
20 **ROBERT DENIS QUINN**
7475 Balboa Road
21 Atascadero, CA 93422
Pharmacist License No. RPH 32154,
22 **NATALIYA McELROY MILLER**
522 Playa Circle
23 Paso Robles, CA 93446
24 **Pharmacist License No. RPH 70014**

FIRST AMENDED ACCUSATION

25 and

26 **ANTHONY SINCONIS,**
PO Box 75
27 Avila Beach, CA 93424
28 **Pharmacist License No. RPH 71144**

Respondents.

1 Complainant alleges:

2 **PARTIES**

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

6 2. On or about April 20, 2010, the Board of Pharmacy issued Pharmacy Permit Number
7 PHY 50264 to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana
8 Pharmacy and Center for Regenerative Medicine (Respondent Pharmacy). Pursuant to the
9 Board's records, both Alan James Martin and Robert Denis Quinn are and have been a director
10 and 50% shareholder of Respondent Pharmacy since April 20, 2010. Alan James Martin,
11 Pharmacist License No. RPH 37337¹ (Pharmacist Martin) was the Pharmacist-in-Charge of
12 Respondent Pharmacy from April 20, 2010 to October 16, 2013. Respondent Robert Denis Quinn
13 has been the Pharmacist-in-Charge of Respondent Pharmacy from November 16, 2013 to the
14 present. The Pharmacy Permit was in full force and effect at all times relevant to the charges
15 brought herein and will expire on April 1, 2018, unless renewed.

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

20 4. On or about August 3, 1978, the Board of Pharmacy issued Pharmacist License
21 Number RPH 32154 to Robert Denis Quinn (Respondent Quinn). The Pharmacist License was in
22 full force and effect at all times relevant to the charges brought herein and will expire on June 30,
23 2018, unless renewed.

24
25
26 ¹ Alan James Martin entered into a stipulated settlement of Accusation No. 5556, which
was adopted by the Board, effective May 19, 2017.

27 ² On or about June 14, 2017, Kohana Pharmacy and Center for Regenerative Medicine,
28 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.

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

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

5 13. Section 4301 of the Code states, in part:

6 “The board shall take action against any holder of a license who is guilty of unprofessional
7 conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is
8 not limited to, any of the following:

9

10 (j) The violation of any of the statutes of this state, of any other state, or of the United States
11 regulating controlled substances and dangerous drugs.

12 ...

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

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

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

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

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

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

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

3 (b) Manager, administrator, owner, member, officer, director, associate, partner, or any
4 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.

5 (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.
6 However, no order may be issued in that case except as to a person who is named in the caption,
7 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
8 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision
9 shall be in addition to the board's authority to proceed under Section 4339 or any other provision
of law.

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

11 "(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs
12 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
13 current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary
food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital,
14 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
15 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.

16 "(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal
17 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."
18

19 REGULATORY PROVISIONS

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

21 "For the purpose of denial, suspension, or revocation of a personal or facility license
22 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
23 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
24 consistent with the public health, safety, or welfare."

25 18. California Code of Regulations section 1735 states, in part;

26 "(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:

27 (1) Altering the dosage form or delivery system of a drug."
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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.

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

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

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

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

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

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

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

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

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

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

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

27 (1) Procedures for notifying staff assigned to compounding duties of any changes in
28 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."

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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

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

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

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

7 **COST RECOVERY**

8 28. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
9 administrative law judge to direct a licentiate found to have committed a violation or violations of
10 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
11 enforcement of the case, with failure of the licentiate to comply subjecting the license to not being
12 renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be
13 included in a stipulated settlement.

14 **AVASTIN**

15 29. Avastin (bevacizumab) is a dangerous drug pursuant to Section 4022. It is used to
16 treat various cancers. It is usually given as an infusion. Avastin is restricted for purchase to
17 hospital, federal accounts, physician's offices, and authorized specialty pharmacies. Avastin does
18 not contain any preservatives, and, therefore, is meant for immediate one time use. Any unused
19 portions left in a vial of Avastin should be discarded. Diluted Avastin solutions may be stored at
20 2–8°C (36–46°F) for up to 8 hours. Avastin is available in a 100mg/4ml (also referred to as
21 25mg/ml 4ml) single use vial and a 400mg/16ml single use vial.

22 30. Avastin has an off label use in the treatment of macular degeneration. Avastin is
23 commercially available in a much larger quantity vial than is needed for a single dose
24 administration in the treatment of eye disease. Generally, the 4ml vial is used to produce between
25 50 to 80 doses. Dividing a vial of Avastin into numerous tiny doses for injection into the eye
26 introduces the risk of bacterial contamination, which may cause severe eye infections and
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1 blindness. Pharmacies compounding Avastin must adhere to the sterile techniques and standards
2 outlined in USP Chapter 797.³

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

8 FACTUAL SUMMARY

9 32. On or about February 19, 2013, French Hospital Medical Center (French Hospital),
10 located at 1911 Johnson Avenue, San Luis Obispo, California, notified the Board that employees
11 of French Hospital, one of which was Pharmacist Martin's wife, were ordering Avastin through
12 the French Hospital Pharmacy and reselling it to Respondent Pharmacy and Center for
13 Regenerative Medicine (Respondent Pharmacy). Respondent Pharmacy paid in cash for the
14 Avastin. According to French Hospital, there were 12 orders of Avastin placed and received on
15 Respondent Pharmacy's behalf over the course of 15 months (November 2011 through January
16 15, 2013). None of these 12 orders were needed or used by French Hospital patients and there
17 was no on-hand inventory of Avastin. French Hospital did not maintain any accounting records
18 of Respondent Pharmacy's Avastin orders and payments. French Hospital tracked the orders
19 through the hospital's vendors. French Hospital did not provide Respondent Pharmacy with any
20 invoices for the Avastin and Respondent Pharmacy did not provide any receipts for its payments.
21 There was no paper documentation that showed how much Respondent Pharmacy paid for each
22 order or for which orders payments had been received.

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25 ³ USP Chapter 797 "provides procedures and requirements for compounding sterile
26 preparations. General Chapter 797 describes conditions and practices to prevent harm to patients
27 that could result from microbial contamination, excessive bacterial endotoxins, variability in
28 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.)

1 33. The Board's investigation revealed that from November 2011 through January 15,
2 2013, Respondent Pharmacy purchased 19 to 21 vials of Avastin 25mg/ml 4ml⁴ from French
3 Hospital, and that records of purchase and sale were not maintained.⁵

4 34. The Board's investigation also revealed that from August 15, 2011, through February
5 12, 2013, 1997 syringes of Avastin were dispensed by Respondent Pharmacy.⁶ Respondent
6 Pharmacy compounded the 1997 non-patient specific doses of Avastin for off label ophthalmic
7 use and sold it to a few physicians' offices to treat patients with macular degeneration.
8 Pharmacist Martin and Respondent Quinn were responsible for compounding the Avastin
9 ophthalmic preparations. Of the 1997 doses, Pharmacist Martin was responsible for at least 1917
10 doses and Respondent Quinn was responsible for at least 80 doses. During this period, Pharmacist
11 Martin was the pharmacist-in-charge of Respondent Pharmacy. Respondent Pharmacy was not
12 licensed as a drug manufacturer.

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

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

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

23 ⁴ The invoices from French Hospital's vendors refer to the vials purchased as Avastin
24 25mg/ml 4ml or Avastin 100mg/4ml. Each ml of concentrate contains 25mg of Avastin. Each
4ml vial contains 100mg of Avastin.

25 ⁵ Respondent Pharmacy's records showed it purchased 19 vials of 4ml Avastin for a
26 purchase amount of approximately \$11,823.32. French Hospital stated they sold 21 vials of 4ml
27 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.

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

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

7 **FIRST CAUSE FOR DISCIPLINE**

8 **(Failure to Maintain Records of Acquisition)**

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

17 **SECOND CAUSE FOR DISCIPLINE**

18 **(Failure to Maintain Required Compounding Records)**

19 39. Respondents Pharmacy and Quinn are subject to disciplinary action under section
20 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply
21 with California Code of Regulations, title 16, section 1735.3, subdivisions (a) and (b).
22 Specifically, between August 15, 2011, through February 12, 2013, while Pharmacist Martin was
23 working as the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vials to
24 compound Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondent
25 Pharmacy compounded 1997 doses of Avastin. Respondent Quinn was responsible for at least 80
26 doses. Respondents did not maintain compounding records. Complainant refers to, and by this
27 reference incorporates, the allegations set forth above in paragraphs 32 through 37, as if set forth
28 in full herein.

1 **THIRD CAUSE FOR DISCIPLINE**

2 **(Failure to Comply with Sterile Injectable Recordkeeping Requirements)**

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

14 **FOURTH CAUSE FOR DISCIPLINE**

15 **(Acting as a Drug Manufacturer without a Permit)**

16 41. Respondents Pharmacy and Quinn are subject to disciplinary action under section
17 4301, subdivisions (j) and (o), on the grounds of unprofessional conduct, in conjunction with
18 Section 4033, subdivision (a)(1), for acting as a drug manufacturer without a permit. Specifically,
19 from August 15, 2011 to February 12, 2013, while Pharmacist Martin was working as the
20 pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vials to compound 1997
21 Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondent Quinn was
22 responsible for at least 80 doses. The product was transferred into 1ml tuberculin syringes, which
23 changed the dosage form and delivery system from intravenous (IV) to intra-ocular injection.
24 Respondents then sold the 1997 non-patient specific doses to physicians' offices to use on their
25 patients. Complainant refers to, and by this reference incorporates, the allegations set forth above
26 in paragraphs 32 through 37, as if set forth in full herein.

1 **FIFTH CAUSE FOR DISCIPLINE**

2 **(Failure to Comply with Compounding Limitations and Requirements)**

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

15 **SIXTH CAUSE FOR DISCIPLINE**

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

17 43. Respondents Pharmacy and Quinn are subject to disciplinary action under section
18 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply
19 with California Code of Regulations, title 16, section 1735.5, subdivision (c), which requires that
20 a pharmacy's policy and procedure manual include the following: "(5) Documentation of the
21 methodology used to determine appropriate expiration dates for compounded drug products."
22 Specifically, from August 15, 2011 to February 12,2013, while Pharmacist Martin was working as
23 the pharmacist-in-charge, Respondent Pharmacy used Avastin 25mg/ml 4ml vial to compound
24 Avastin 0.05ml syringes for intravitreal (inside the eye) sterile injection. Respondent Pharmacy
25 compounded 1997 doses and failed to document the methodology used to establish a beyond use
26 date that exceeded the manufacturer's and USP 797 guidelines. Respondent Quinn was
27 responsible for at least 80 doses. Complainant refers to, and by this reference incorporates, the
28 allegations set forth above in paragraphs 32 through 37, as if set forth in full herein.

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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

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

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

6 49. Respondent Pharmacy placed extended "beyond use date" or BUD⁷ on compounded
7 eye drops without performing the required tests such as method suitability, container closure
8 integrity, or stability studies to support such extended BUD. Respondent Pharmacy specifically
9 compounded small lots of ophthalmic solution for extended BUD testing that were compounded
10 using a *sterilization grade filter*, and then placed the extended BUDs from the testing of these lots
11 to much larger lots of compounded ophthalmic solution that were compounded using a *non-*
12 *sterilizing filter* and used additional compounding steps. These tested and untested batches were
13 not identical in specific and essential compounding steps.

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

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

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

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

1 **NINTH CAUSE FOR DISCIPLINE**

2 **(Failure to follow manufacturer's instructions)**

3 53. Respondents Pharmacy, Quinn, and Sinconis are subject to disciplinary action under
4 section 4301, subdivision (o), for violating California Code of Regulations, title 16, section
5 1735.6, subdivision (b), by failing to ensure equipment used to compound drug preparations was
6 in accordance with manufacturer's specifications. Specifically, Respondent Pharmacy used a
7 Thermo Fisher Filter Assembly, product number SH00055-I, as the sterilization method to
8 prepare a sterile compound from one or more non-sterile ingredients. The product page for the
9 Thermo Fisher Filter Assembly stated "Filter Assembly is not intended as a final sterilization
10 filter." Complainant refers to, and by this reference incorporates, the allegations set forth above in
11 paragraphs 46 through 52, as if set forth in full herein.

12 **TENTH CAUSE FOR DISCIPLINE**

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

14 54. Respondents Pharmacy, Quinn, and Sinconis are subject to disciplinary action under
15 section 4301, subdivision (o), for violating California Code of Regulations Section 1735.2,
16 subdivision (i)(3), by failing to ensure the required valid testing was completed prior to
17 dispensing of compounded preparations with extended beyond use dates. Specifically,
18 Respondent Pharmacy dispensed ophthalmic preparations, compounded from one or more non-
19 sterile ingredients, with extended beyond use dates that were not supported by required testing.
20 Lot # 02152017@9 was given a beyond use date of 180 days based on data from testing lot #
21 05062015@26. Respondent Pharmacy could not provide data to support the required Method
22 Suitability Test, Container Closure Integrity Test and Stability Studies for lot # 02152017@9.
23 Complainant refers to, and by this reference incorporates, the allegations set forth above in
24 paragraphs 46 through 52, as if set forth in full herein.

25 **ELEVENTH CAUSE FOR DISCIPLINE**

26 **(Using Invalid Extended Beyond Date)**

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

1 subdivision (i)(4), by using extended beyond date that was invalid for current compounding
2 process. Specifically, Respondent Pharmacy used compounded preparation lot # 12152016@13
3 (compounded from one or more non-sterile ingredients) for testing to establish the extended
4 beyond use date applied to lot # 02132017@1, which was not identical in specific and essential
5 compounding steps. Respondent Pharmacy used compounded preparation lot # 05062015@26
6 (compounded from one or more non-sterile ingredients) for extended beyond use dating for lot #
7 02152017@9, which was not identical in specific and essential compounding steps. Respondent
8 Pharmacy compounded a preparation for testing for extended beyond use date. The extended
9 beyond use date was assigned to a current compounded preparation (compounded from one or
10 more non-sterile ingredients) which did not utilize the same essential compounding processes.
11 Complainant refers to, and by this reference incorporates, the allegations set forth above in
12 paragraphs 46 through 52, as if set forth in full herein.

13 **TWELFTH CAUSE FOR DISCIPLINE**

14 **(Failure to Clean ISO 5 Surfaces Daily)**

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

24 **THIRTEENTH CAUSE FOR DISCIPLINE**

25 **(Failure to Adequately Train Sterile Compounding Staff)**

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

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

9 **FOURTEENTH CAUSE FOR DISCIPLINE**

10 **(Unlicensed Activity: Acting as a Manufacturer)**

11 58. Respondents Pharmacy, Quinn, and Miller are subject to disciplinary action under
12 section 4033, subdivision (a)(1), and California Code of Regulations Section 1735.2 subdivision
13 (a), by acting as a manufacturer in preparation of compounded ophthalmic solutions for
14 dispensing to physician offices under the pretense of patient specific prescriptions. Specifically
15 Respondent Pharmacy dispensed ophthalmic solutions pursuant to prescriptions which did not
16 contain all of the required elements of a valid prescription, such as individual patient addresses or
17 patient directions. Prescriptions were dispensed in amounts greater than a reasonable quantity for
18 a specific patient, such as: Rx# 127104 dispensed to K.S. for 30ml on March 1, 2017, and March
19 7, 2017. The ophthalmic solution compounded preparations were labeled with and placed in an
20 individual box that resembled a professionally manufactured product. Respondent Pharmacy had
21 a preprinted prescription form with ophthalmic drops listed. Respondent Pharmacy's pre-printed
22 prescription form had a number resembling a FDA issued National Drug Code listed in front of
23 each type of ophthalmic solution; such as found with Rx #127106, Rx# 127104, and Rx# 127335.
24 Respondent Pharmacy prepared large volume batches of the ophthalmic solution combination
25 prednisolone sodium 1%/moxifloxacin HCL 0.5%/bromfenac sodium 0.09%: 648 containers on
26 February 13, 2017, and 552 containers on February 27, 2017; and 276 containers of prednisolone
27 sodium 1%/moxifloxacin 0.5% on February 15, 2017. When recalling 121 containers of
28 ophthalmic solution, Respondent Pharmacy only contacted 6 individual patients and prescribers

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

4 **FIFTEENTH CAUSE FOR DISCIPLINE**

5 **(Erroneous or Uncertain Prescriptions)**

6 59. Respondents Pharmacy, Quinn, and Miller are subject to disciplinary action under
7 section 4301, subdivision (o), for violating California Code of Regulations Section 1761(a), by
8 dispensing dangerous drugs without first contacting the prescribers to obtain the needed
9 information on uncertain, ambitious, and irregular prescriptions. Specifically, Respondent
10 Pharmacy dispensed ophthalmic solutions pursuant to prescriptions which did not contain all of
11 the required elements of a valid prescription, such as individual patient addresses or patient
12 directions. Prescriptions were dispensed in amounts greater than a reasonable quantity for a
13 specific patient, such as: Rx# 127104 dispensed to K.S. for 30ml on March 1, 2017, and March 7,
14 2017. The ophthalmic solution compounded preparations were labeled and placed in an
15 individual box that resembled a professionally manufactured product. Respondent Pharmacy had
16 a preprinted prescription form with ophthalmic drops listed. Respondent Pharmacy's pre-printed
17 prescription form had a number resembling a FDA issued National Drug Code listed in front of
18 each type of ophthalmic solution; such as found with Rx #127106, Rx# 127104, and Rx# 127335.
19 Respondent Pharmacy prepared large volume batches of the ophthalmic solution combination
20 prednisolone sodium 1%/moxifloxacin HCL 0.5%/bromfenac sodium 0.09%: 648 containers on
21 2/13/17 and 552 containers on 2/27/17; and 276 containers of prednisolone sodium
22 1%/moxifloxacin 0.5% on 2/15/17. When recalling 121 containers of ophthalmic solution,
23 Respondent Pharmacy only contacted 6 individual patients, and prescribers were contacted to
24 return the remaining 115 dispenses. Complainant refers to, and by this reference incorporates, the
25 allegations set forth above in paragraphs 46 through 58, as if set forth in full herein.

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1 **SIXTEENTH CAUSE FOR DISCIPLINE**

2 **(Unprofessional Conduct)**

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

6 **DISCIPLINARY CONSIDERATIONS**

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

9 **Respondent Pharmacy**

10 62. On or about February 18, 2014, in a prior action, the Board issued Citation Number
11 CI 2012 57004 to Kohana Pharmacy and Center for Regenerative Medicine, PHY 50264 for
12 violating California Code of Regulations, title 16, section 1717.3, subdivision (b) (dispensing a
13 controlled substance pursuant to a preprinted multiple check-off prescription blank) and fined
14 \$2,000. Specifically, from a date unknown through July 31, 2013, Respondent Pharmacy filled
15 1087 prescription orders containing ketamine, a controlled substance, pursuant to a preprinted,
16 multiple check-off prescription blank. That Citation is now final and is incorporated by reference
17 as if fully set forth.

18 **OTHER MATTERS**

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

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

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

6 **PRAYER**

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

9 1. Revoking or suspending Pharmacy Permit Number PHY 50264, issued to Kohana
10 Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for
11 Regenerative Medicine;

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

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

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

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

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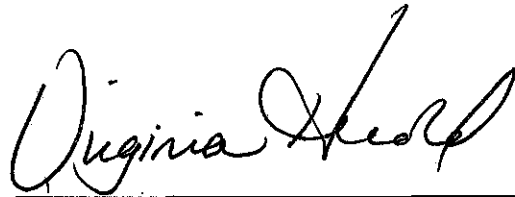
1 .Regenerative Medicine, Inc. dba Kohana Pharmacy and Center for Regenerative Medicine is
2 revoked;

3 7. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the
4 investigation and enforcement of this case, pursuant to Business and Professions Code section
5 125.3;

6 8. Taking such other and further action as deemed necessary and proper.
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8
9
10 DATED:

12/11/17



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

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Attorneys for Complainant

**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**

A C C U S A T I O N

Respondents.

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

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

5 12. Section 4301 of the Code states, in part:

6 “The board shall take action against any holder of a license who is guilty of unprofessional
7 conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.

8 Unprofessional conduct shall include, but is not limited to, any of the following:

9 ...

10 “(j) The violation of any of the statutes of this state, or any other state, or of the United
11 States regulating controlled substances and dangerous drugs.

12 ...

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 REGULATORY PROVISIONS

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

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

9 17. California Code of Regulations section 1735 states, in part,

10 "(a) 'Compounding' means any of the following activities occurring in a licensed
11 pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

12 (1) Altering the dosage form or delivery system of a drug."

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

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

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

23 ...

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

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

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

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

- 6 (1) The master formula record.
- 7 (2) The date the drug product was compounded.
- 8 (3) The identity of the pharmacy personnel who compounded the drug product.
- 9 (4) The identity of the pharmacist reviewing the final drug product.
- 10 (5) The quantity of each component used in compounding the drug product.
- 11 (6) The manufacturer, expiration date and lot number of each component. If the

12 manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.

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

- 18 (7) A pharmacy assigned reference or lot number for the compounded drug product.
- 19 (8) The expiration date of the final compounded drug product.
- 20 (9) The quantity or amount of drug product compounded.

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

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

28

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

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

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

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

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

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

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

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

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

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

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

25 “(a) Pharmacies compounding sterile injectable products for future use pursuant to section
26 1735.2 shall, in addition to those records required by section 1735.3, make and keep records
27 indicating the name, lot number, amount, and date on which the products were provided to a
28 prescriber.”

1 COST RECOVERY

2 22. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
3 administrative law judge to direct a licentiate found to have committed a violation or violations of
4 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
5 enforcement of the case, with failure of the licentiate to comply subjecting the license to not being
6 renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be
7 included in a stipulated settlement.

8 AVASTIN

9 23. Avastin (bevacizumab) is a dangerous drug pursuant to Section 4022. It is used to
10 treat various cancers. It is usually given as an infusion. Avastin is restricted for purchase to
11 hospital, federal accounts, physician's offices, and authorized specialty pharmacies. Avastin does
12 not contain any preservatives, and, therefore, is meant for immediate one time use. Any unused
13 portions left in a vial of Avastin should be discarded. Diluted Avastin solutions may be stored at
14 2–8°C (36–46°F) for up to 8 hours. Avastin is available in a 100mg/4ml (also referred to as
15 25mg/ml 4ml) single use vial and a 400mg/16ml single use vial.

16 24. Avastin has an off label use in the treatment of macular degeneration. Avastin is
17 commercially available in a much larger quantity vial than is needed for a single dose
18 administration in the treatment of eye disease. Generally, the 4ml vial is used to produce between
19 50 to 80 doses. Dividing a vial of Avastin into numerous tiny doses for injection into the eye
20 introduces the risk of bacterial contamination, which may cause severe eye infections and
21 blindness. Pharmacies compounding Avastin must adhere to the sterile techniques and standards
22 outlined in USP Chapter 797.¹

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

25 ¹ USP Chapter 797 “provides procedures and requirements for compounding sterile
26 preparations. General Chapter 797 describes conditions and practices to prevent harm to patients
27 that could result from microbial contamination, excessive bacterial endotoxins, variability in
28 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.)

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

4 FACTUAL SUMMARY

5 26. On or about February 19, 2013, French Hospital Medical Center (French Hospital),
6 located at 1911 Johnson Avenue, San Luis Obispo, California, notified the Board that employees
7 of French Hospital, one of which was Respondent Martin's wife, were ordering Avastin through
8 the French Hospital Pharmacy and reselling it to Respondent Pharmacy and Center for
9 Regenerative Medicine (Respondent Pharmacy). Respondent Pharmacy paid in cash for the
10 Avastin. According to French Hospital, there were 13 orders of Avastin placed and received on
11 Respondent Pharmacy's behalf over the course of 15 months (November 2011 through January
12 15, 2013). None of these orders were needed or used by French Hospital patients and there was

13 no on-hand inventory of Avastin. French Hospital did not maintain any accounting records of
14 Respondent Pharmacy's Avastin orders and payments. French Hospital tracked the orders
15 through the hospital's vendors. French Hospital did not provide Respondent Pharmacy with any
16 invoices for the Avastin and Respondent Pharmacy did not provide any receipts for its payments.
17 There was no paper documentation that showed how much Respondent Pharmacy paid for each
18 order or for which orders payments had been received.

19 27. The Board's investigation revealed that from November 2011 through January 15,
20 2013, Respondent Pharmacy purchased 19 to 21 vials of Avastin 25mg/ml 4ml² from French
21 Hospital, and that records of purchase and sale were not maintained.³

22 28. The Board's investigation also revealed that from August 15, 2011, through February
23 12, 2013, 1997 syringes of Avastin were dispensed by Respondent Pharmacy.⁴ Respondent

24 ² The invoices from French Hospital's vendors refer to the vials purchased as Avastin
25 25mg/ml 4ml or Avastin 100mg/4ml. Each ml of concentrate contains 25mg of Avastin. Each
26 4ml vial contains 100mg of Avastin.

27 ³ Respondent Pharmacy's records showed it purchased 19 vials of 4ml Avastin for a
28 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.

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

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

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

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

24 **FIRST CAUSE FOR DISCIPLINE**

25 **(Failure to Maintain Records of Acquisition)**

26 _____
27 (...continued)

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

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

5 **FOURTH CAUSE FOR DISCIPLINE**

6 **(Acting as a Drug Manufacturer without a Permit)**

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

18 **FIFTH CAUSE FOR DISCIPLINE**

19 **(Failure to Comply with Compounding Limitations and Requirements)**

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

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

4 **SIXTH CAUSE FOR DISCIPLINE**

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

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

18 **SEVENTH CAUSE FOR DISCIPLINE**

19 **(Failure to Exercise Professional Judgment)**

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

1 exceeded the manufacturers beyond use date and exceeded USP 797 guidelines. Complainant
2 refers to, and by this reference incorporates, the allegations set forth above in paragraphs 26 and
3 36, as if set forth in full herein.

4 **EIGHTH CAUSE FOR DISCIPLINE**

5 **(Unprofessional Conduct)**

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

9 **DISCIPLINARY CONSIDERATIONS**

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

12 **Respondent Pharmacy**

13 41. On or about February 18, 2014, in a prior action, the Board issued Citation Number
14 CI 2012 57004 to Kohana Pharmacy and Center for Regenerative Medicine, PHY 50264 for
15 violating California Code of Regulations, title 16, section 1717.3, subdivision (b) (dispensing a
16 controlled substance pursuant to a preprinted multiple check-off prescription blank) and fined
17 \$2,000. Specifically, from a date unknown through July 31, 2013, Respondent Pharmacy filled
18 1087 prescription orders containing ketamine, a controlled substance, pursuant to a preprinted,
19 multiple check-off prescription blank. That Citation is now final and is incorporated by reference
20 as if fully set forth.

21 **Respondent Martin**

22 42. On or about February 18, 2014, in a prior action, the Board issued Citation Number
23 CI 2013 60038 to Respondent Martin for violating California Code of Regulations, title 16,
24 section 1717.3, subdivision (b) (dispensing a controlled substance pursuant to a preprinted
25 multiple check-off prescription blank) and fined \$2000. Specifically, from a date unknown
26 through July 31, 2013, Respondent Martin, while acting as the pharmacist-in-charge of
27 Respondent Pharmacy, filled or caused to be filled 1087 prescription orders containing ketamine,
28

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

3 43. On or about June 27, 2011, in a prior action, the Board issued Citation Number CI
4 2010 48685 to Respondent Martin for violating California Code of Regulations, title 16, section
5 1761, subdivision (a), as it relates to Health and Safety Code, section 11170, which prohibits
6 furnishing erroneous or uncertain prescriptions, to wit, controlled substance prescriptions written
7 by a prescriber for himself, and fined \$250. Specifically, on January 7, 2010, Respondent Martin,
8 while working at Healthplus Pharmacy (PHY 43683), located at 948 A Foothill Blvd., San Luis
9 Obispo, CA 93405, furnished 6mls of testosterone 25mg/0.1ml, a schedule III controlled
10 substance, pursuant to a prescription written by Dr. Jeffrey Reinking for himself. That Citation is
11 now final and is incorporated by reference as if fully set forth.

12 **OTHER MATTERS**

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

20 45. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number
21 PHY 50264 to Kohana Pharmacy and Center for Regenerative Medicine, Inc. dba Kohana
22 Pharmacy and Center for Regenerative Medicine while Alan James Martin and/or Robert Denis
23 Quinn have been an officer and owner and had knowledge of or knowingly participated in any
24 conduct for which the licensee was disciplined, Alan James Martin and/or Robert Denis, as
25 applicable, shall be prohibited from serving as a manager, administrator, owner, member, officer,
26 director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49140
27 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;

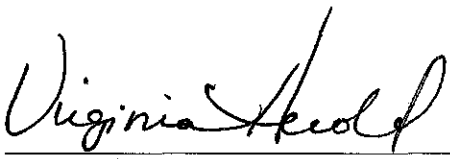
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7. Prohibiting Robert Denis Quinn from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50264 is placed on probation or until Pharmacy Permit Number 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
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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