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

In the Matter of the Accusation Against:

KOHANA PHARMACY & CENTER FOR REGENERATIVE MEDICINE, INC., dba KOHANA PHARMACY AND CENTER FOR REGENERATIVE MEDICINE; ROBERT DENIS QUINN, OWNER,

Original Pharmacy Permit No. PHY 50264, and

ROBERT DENIS QUINN,

Original Pharmacist License No. RPH 32154,

Respondents.

Agency Case No. 6922

OAH No. 2020080010

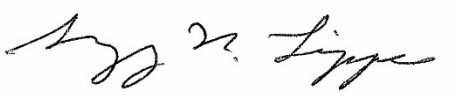
DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on May 12, 2021.

It is so ORDERED on April 12, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Greg Lippe
Board President

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PROPOSED DECISION

Administrative Law Judge Michael C. Starkey, State of California, Office of Administrative Hearings, heard this matter on January 27 and 28, 2021, via telephone and videoconference.

Supervising Deputy Attorney General Joshua A. Room represented complainant Anne Sodergren, Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

Attorney Herbert L. Weinberg represented respondent Kohana Pharmacy & Center for Regenerative Medicine, Inc., and respondent Robert Denis Quinn, who was present.

The record closed and the matter was submitted on January 28, 2021.

FACTUAL FINDINGS

Jurisdictional Matters

1. On or about April 20, 2010, the Board of Pharmacy issued Original Pharmacy Permit Number PHY 50264 to Kohana Pharmacy & Center for Regenerative Medicine, Inc., doing business as Kohana Pharmacy and Center for Regenerative Medicine (Kohana). Since April 1, 2015, Robert Denis Quinn (Quinn) has been President and 100% shareholder of Kohana. The pharmacy permit was in full force and effect at all relevant times and will expire on June 30, 2022, unless renewed.

2. On August 3, 1978, the Board of Pharmacy issued Original Pharmacist License Number RPH 32154 to Quinn. The license was in full force and effect at all relevant times and will expire on April 1, 2021, unless renewed. Since November 16, 2013, Quinn has served as Pharmacist in Charge (PIC) for Kohana.

3. On May 6, 2020, complainant Anne Sodergren issued the accusation solely in her capacity as Executive Officer of the Board of Pharmacy, Department of Consumer Affairs. Complainant alleges that respondents failed to maintain adequate

records of acquisition and disposition; sold dangerous drugs that were adulterated and/or misbranded; and engaged in the unlicensed manufacture of new drugs. Complainant further alleges that respondent Quinn committed acts of fraud, deceit, or corruption by making misleading or untrue statements to Board inspectors and in advertisements for compounded cannabidiol (CBD) products; subverted a Board investigation; and engaged in unprofessional conduct and/or misused his education as a pharmacist. Respondents timely submitted a notice of defense and this proceeding followed.

Issues

4. The issues in this case are: (a) whether complainant established cause to discipline respondents' licenses; (b) if so, to what extent did respondents prove mitigation or rehabilitation; (c) what is the appropriate level of discipline; (d) what is the amount of costs reasonably incurred by complainant in the investigation and prosecution of this matter; and (e) to what extent, if any, are respondents liable for such costs?

Standard of Proof

5. Complainant is required to prove cause for discipline of a professional license or registration by "clear and convincing proof to a reasonable certainty." (Cf. *Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856; see Bus. & Prof. Code, § 23.7 [all statutory references are to the Business and Professions Code, unless otherwise stated].) If respondents contend mitigation or rehabilitation, it is their burden to prove those contentions by a preponderance of the evidence. (Evid. Code, §§ 115, 500.)

Background

6. Between February 15, 2019, and December 30, 2019, Board inspectors conducted an investigation into the patterns and practices of Kohana and Quinn. Inspections of Kohana's premises and records were undertaken by the inspectors on June 18 and 26, 2019. Quinn was present during both inspections.

7. On June 25, 2019, the Board issued stipulated disciplinary orders effective July 25, 2019, placing the licenses held by Kohana and Quinn on probation for a period of five years. Respondents admitted that complainant could prove they had engaged in a practice of buying dangerous drugs (Avastin) from a nearby hospital, paying cash for these drugs, not generating or receiving any acquisition records for these drugs, and engaging in inappropriate compounding practices with some of these drugs.

The June 18, 2019 Inspection

8. Kohana's premises consist of a large pharmacy section and an over-the-counter (OTC) section with multiple smaller offices around the perimeter. The businesses advertised in the smaller offices were related to family/marriage counseling, chiropractic treatment, and massage therapy. The pharmacy section had a front counter section, an active drug stock and prescription filling section, a lab section with multiple counters and shelving, a non-sterile compounding room with an attached storage room, a conference room, and a combined storage and employee break room area with a smaller hallway leading to another room with no visible signage on the door (Back Room). The door to the Back Room was locked. Quinn stated the Back Room was leased by another company.

9. Board inspectors conducted a full inspection, documented numerous minor violations, and had a discussion with Quinn. Quinn reported that Kohana used to engage in the compounding of pain creams but they "really don't" any longer.

10. One of the inspectors later entered the Back Room through a different, unlocked door and discovered that it appeared to be a compounding room with a powder-containment hood, mixing machines, scales, binders, and compounding supplies. Quinn entered the room and told the inspector that he was not allowed in the Back Room because it belonged to another business and that the door was not supposed to be unlocked.

11. The inspector left the room, but both inspectors returned to the room and began looking in cabinets and drawers. They discovered additional compounding instruments and supplies, including Microsome Plus, which is a "dangerous drug" pursuant to section 4022 and only sold to pharmacists to be used as a base cream for compounding. They discovered formulas and invoices showing that Microsome Plus was purchased and delivered to Kohana and used in the compounding of pain creams and capsules in the name of "7-Sister Pharmaceuticals," (also known as "Seven Sisters Pharmaceuticals") and "Blue Gaja."

12. The inspectors also found various containers labelled with the names of OTC medications combined with CBD and tetrahydrocannabinol (THC) (e.g. "CBD Pain Fighter Cream" and "Medi Haze" with a "1:1 ratio of CBD/THC") (THC is the principal psychoactive chemical in cannabis). Many were improperly labeled and/or could not be traced to a licensed manufacturer for the product or the ingredients.

13. Quinn re-entered the Back Room and again stated that the inspectors were not allowed in the room because it belonged to another company. Quinn

identified "Blue Gaja" as the name of the company. When asked for a copy of the lease agreement, Quinn stated that it was not readily available, but he was sure he had it somewhere in his office. When asked "[w]hat's really going on in here?" Quinn stated that he had no idea what the company was doing in the room. When asked about "A.R.M. Pharmaceuticals" (the name on multiple bottles of pills), Quinn stated it was another company that also leased the Back Room to make products. The inspectors found and showed to Quinn boxes labelled "Ship to: Kohana Pharmacy" and he stated that he sold the companies some jars and compounding supplies. The inspectors found compounding documents (including formulas) and order forms with the following additional company names: "7-Sister Pharmaceuticals," "Green Research Labs," "Institute for Green Science Research" (IGSR), and "CaliFuzion."

14. The Inspectors embargoed the misbranded products to prevent furnishing, including 232 unlabeled blue jars containing an opaque cream.

15. During their search, the Board Inspectors also found a box labeled "Kohana Pharmacy" containing a dry, leafy material with a strong cannabis odor, and a white plastic bag containing more dry, leafy material that smelled like cannabis. When asked, Quinn claimed to have no knowledge of the dry, leafy material. He directed the inspectors to A.A., a pharmacy technician employed by Kohana. Quinn reported that A.A. also worked for one or more of "the companies," but Quinn claimed that he did not know for which company A.A. worked, or how he was paid for that work.

16. The inspectors also discovered:

- A log of non-sterile compounded medications maintained by Kohana showing that numerous topical creams for the treatment of pain had been prepared during the month of May 2019.

- Compounding formula work sheets documenting various topical and oral non-sterile compounding formulations containing CBD, various OTC drugs, amino acids (e.g., DL-Phenylalanine), nutritional supplements, and inactive ingredients, listing "compounded" dates in 2018 and 2019. Most of the worksheets bore initials of A.A. and many had a second set of initials subsequently confirmed as Quinn's.

- "Institute for Green Science Research/CaliFuzion" invoice/order forms showing the filling of orders in 2018 for "Ultra Strength Pain Cream" for various clients ("100% Chiro," "MCK," and "J. Argie,") with at least one containing a note addressed to "Bob," which is what Quinn is commonly called.

- Email correspondence between Ernie Cavallaro (CaliFuzion email domain), Quinn and another individual concerning an order for "Jenny Argie" and discussing the process of decarboxylation of "CBDA and "THCA" to CBD and THC, and use of the "whole plant" of the "cannabis" plant.

- A price list and brochures for IGSR and a label sheet and brochures for 7-Sisters Pharmaceuticals. The brochure for IGSR included the following statements: "Compounding pharmacy researchers and manufacturers." "We currently offer products to be used as 'adjunctive' therapy for the following: Pain, Anxiety, Depression, PTSD, Sleep, Cancer." "Compounding Pharmacists working with Physicians for your health." The brochure for 7-Sisters Pharmaceuticals listed the same address and phone as Kohana, featured a photograph of Quinn and his wife, and included the following statements: "Product Formulators (R&D)." "Compounding Pharmacy Researchers and Manufacturers." "Our Advantage: As Pharmacists, we are drug EXPERTS! We

understand precise/precision formulation processes and the 'Mechanism of Action' of Cannabinoids. We can evaluate potential Drug-Drug interactions with other medications (both prescription and non-prescription)!" "*All of our products are made under the direct supervision of a Licensed Compounding Pharmacy!" "'Cannaceuticals' – Made by Compounding Pharmacists, our CBD is infused with amino acids and homeopathics to create a powerful synergistic blend for the relief of: Pain, Anxiety, Sleep, PTSD, Depression." Interviews with Kohana staff confirmed that they were instructed to provide the brochures to pharmacy customers who inquired about CBD products.

17. Following the June 18, 2019 pharmacy inspection, the inspectors conducted research on the internet and through public sources, and discovered the following information:

- Websites for: Blue Gaja (showing products containing CBD for sale); Jenny Argie, Founder, "Baked at Home" (referencing different cannabis/CBD/THC products); Marty's Cobra Kove (corresponding to the "MCK" materials listed above), advertising "Ultra Strength Pain Relief Cream" for sale with the product pictured, matching the blue jars found in the pharmacy, and promoting IGSR; IGSR, with various CBD products offered for sale; and a Biopharmrx Services LLC Bizapedia page showing Robert Quinn as the Registered Agent.

- The website for 7-Sisters Pharmaceuticals featured a photograph of Quinn and his wife. The "About Us" page included the following statements: "The products we recommend utilize the expertise of Organic Growers, State-of-the-Art Extractors, Product Formulators, Compounding Pharmacists,

Physicians, and other Healthcare Practitioners. The resulting 'CannaCeuticals' are made according to United States Pharmacopea (USP) Standards and truly are 'Pharmaceutical Grade.'" Public records show that Quinn's wife is the Registered Agent, and their home address is listed as the entity's address.

- State of California business records list the California address for IGSR as an address that is also listed in Board records as being associated with Quinn.

The June 26, 2019 Inspection

18. During the June 26, 2019 pharmacy inspection, the inspectors conducted interviews with several Kohana staff members and other witnesses. During the interview with pharmacy technician A.A. the inspectors learned:

- That A.A. had worked for Kohana for about two years as the main "after hours" compounding technician.

- That A.A. worked directly with Quinn in the Back Room on CBD compounding projects for various companies, including 7-Sisters Pharmaceuticals, which is owned by Quinn, which takes orders for compounded CBD products and moves inventory from Kohana to the other companies, Green Research Labs, IGSR, Blue Gaja, and CaliFuzion. A.A. said that he was paid for his "after hours" work via checks handed to him by Quinn, drawn on an account in the name of CaliFuzion.

- A.A. reported that Quinn helped with the labeling of the jars/products that were being created for Blue Gaja.

- A.A. reported that Quinn would come into the Back Room to check on him, to validate certain formula calculations, and to "sign off" on final products.

- A.A. reported that Quinn acquired the green, dry, leafy material, which was whole plant cannabis, and that they heat dried it in a microwave and used it to extract a tincture containing cannabinoids (CBD and/or THC). A.A. claimed that the cannabis was used twice and only for testing.

19. During his June 26, 2019 interview, Quinn told the inspectors:

- IGSR is based in Nevada, and is a collection of various researchers pooling their knowledge about "natural" health products. Quinn is both a consultant to, and partial business partner of, IGSR.

- CaliFuzion is wholly owned by the same people who primarily own IGSR.

- 7-Sisters Pharmaceuticals is owned by Quinn and his wife.

- Blue Gaja "leased" the Back Room and the services of A.A., who was assisted by Quinn on some of the compounding worksheets.

- Quinn denied knowledge of the source of the dry, leafy material.

Subsequent Information

20. On or about September 10, 2019, the inspectors received a statement from the owner of the Blue Gaja company, in which he confirmed:

- His business transactions with Quinn/Kohana were on an oral/handshake basis, and there were no invoices, bills of sale, or other paperwork.

- On or about May 11, 2019, he requested that Quinn make 200 jars of Extra Strength topical pain relief cream containing CBD.

- It was agreed that Blue Gaja would pay one price to include all ingredients, rental of the "back room," and Quinn's oversight.

21. The owner of the Blue Gaja company provided a copy of his payment to Quinn. It is a check in the amount of $2,594.70 made out to Quinn, drawn on the account of "Sustenance, Inc." and bearing what appears to be Quinn's endorsement on the back side. The document reflects that payment of the check posted on June 3, 2019.

Respondents' Evidence

22. Quinn holds a bachelor's degree in chemistry and a doctor of pharmacy degree. He has been licensed as a pharmacist in California since 1978. He has practiced in community pharmacies, hospitals, and psychiatric centers in various capacities including serving as director and chair. He has owned Kohana since 2010.

23. Quinn reports that the purpose of Kohana was to establish a collaborative practice with other health care professionals, emphasizing whole-body, personalized care.

24. Quinn reports that the Back Room was regularly used to compound pain cremes until insurance companies stopped paying for that in 2015. He also reports that his wife died around that time and that was also a reason Kohana stopped using the Back Room to compound pain cremes. He reports the Back Room was mostly used for storage between that time and 2019. He admits that the Back Room is part of Kohana's premises.

25. Quinn admits that the CBD brochures were intended for Kohana customers who inquired about CBD, but maintains that Kohana staff were instructed to bring him to such customers and then he would hand out the brochures. He explained that was because the employees were not qualified to converse about CBD. Quinn reports that Kohana never sold CBD products to its customers and never planned to do so. He later clarified that Kohana did not engage in retail sales of CBD products.

26. Quinn admits that he was not "fully forthcoming" in his responses to the inspectors. He reports that this was because he was nervous.

27. Quinn testified that the Back Room was "rented" to various companies on a short-term basis for use on weekends and evenings, but admitted that no such person or company had any exclusive rights to the Back Room. He admits that on June 18, 2019, he was not urging the inspectors to leave the Back Room on a renter's behalf. Quinn reports that in the first half of 2019 he was renting the Back Room to Blue Gaja and to IGSR, of which he is a part owner. Quinn claims that he exchanged funds with IGSR, but in no "specific amount" because he received 50 percent of sales. Quinn admitted that his deal with IGSR included use of the Back Room, A.A.'s work as a technician, and Quinn's supervision of A.A.'s work.

28. Quinn reports that his partner in IGSR provided the CBD in oil form and also handled the sales. Quinn maintains that the CBD was not extracted from cannabis, but rather from industrial hemp, which has a very low concentration of THC (less than 0.3 percent). Quinn struggled to reconcile that contention with the statements in the brochures, which he admits strongly imply that IGSR products have cannabis CBD, not hemp CBD.

29. Quinn admitted that he had provided the green leafy material found by the inspectors. He claims that material was industrial hemp, which he knew because he saw a certificate of analysis, although such a certificate was not stored with the material or submitted in evidence.

30. Quinn admits that Blue Gaja paid him approximately $2,500 and that payment was for his time as a supervising pharmacist, overseeing compounding. However, Quinn also testified that his participation was in the form of product formulation, not compounding.

31. Quinn admits that he co-owns 7 Sisters Pharmaceuticals with his current wife and that the company's brochure claims that "[a]ll of our products are made under the direct supervision of a Licensed Compounding Pharmacist." Quinn denies that this is false advertising but maintains that he did not actually watch A.A. perform compounding work. Quinn admits that he was supervising A.A.'s work and ensuring what he was "about to mix" and that the "finished product was correct." However, Quinn admits that the "Compounding Pharmacist" listed in the brochure was a reference to him.

32. Quinn admits that Kohana was the lessor of the premises and all of the lease agreements with the other subtenants were with Kohana, as the lessor. However, he reports that Kohana received nothing from his arrangement with IGSR.

33. Quinn testified that he understood that CBD was not a dangerous drug and did not require a prescription because he had seen CBD products sold OTC in multiple retail pharmacies. He submitted photographs of CBD products offered for OTC sale at two different CVS pharmacies in California. Quinn reports that he also saw an unnamed pharmacy in Anaheim manufacturing CBD products. Quinn reports that,

for those reasons, prior to the inspection he believed that his provision of the Back Room to renters was legal. However, he now understands that it was not. Quinn reports that he did not consult legal counsel regarding the legality of CBD products. He thought one could legally manufacture CBD products as long as no health claims were made. He reports that he was unaware his brochures were making health claims.

34. At hearing, Quinn apologized to the inspectors and those involved in this proceeding. Quinn reports that he has learned that he must practice to the "letter of the law." He loves helping people as a pharmacist and wants to make amends for his misconduct.

35. James Bateman testified at hearing and wrote a letter in support of Quinn. Bateman is the pharmacist appointed as Kohana and Quinn's probation monitor in March 2020. Bateman views Quinn as "ahead of his time." Bateman reports that in 40 years of pharmacy practice, Kohana is the first pharmacy that he has seen "actually embrace" a "truly integrated practice of Physician's Assistants, Nurse Practitioners, wellness counseling, Sauna and detoxification programs, massage therapy, compound medications, nutritional supplements and homeopathic medications." Bateman believes that Quinn now has a "clear understanding of the issues arising from the" stipulated settlement and disciplinary orders, and, "expresses remorse for his actions." Bateman believes that Quinn deserves "another chance" because the misconduct currently in question took place prior to Bateman's monitoring of Kohana, Bateman will continue to monitor Kohana for more than four years, consumers deserve to have a "state of the art pharmacy of the future," and Quinn has created an "extraordinary connection" with his clientele.

36. Quinn also submitted character reference letters from: a pharmacist he has known since they went to high school together, Kohana's pharmacy manager, and

Kohana's accountant. These individuals express high regard for Quinn's character for honesty, his professional ethics, and his generosity.

37. Respondents do not claim to meet the registration or new drug requirements to legally manufacture drugs or to be licensed under California law to manufacture cannabis. Respondents do not claim that the CBD or THC products compounded in the Back Room were compounded pursuant to patient-specific prescriptions received in advance of preparation, or in limited quantities anticipating such prescriptions based on a history of prescribing or any other pharmacy exception to manufacturer laws and regulations.

Ultimate Findings

38. Quinn directed and supervised the compounding of CBD products in the Back Room, which is part of the premises of Kohana. The CBD used in this compounding was derived from cannabis, not industrial hemp. Quinn's claims to the contrary are not credible in light of the statements of A.A., the multiple statements in the brochures touting the advantages of CBD derived from cannabis as opposed to hemp, and other evidence including Quinn's own admissions that he made false or misleading statements to Board inspectors, and the fact that the inspectors discovered containers in the Back Room labelled with the names of OTC medications combined with CBD and THC. Kohana and Quinn failed to maintain records of the manufacture, acquisition, receipt, sale and disposition of the materials used to create and furnish those products.

39. The CBD products compounded in the Back Room were drugs manufactured without proper permitting or authorization, under conditions not

designed for drug manufacture, and were not labeled appropriately for manufacturer distribution.

40. Respondents were never licensed to manufacture drugs.

41. Quinn made evasive and untruthful statements to the Board inspectors regarding the activities in the Back Room. Those statements were intended to subvert a Board investigation.

42. It was not proven that Quinn made significantly untrue and/or misleading statements to the public regarding the health benefits, treatment indications, and/or other qualities of compounded CBD products.

Costs

43. In connection with the investigation and enforcement of this accusation, complainant requests an award of costs in the total amount of $48,733.25, for investigation costs in the amount of $17,787, and attorney and paralegal services provided by the Department of Justice and billed to the Board in the amount of $30,946.25. That request is supported by declarations. In the absence of any argument or evidence to the contrary, these costs are found to be reasonable.

LEGAL CONCLUSIONS

First Cause for Discipline (Incomplete Inventory and/or Records of Acquisition and/or Disposition)

1. The Board may discipline the license of a licensee who commits unprofessional conduct, which includes any violations of state or federal laws

regulating controlled substances and dangerous drugs or the practice of pharmacy. (§ 4301, subds. (j) & (o).) Additionally, the PIC is responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. (§ 4113, subd. (c).) All records of the manufacture, acquisition, receipt, sale and disposition of dangerous drugs by any entity licensed by the Board must be retained on the licensed premises in a readily retrievable form for at least three years from the date of making. (§§ 4081, 4105.) Failing to maintain such records is a misdemeanor. (§ 4332.)

2. Cannabis, even the portions without psychoactive properties (called "marihuana" at the federal level) remains a Schedule I controlled substance under both federal and California law, subject to appropriate controls. (21 U.S.C. § 841 et seq.; 21 C.F.R. § 1308.11(d), (d)(23), (d)(38), (d)(58); Health & Saf. Code, §§ 11018, 11018.1, 11054, subds. (d), (d)(13), (d)(20), 11210.) Cannabis with a THC concentration of not more than 0.3 percent is defined as industrial hemp and not a controlled substance. (See, e.g., 7 U.S.C. § 5940, Health & Saf. Code, §§ 11018, 11018.5; Food & Agr. Code, § 81000.) However, under federal law it remains illegal to add CBD derived from cannabis or industrial hemp to food items, or to market dietary supplements containing CBD or THC, regardless of whether the substances are derived from hemp or cannabis, because both CBD and THC are active ingredients in FDA-approved drugs (e.g., Epidiolex and Marinol).

3. The CBD products compounded in the Back Room were subject to the record-keeping requirements of sections 4081, 4105 and 4332, and respondents failed to maintain records of the manufacture, acquisition, receipt, sale and disposition of the materials used to create and furnish those products. (Finding 38.) Cause was

established to discipline Kohana's pharmacy permit and Quinn's pharmacist license under sections 4301, subdivisions (j) & (o), and 4113, subdivision (c).

Second Cause for Discipline (Adulterated and Misbranded Drugs)

4. It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated. (Health & Saf. Code, § 111295.)

> Any drug or device is adulterated if the methods, facilities, or controls used for its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

(Health & Saf. Code, § 111260, see 21 U.S.C. § 351.)

5. It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded. (Health & Saf. Code, § 111440.) "Any drug or device is misbranded if its labeling is false or misleading in any particular" (Health & Saf. Code, § 111330) or "its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)." (Health & Saf. Code, § 111335, see 21 U.S.C. § 352.) Any drug is misbranded unless it bears a label containing the name and place of business of the manufacturer, packer, or distributor, and an "accurate statement of the quantity of the contents in terms of weight, measure, or numerical count," with reasonable variations permitted. (Health & Saf. Code, § 111340.)

6. The CBD products compounded in the Back Room were drugs manufactured without proper permitting or authorization, under conditions not designed for drug manufacture, and were not labeled appropriately for manufacturer distribution in violation of Health and Safety Code sections 111260, 111295, 111330, 111335, 111340, and 111440 and Title 21, United States Code, sections 351 and 352. (Finding 39.) Cause was established to discipline Kohana's pharmacy permit and Quinn's pharmacist license under sections 4301, subdivisions (j) & (o), and 4113, subdivision (c), for the manufacture and sale of adulterated and misbranded drugs.

Third Cause for Discipline (Unlicensed Manufacturer Activity)

7. State and federal law generally prohibit manufacture of any drug without a license. (Health & Saf. Code, § 111615, 21 U.S.C. § 321.) Exceptions exist for compounding by a pharmacist for individual patients pursuant to a valid prescription, or for compounding in limited quantities based on a history of receiving such "valid prescription orders," or limited anticipatory pharmacy compounding for "prescriber office use." (21 U.S.C. § 353a(a); see § 4052, subd. (a)(1); Cal Code Regs., tit. 16, § 1735.2, subd. (c).)

8. The compounding of CBD products by respondents in the Back Room constituted the manufacture of drugs. (Findings 38 & 39 and Legal Conclusions 2 & 7.) Respondents were never licensed to manufacture drugs. (Finding 40.) No exception is applicable. (Finding 37) Cause was established to discipline Kohana's pharmacy permit and Quinn's pharmacist license under sections 4301, subdivisions (j) & (o), and 4113, subdivision (c), for the unlicensed manufacture of drugs.

Fourth Cause for Discipline (Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption / False or Misleading Statements)

9. Unprofessional conduct includes the commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption. (§ 4301, subd. (f).) Quinn made evasive and untruthful statements to the Board inspectors regarding the activities in the Back Room. (Finding 41.) Cause for discipline of Quinn's license exists under section 4301, subdivision (f).

10. Complainant also alleges cause to discipline Quinn's license under section 4301, subdivisions (j) & (o), for violation of section 17500, which prohibits false or misleading statements to the public in advertising for business products or services. Cause for discipline was not proven for such statements because no significantly untrue and/or misleading statements to the public were proven. (Finding 42.)

Fifth Cause for Discipline (Subverting an Investigation)

11. Unprofessional conduct includes "engaging in any conduct that subverts or attempts to subvert" a Board investigation. (§ 4301, subd. (q).) Quinn attempted to subvert a Board investigation. (Finding 41.) Cause for discipline of Quinn's license exists under section 4301, subdivision (q).

Sixth Cause for Discipline (Unprofessional Conduct/Misuse of Education)

12. Unprofessional conduct includes the "inappropriate exercise" of the licensee's "education, training, or expertise as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy....." (§ 4306.5, subd. (a).) Quinn's direction and supervision of the compounding of CBD products in the Back

Room was an inappropriate exercise of his education, training, or expertise as a pharmacist. (Findings 38–40.) Cause for discipline of Quinn's pharmacist license exists under sections 4301 and 4306.5, subdivision (a).

Determination of Discipline

13. Cause for discipline having been established, the remaining issue is what level of discipline is required to protect the public. Protection of the public "shall be paramount." (§ 4001.1.) Where a licensee has repeat or serious violation(s) involving the improper compounding of drug products or repeat or serious violation(s) resulting from the misuse of education or licensing privileges, the Board's disciplinary guidelines recommend a minimum discipline of revocation, stayed, a 90-day term of actual suspension, a three- to five-year term of probation, with standard and optional conditions of probation as appropriate; and a maximum discipline of revocation. (Disciplinary Guidelines, A Manual of Disciplinary Guidelines and Model Disciplinary Orders (Feb. 2017 Rev.) (Disciplinary Guidelines), at pp. 11–12; Cal. Code Regs., tit. 16, § 1760.) In determining whether the minimum, maximum, or an intermediate penalty is to be imposed in a given case, the relevant factors include: nature and severity of the acts; actual or potential harm to the public; actual or potential harm to any consumer; time passed since the act(s); aggravating and mitigating evidence; and rehabilitation evidence. (Disciplinary Guidelines at p. 4.)

14. Prior to 2019, neither Kohana nor Quinn had any record of license discipline. Quinn practiced as a pharmacist for over 40 years without discipline; Kohana operated for approximately nine years without license discipline. Quinn submitted the supporting letter and testimony of his probation monitor Bateman and three other professional support letters. Quinn accepted responsibility for the majority of his misconduct and appeared to be remorseful. No actual harm to the public was shown.

15. However, respondents engaged in the improper compounding of a variety of CBD products, which constitutes the unlicensed manufacture of drugs. Respondents broadly failed to properly maintain an inventory and records of acquisition and/or disposition of those drugs. This misconduct persisted months after respondents were discovered to have engaged in a practice of paying cash for dangerous drugs (Avastin) from a nearby hospital, not generating or receiving any acquisition records for these drugs, and engaging in inappropriate compounding practices with some of these drugs. Quinn made misleading and evasive statements to Board investigators multiple times during the investigation. Even at hearing Quinn was not candid as to the source of the CBD, falsely claiming that it was derived from industrial hemp. That continued lack of candor suggests that respondents are not good candidates for further probation. Respondents failed to present evidence of rehabilitation sufficient to assure the Board that they are safe to continue practicing. Public protection requires revocation of Kohana's pharmacy permit and Quinn's pharmacist license.

Other Matters

16. Pursuant to section 4307, if discipline is imposed on Original Pharmacy Permit Number PHY 50264 issued to Kohana, Kohana shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee until Original Pharmacy Permit Number PHY 50264 is reinstated if it is revoked.

17. Pursuant to section 4307 of the Code, if discipline is imposed on Original Pharmacy Permit Number PHY 50264 issued to Kohana while Quinn has been an officer or owner and had knowledge of or knowingly participated in any conduct for which the license was disciplined, Quinn shall be prohibited from serving as a

manager, administrator, owner, member, officer, director, associate, or partner of a licensee until Original Pharmacy Permit Number PHY 50264 is reinstated if it is revoked.

18. Pursuant to section 4307 of the Code, if discipline is imposed on Original Pharmacist License Number RPH 32154 issued to Quinn, Quinn shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee until Original Pharmacist License Number RPH 32154 is reinstated if it is revoked.

Costs

19. A licensee who is found to have committed a violation of the licensing act may be ordered to pay a sum not to exceed the reasonable costs of investigation and enforcement. (§ 125.3.) Cause exists to order respondent to pay the Board's costs in the amount of $48,733.25. (Factual Finding 43 & Legal Conclusions 3, 6, 8, 9, 11 & 12.)

20. Cost awards must not deter licensees with potentially meritorious claims from exercising their right to an administrative hearing. (*Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, 45.) Cost awards must be reduced where a licensee has been successful at hearing in getting the charges dismissed or reduced; a licensee is unable to pay; or where the scope of the investigation was disproportionate to the alleged misconduct. (*Ibid.*) The agency must also consider whether the licensee has raised a colorable challenge to the proposed discipline, and a licensee's good faith belief in the merits of his or her position. (*Ibid.*) Respondents failed to establish cause for a reduction of the cost award.

ORDER

1. Original Pharmacy Permit Number PHY 50264, issued to Kohana Pharmacy & Center for Regenerative Medicine, Inc., doing business as Kohana Pharmacy and Center for Regenerative Medicine; Robert Denis Quinn, Owner (Kohana) is revoked.

2. Original Pharmacist License Number RPH 32154, issued to Robert Denis Quinn (Quinn), is revoked.

3. Kohana is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee until Original Pharmacy Permit Number PHY 50264 is reinstated.

4. Quinn is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee until Original Pharmacy Permit Number PHY 50264 is reinstated.

5. Quinn is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee until Original Pharmacist License Number RPH 32154 is reinstated.

6. Kohana and Quinn, jointly and severally, are ordered to pay the Board of Pharmacy $48,733.25 for the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3.

DATE: 02/25/2021

MICHAEL C. STARKEY
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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against**:** **KOHANA PHARMACY & CENTER FOR REGENERATIVE MEDICINE, INC., DBA KOHANA PHARMACY AND CENTER FOR REGENERATIVE MEDICINE;** **ROBERT DENIS QUINN, OWNER** **181 Tank Farm Rd., #120** **San Luis Obispo, CA 93401** **Original Pharmacy Permit No. PHY 50264** **and** **ROBERT DENIS QUINN** **181 Tank Farm Rd., #120** **San Luis Obispo, CA 93401** **Original Pharmacist License No. RPH 32154** Respondents.	Case No. 6922 **ACCUSATION**

PARTIES

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

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2. On or about April 20, 2010, the Board of Pharmacy issued Original Pharmacy Permit Number PHY 50264 to Kohana Pharmacy & Center for Regenerative Medicine, Inc., dba Kohana Pharmacy and Center for Regenerative Medicine (Respondent Kohana). Since on or about April 1, 2015, Robert Denis Quinn has been President and 100% shareholder of Respondent Kohana. The Original Pharmacy Permit was in full force and effect at all times relevant to the charges herein and will expire on January 1, 2021, unless renewed. Effective July 25, 2019, in a Decision and Order by the Board of Pharmacy in a disciplinary matter titled *In the Matter of the Accusation Against Kohana Pharmacy & Center for Regenerative Medicine, Inc., dba Kohana Pharmacy and Center for Regenerative Medicine; Robert Denis Quinn, Owner; Robert Denis Quinn; Nataliya McElroy Miller, and Anthony Sinconis*, Board Case No. 5556, Original Pharmacy Permit Number PHY 50264 was revoked, with the revocation stayed and the license placed on probation for five (5) years, on specified terms and conditions.

3. On or about August 3, 1978, the Board of Pharmacy issued Original Pharmacist License Number RPH 32154 to Robert Denis Quinn (Respondent Quinn). The Original Pharmacist License was in full force and effect at all times relevant to the charges herein and will expire on June 30, 2020, unless renewed. Since on or about November 16, 2013, Respondent Quinn has served as Pharmacist In Charge (PIC) for Respondent Kohana. Effective July 25, 2019, in a Decision and Order by the Board of Pharmacy in a disciplinary matter titled *In the Matter of the Accusation Against Kohana Pharmacy & Center for Regenerative Medicine, Inc., dba Kohana Pharmacy and Center for Regenerative Medicine; Robert Denis Quinn, Owner; Robert Denis Quinn; Nataliya McElroy Miller, and Anthony Sinconis*, Board Case No. 5556, Original Pharmacist License Number RPH 32154 was revoked, with the revocation stayed and the license placed on probation for five (5) years, on specified terms and conditions.

JURISDICTION

4. 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 (Code) unless otherwise indicated.

5. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

6. Section 4300, subdivision (a), of the Code provides that every license issued by the Board may be suspended or revoked.

7. Section 4300.1 of the Code provides that the expiration, cancellation, forfeiture, or suspension of a Board-issued license, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee, shall not deprive the Board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY PROVISIONS

8. Section 4081 of the Code provides, in pertinent part, that all records of manufacture, sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be kept open to inspection and retained for at least three years, that a current inventory shall be kept by every pharmacy that maintains a stock of dangerous drugs or dangerous devices, and that the owner(s), officer(s), partner(s), and pharmacist in charge or designated representative in charge shall be jointly responsible for maintaining the records and keeping the inventory.

9. Section 4105 of the Code requires, in pertinent part, that unless a waiver is granted by the board, all records and other documentation of the acquisition and disposition of dangerous drugs and devices by any entity licensed by the board be retained on the licensed premises, in a readily retrievable form, for three years from the date of making.

10. Section 4113, subdivision (c), of the Code states:

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

11. Section 4301 of the Code provides, in pertinent part, that the Board shall take action against any holder of a license who is guilty of "unprofessional conduct," defined to include, but not be limited to, any of the following:

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

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

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

(q) Engaging in conduct that subverts or attempts to subvert an investigation of the board.

12. Section 4306.5, subdivision (a), of the Code states:

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

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

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

> Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manger, administrator, owner, member, officer, director, associate, or partner had knowledge or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:
>
> (1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.
>
> (2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

14. Section 4332 of the Code makes it unlawful for any person: to fail, neglect, or refuse to maintain the records required by Section 4081; or, when called upon by an authorized officer or a member of the board, to fail, neglect, or refuse to produce or provide the records within a reasonable time; or to willfully produce or furnish records that are false.

15. Section 17500 of the Code states, in pertinent part:

> It is unlawful for any person, firm, corporation or association, or any employee thereof with intent directly or indirectly to dispose of real or personal property or to perform services, professional or otherwise, or anything of any nature whatsoever or to induce the public to enter into any obligation relating thereto, to make or disseminate or cause to be made or disseminated before the public in this state, or to make or disseminate or cause to be made or disseminated from this state before the public in any state, in any newspaper or other publication, or any advertising device, or by public outcry or proclamation, or in any other manner or means whatever, including over the Internet, any statement, concerning that real or personal property or those services, professional or otherwise, or concerning any circumstance or matter of fact connected with the proposed performance or disposition thereof, which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading, or for any person, firm, or corporation to so make or disseminate or cause to be so made or disseminated any such statement as part of a plan or scheme with the intent not to sell that personal property or those services, professional or otherwise, so advertised at the price stated therein, or as so advertised. Any violation of the provisions of this section is a misdemeanor punishable by imprisonment in the county jail not exceeding six months, or by a fine not exceeding two thousand five hundred dollars ($2,500), or by both . . .

16. Health and Safety Code section 111260 states:

"Any drug or device is adulterated if the methods, facilities, or controls used for its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess."

17. Health and Safety Code section 111295 states:

"It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug or device that is adulterated."

18. Health and Safety Code section 111330 states:

"Any drug or device is misbranded if its labeling is false or misleading in any particular."

19. Health and Safety Code section 111335 states:

"Any drug or device is misbranded if its labeling or packaging does not conform with the requirements of Chapter 4."

20. Health and Safety Code section 111340 provides that any drug or device is misbranded unless it bears a label containing all of the following information:

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

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

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

21. Health and Safety Code section 111440 states:

"It is unlawful for any person to manufacture, sell deliver, hold or offer for sale any drug or device that is misbranded."

22. Health and Safety Code section 111615 states, in pertinent part:

"No person shall manufacture any drug or device in this state unless he or she has a valid license from the department. The license is valid for two calendar years from the date of issue, unless it is revoked. The license is not transferable. . . ."

23. 21 U.S.C. § 351 provides definitions for "Adulterated Drugs and Devices." Subdivision (a) thereof states, in pertinent part:

A drug or device shall be deemed to be adulterated--
(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture
(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess . . .

24. 21 U.S.C. § 352, "Misbranded Drugs and Devices," states, in pertinent part:

A drug or device shall be deemed to be misbranded—
(a) False or misleading label
(1) If its labeling is false or misleading in any particular. . . .

(b) Package form; contents of label
If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

. . .

(f) Directions for use and warnings on label
Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

. . .

(i) Drug; misleading container; imitation; offer for sale under another name
(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

. . .

(n) Prescription drug advertisements: established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; false advertising; labeling; construction of the Convention on Psychotropic Substances

In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in paragraph (e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under paragraph (e), and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with section 371(a) of this title, and in the case of published direct-to-consumer advertisements the following statement printed in conspicuous text: "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.", ...

(o) Drugs or devices from nonregistered establishments
If it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 360 of this title, if it is a drug and was imported or offered for import by a commercial importer of drugs not duly registered under section 381(s) of this title, if it was not included in a list required by section 360(j) of this title, if a notice or other information respecting it was not provided as required by such section or section 360(k) of this title, or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 360(e) of this title as the Secretary by regulation requires.

. . .

(aa) Unpaid fees; failure to submit identifying information
If it is a drug, or an active pharmaceutical ingredient, and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 379j-42(a)(4) of this title or for which identifying information required by section 379j-42(f) of this title has not been submitted, or it contains an active pharmaceutical ingredient that was manufactured, prepared, propagated, compounded, or processed in such a facility.

(bb) False or misleading advertisement or promotion of compounded drug
If the advertising or promotion of a compounded drug is false or misleading in any particular.

(cc) Failure to bear product identifier
If it is a drug and it fails to bear the product identifier as required by section 360eee-1 of this title.

. . .

(ff) If it is a drug and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 744M.

25. 21 U.S.C. § 353a, in pertinent part, provides for "Pharmacy Compounding" under certain conditions defined by the statute:

(a) In general
Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding—

(1) is by—
(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or
(B) a licensed physician,
on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or
(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and
(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—
(i) the licensed pharmacist or licensed physician; and
(ii)(I) such individual patient for whom the prescription order will be provided; or
(II) the physician or other licensed practitioner who will write such prescription order.

(b) Compounded drug
(1) Licensed pharmacist and licensed physician
A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician—

(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations—
(i) that—
(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;
(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c);
(ii) that are manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(i) of this title); and
(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;
(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;
(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and
(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

26. 21 U.S.C. § 355, subdivision (a), states:

"(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."

REGULATORY PROVISIONS

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

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

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COST RECOVERY

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

CONTROLLED SUBSTANCES / DANGEROUS DRUGS

29. Section 4021 of the Code states:

"'Controlled substance' means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code."

30. Section 4022 of the Code states, in pertinent part:

"'Dangerous drug' or 'dangerous device' means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, 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.

. . .

"(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."

31. **Cannabis** (aka **marijuana**) is a Schedule I controlled substance as designated by Health and Safety Code section 11054, subdivision (d)(13). It is a hallucinogenic drug.

32. **Tetrahydrocannabinols** (aka **THC**) is a psychoactive cannabinoid (derivative) of **cannabis** that is, in its natural and synthetic forms, a Schedule I controlled substance in its own right, as designated by Health and Safety Code section 11054, subdivision (d)(20).

33. **Cannabidiol** (aka **CBD**) is a non-psychoactive cannabinoid (derivative) of **cannabis** that is, to the extent it is derived from a **cannabis** plant, by reference to Health and Safety Code section 11018, considered part of the **cannabis** plant and, therefore, a Schedule I controlled substance as designated by Health and Safety Code section 11054, subdivision (d)(13).

34. **Microsome Plus™** is a brand name for a base cream used for compounding. It is a dangerous drug as designated by section 4022 of the Code.

35. **Epidiolex** is a brand name for a certain suspension and concentration of **cannabidiol** (aka **CBD**), a non-psychoactive cannabinoid of **cannabis**, with no more than 0.1% **THC**, that is a federally-listed Schedule V controlled substance as designated by 21 C.F.R. § 1308.15(f). It is also a dangerous drug as designed by section 4022 of the Code.

FACTUAL ALLEGATIONS

36. Between on or about February 15, 2019 and on or about December 30, 2019, the Board of Pharmacy (Board), through its Board Inspector(s), conducted an investigation into the patterns and practices of Respondents Kohana and Quinn. An initial inspection of Respondent Kohana was undertaken by Board Inspectors on or about June 18, 2019. A second inspection of Respondent Kohana was undertaken by Board Inspectors on or about June 26, 2019. During and subsequent to both visits, the Board Inspectors were in communication with Respondent Quinn.

37. On July 25, 2019, disciplinary orders placing the licenses held by Respondent Kohana and Respondent Quinn on probation went into effect. On or about September 18, 2019 and December 18, 2019, Board Inspectors made additional visits to the premises. On both occasions, Respondent Quinn was present for and participated in the inspections.

38. During their initial inspection on June 18, 2019, Respondent Quinn told the Board Inspectors that the pharmacy used to compound "pain creams," but "really doesn't" anymore.

39. During this inspection, the Inspectors found a back room at the pharmacy containing equipment and supplies for pharmacy compounding. Respondent Quinn said the room was supposed to be locked, and was sub-leased to another company ("Blue Gaja"). When asked what that company was doing, Respondent Quinn said he had no idea. The Inspectors noticed another company name ("A.R.M. Pharmaceuticals") on materials and supplies in the room, and asked about that company. Respondent Quinn said it was another company that also leased the room. Additional company names discovered in the room included: "7-Sisters Pharmaceuticals," "Green Research Labs," "Institute for Green Science Research," and "Califuzion." Among the materials in the room were boxes with "Ship To: Kohana Pharmacy" labels. Respondent Quinn explained that he would sell supplies (i.e., jars and labels) to "the companies" if needed.

40. Also in this back room, the Inspectors found numerous containers labeled with various over-the-counter medication names combined with **CBD** and/or **THC** as ingredients. Many were improperly labeled and/or could not be traced to a licensed manufacturer for the product or the ingredients. The Inspectors went about embargoing these misbranded products to prevent furnishing, including two hundred and thirty-two (232) unlabeled blue jars containing an opaque cream. During their search, the Board Inspectors also found a box labeled "Kohana Pharmacy" containing a dry, leafy material with a strong **marijuana** odor, and a white plastic bag containing more dry, leafy material that smelled like **marijuana**.

41. When asked, Respondent Quinn claimed to have no knowledge of the dry, leafy material. He directed the Inspectors to a pharmacy technician employed by Respondent Kohana (technician "A.A.") who also worked for one or more of "the companies," but claimed that he did not know for which company A.A. worked, or how he was paid for that work.

42. Subsequent interviews with other staff of the pharmacy and neighboring businesses confirmed that, contrary to Respondent Quinn's claim, the back room was routinely left open to foot traffic during pharmacy hours. These interviews also confirmed that it was primarily used "after hours" by separate companies. Most staff of the pharmacy claimed to have no knowledge of the specific activities. Those who had been with the pharmacy for a while remembered that back room being designated the "Pain Cream Lab" in years past and pharmacy staff being involved in the compounding of pain creams in that room. More recently, however, the room was used "after hours," and technician A.A. was the only pharmacy staff member regularly involved.

43. The various inspections of the pharmacy, documents and materials that were collected on the premises, and additional interviews and investigation uncovered, in the pharmacy:

- Contrary to Respondent Quinn's representation, a log of non-sterile compounded medications maintained by the pharmacy showed that numerous topical creams for the treatment of pain had been prepared during the month of May 2019.
- Documents pertaining to two patients for whom pain creams were prepared in or about April, May, and June 2019.
- Invoices/order forms under the name "7-Sisters Pharmaceuticals" dated June 5, 2019 and June 13, 2019 for "pain" creams and capsules containing CBD to be delivered to a "Physician's Office" under the names "Rancho Ecomar" and "Blue Gaja." The creams were to be made using **Microsome Plus™** Base Cream.

- Invoices in the name of Respondent Kohana showing purchase by and delivery to the pharmacy of **Microsome Plus™** Base, Smartbase, and Thick Creams, with a Certificate of Analysis specifying "This product is formulated to be used as a compounding excipient by Pharmacists."

- Numerous compounding formula work sheets containing compounding formulas and compounding logs for various pain cream formulations including **CBD**.

- Compounding formula work sheets bearing the name "Green Research Labs" with hand-written information and several columns completed, documenting various topical and oral non-sterile compounding formulations containing **CBD**, various OTC drugs (e.g., melatonin), amino acids (e.g., DL-Phenylalanine), nutritional supplements, and inactive ingredients, with "compounded" dates ranging from June 30, 2018 to June 13, 2019. Most of the worksheets bore initials for pharmacy technician "A.A." Approximately half of these worksheets had a second set of initials subsequently confirmed as Respondent Quinn's. The majority of these worksheets listed the "Dispense To:" party as "GRL," with others listing "Jac Pederson," IGSR Stock" or "Stock." Some of the quantities listed as being allocated to IGSR Stock or Stock were dated June 13, 2019 and corresponded to the quantities listed on the "7-Sisters Pharmaceuticals" invoice/order form dated June 13, 2019 that listed "Blue Gaja" as the intended recipient.

- "Institute for Green Science Research/CaliFuzion" invoice/order forms showing the filling of orders in 2018 for "Ultra Strength Pain Cream" for various clients ("100% Chiro," "MCK," and "J. Argie,") at least one containing a note addressed to "Bob," which is what Respondent Quinn is commonly called.

- Email correspondence between Ernie Cavallaro (CaliFuzion email domain), Alice Hamrick, and Respondent Quinn concerning an order for "Jenny Argie," discussing, among other things, the process of decarboxylation of CBDA to **CBD** and THCA to **THC**, and use of the "whole plant" of the "cannabis" plant.

- A price list and brochures for Institute for Green Science Research and a label sheet and brochures for 7-Sisters Pharmaceuticals. The brochure for Institute for Green Science Research included the following statements: "Compounding pharmacy researchers and manufacturers." "We currently offer products to be used as 'adjunctive' therapy for the following: Pain, Anxiety, Depression, PTSD, Sleep, Cancer." "Compounding Pharmacists working with Physicians for your health." The brochure for 7-Sisters Pharmaceuticals listed the same address and phone as the pharmacy, featured a photograph of Respondent Quinn and his wife, and included the following statements: "Product Formulators (R&D)." "Compounding Pharmacy Researchers and Manufacturers." "Our Advantage: As Pharmacists, we are drug EXPERTS! We understand precise/precision formulation processes and the 'Mechanism of Action' of Cannabinoids. We can evaluate potential Drug-Drug interactions with other medications (both prescription and non-prescription)!" "*All of our products are made under the direct supervision of a Licensed Compounding Pharmacy!" "'Cannaceuticals' – Made by Compounding Pharmacists, our CBD is infused with amino acids and homeopathics to create a powerful synergistic blend for the relief of: Pain, Anxiety, Sleep, PTSD, Depression."

- Interviews with pharmacy staff confirmed that staff were instructed to provide the brochures to pharmacy customers with questions about CBD products. Staff also confirmed that the initials on the "Green Research Labs" worksheets belonged to pharmacy technician "A.A." and Respondent Quinn.

44. Following the June 18, 2019 pharmacy inspection, the Board Inspectors conducted research on the internet and through public sources, and discovered the following information:

- Websites for: Blue Gaja (showing products containing **CBD** for sale); Jenny Argie, Founder, Baked at Home-Thinking Outside the Bud (referencing different **cannabis**/**CBD**'**THC** products); Marty's Cobra Kove (corresponding to the "MCK" materials listed above), advertising "Ultra Strength Pain Relief Cream" for sale with the product pictured, matching the blue jars found in the pharmacy, and promoting the Institute for Green Science Research; Institute for Green Science Research, with various **CBD** products offered for sale; and a Biopharmrx Services LLC Bizapedia page showing Robert Quinn as the Registered Agent.

- Documents and materials confirming the existence of Rancho Ecomar LLC, Blue Gaja, an affiliate of Blue Gaja called Sustenance Inc.

- The website for 7-Sisters Pharmaceuticals featured a photograph of Respondent Quinn and his wife. The "About Us" page included the following statements: "The products we recommend utilize the expertise of Organic Growers, State-of-the-Art Extractors, Product Formulators, Compounding Pharmacists, Physicians, and other Healthcare Practitioners. The resulting 'CannaCeuticals' are made according to United States Pharmacopea (USP) Standards and truly are 'Pharmaceutical Grade.'" Public records maintained by the State of California show that Respondent Quinn's wife is the Registered Agent, and their home address is the Entity address.

- State of California business records show the California address for IGSR being an address that is listed in Board records as being associated with Respondent Quinn.

45. During the June 26, 2019 pharmacy inspection, the Board Inspectors conducted interviews with several pharmacy staff members and other witnesses. During the interview with pharmacy technician "A.A.," the Inspectors learned:

- That A.A. had worked for Respondent Kohana for about two (2) years as the main "after hours" compounding technician.

- That A.A. worked directly with Respondent Quinn on CBD compounding projects for various companies, including 7-Sisters Pharmaceuticals, which is owned by Respondent Quinn, which takes orders for compounded CBD products and moves inventory from Respondent Kohana to the other companies, Green Research Labs, Institute for Green Science Research, Blue Gaja, and CaliFuzion. A.A. said that his "after hours" work hours were paid by the owners of CaliFuzion.

- A.A. said that Respondent Quinn helped with the labeling of the jars/products that were being created for Blue Gaja.

- A.A. said that Respondent Quinn would come into the "back room" to check on him, to validate certain formula calculations, and to "sign off" on final products.

  A.A. confirmed his and Respondent Quinn's initials on the worksheets.

- A.A. said that Respondent Quinn acquired the dry, leafy material (whole plant **cannabis**/**marijuana**) which they would heat dry in the microwave and use to extract a tincture containing cannabinoids (**CBD** and/or **THC**).

46. During his June 26, 2019 interview, Respondent Quinn said the following:

- The Institute for Green Science Research (IGSR), based in Nevada, is a collection of various researchers pooling their knowledge about "natural" health products. Respondent Quinn is both a consultant and partial business partner.
- CaliFuzion is wholly owned by the same people who primarily own IGSR.
- 7-Sisters Pharmaceuticals is owned by Respondent Quinn and his wife.
- Blue Gaja "leased" the "back room" and the services of technician A.A., who was assisted by Respondent Quinn on some of the compounding worksheets.
- He claimed not to know where the dry, leafy material had come from.

47. On or about September 10, 2019, the Board Inspectors received a statement from the owner of the Blue Gaja company, in which this individual confirmed:

- His business transactions with Respondent Quinn/Respondent Kohana were on an oral/handshake basis, and there were no invoices, bills of sale, or other paperwork.
- On or about May 11, 2019, he requested that Respondent Quinn make two hundred (200) jars of Extra Strength topical pain relief cream containing **CBD**.
- It was agreed that Blue Gaja would pay one price to include all ingredients, rental of the "back room," and a consulting fee including Respondent Quinn's oversight.

CAUSES FOR DISCIPLINE

AS TO BOTH RESPONDENTS

FIRST CAUSE FOR DISCIPLINE

(Incomplete Inventory and/or Records of Acquisition and/or Disposition)

48. Respondents Kohana and Quinn are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to section(s) 4081, 4105, and/or 4332 of the Code, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraphs 38-47 above, Respondents failed to maintain an accurate, complete, and readily retrievable inventory or records of acquisition and disposition. Specifically, Respondents failed to maintain documentation of the acquisition or disposition of the materials used to create and furnish the products compounded in the "back room" of the pharmacy.

SECOND CAUSE FOR DISCIPLINE

(Adulterated and/or Misbranded Drugs)

49. Respondents Kohana and Quinn are each and severally subject to disciplinary action under section 4301, subdivisions (j) and/or (o) and/or section 4113(c) of the Code, Health and Safety Code sections 111260, 111295, 111330, 111335, 111340, and/or 111440, and/or 21 U.S.C. § 351 and/or 352, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraphs 38-47 above, Respondents sold, delivered, held or offered for sale dangerous drugs that were adulterated and/or misbranded, in that the drugs compounded in the "back room" of the pharmacy were manufactured without proper permitting or authorization, under conditions not designed for drug manufacture, and were not labeled appropriately for manufacturer distribution.

THIRD CAUSE FOR DISCIPLINE

(Unlicensed Manufacturer Activity)

50. Respondents Kohana and Quinn are each and severally subject to disciplinary action under section 4301, subdivisions (j) and/or (o) and/or section 4113(c) of the Code, Health and Safety Code section 111615, and/or 21 U.S.C. § 353a and/or 355, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraphs 38-47 above, Respondents engaged in manufacture of new drugs in the "back room" of the pharmacy without having a permit or registration to do so.

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AS TO RESPONDENT QUINN ONLY

FOURTH CAUSE FOR DISCIPLINE

(Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption/Untrue or Misleading Statements)

51. Respondent Quinn is subject to discipline under section 4301(f) and/or section 4301(j) and/or (o) by reference to section 17500 of the Code, for acts involving moral turpitude, dishonesty, fraud, deceit, or corruption, and/or for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, via dissemination of untrue and/or misleading statements regarding drug products or services, in that, as described in paragraphs 38-47 above, during and subsequent to the June 18, 2019 inspection of the pharmacy, Respondent Quinn was evasive and untruthful about the activities taking place in the "back room" of the pharmacy, his knowledge thereof, and his involvement therein, and under the guise of various businesses, Respondent made untrue and/or misleading statements regarding the health benefits, treatment indications, and/or other qualities of compounded CBD products.

FIFTH CAUSE FOR DISCIPLINE

(Subverting an Investigation)

52. Respondent Quinn is subject to discipline under section 4301(q) of the Code, for subversion or attempted subversion of a Board investigation, in that, as described in paragraphs 38-47 above, during and subsequent to the June 18, 2019 inspection of the pharmacy, Respondent Quinn was evasive and untruthful about the activities taking place in the "back room" of the pharmacy, his knowledge thereof, and his involvement therein.

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct/Misuse of Education)

53. Respondent Quinn is subject to discipline under section 4301 and/or 4306.5 of the Code, in that, as described in paragraphs 38-52 above, Respondent Quinn engaged in unprofessional conduct and/or misused his education as a pharmacist

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DISCIPLINARY CONSIDERATIONS

54. To determine the degree of discipline, if any, to be imposed on Respondents Kohana and Quinn, Complainant alleges that effective July 25, 2019, in a Decision and Order by the Board of Pharmacy in a disciplinary matter titled *In the Matter of the Accusation Against Kohana Pharmacy & Center for Regenerative Medicine, Inc., dba Kohana Pharmacy and Center for Regenerative Medicine; Robert Denis Quinn, Owner; Robert Denis Quinn; Nataliya McElroy Miller, and Anthony Sinconis*, Board Case No. 5556, Original Pharmacy Permit Number PHY 50264, issued to Respondent Kohana, and Original Pharmacist License Number RPH 32154, issued to Respondent Quinn, were each revoked, with the revocations stayed and the licenses placed on probation for five (5) years, on specified terms and conditions. The Accusation in that case, which Respondents agreed that Complainant could establish a factual basis to support and gave up their right to contest, and which Respondents agreed established a basis for discipline against their licenses, included allegations that Respondents had engaged in a practice of buying dangerous drugs (Avastin) from a nearby hospital, paying cash for these drugs, not generating or receiving any acquisition records for these drugs, and engaging in inappropriate compounding practices with some of these drugs. The Accusation included causes for discipline for failing to maintain records of acquisition, failing to maintain required compounding records, failing to comply with sterile injectable recordkeeping requirements, acting as a drug manufacturer without a permit, failing to comply with compounding limitations and requirements, failing to exercise appropriate professional judgment, and unprofessional conduct. Those disciplinary orders are now final and currently in effect, and incorporated herein by reference.

OTHER MATTERS

55. Pursuant to section 4307 of the Code, if discipline is imposed on Original Pharmacy Permit Number PHY 50264 issued to Respondent Kohana, Respondent Kohana shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 50264 is placed on probation or until Original Pharmacy Permit Number PHY 50264 is reinstated if it is revoked.

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56. Pursuant to section 4307 of the Code, if discipline is imposed on Original Pharmacy Permit Number PHY 50264 issued to Respondent Kohana while Respondent Quinn has been an officer or owner and had knowledge of or knowingly participated in any conduct for which the license was disciplined, Respondent Quinn shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 50264 is placed on probation or until Original Pharmacy Permit Number PHY 50264 is reinstated if it is revoked.

57. Pursuant to section 4307 of the Code, if discipline is imposed on Original Pharmacist License Number RPH 32154 issued to Respondent Quinn, Respondent Quinn shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacist License Number RPH 32154 is placed on probation or until Original Pharmacist License Number RPH 32154 is reinstated if it is revoked.

PRAYER

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

1. Revoking or suspending Original Pharmacy Permit Number PHY 50264, issued to Kohana Pharmacy & Center for Regenerative Medicine, Inc., dba Kohana Pharmacy and Center For Regenerative Medicine; Robert Denis Quinn, Owner (Respondent Kohana);

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

3. Prohibiting Respondent Kohana from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 50264 is placed on probation or until Original Pharmacy Permit Number PHY 50264 is reinstated if it is revoked;

4. Prohibiting Respondent Quinn from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 50264 is placed on probation or until Original Pharmacy Permit Number PHY 50264 is reinstated if it is revoked;

5. Prohibiting Respondent Quinn from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacist License Number RPH 32154 is placed on probation or until Original Pharmacist License Number RPH 32154 is reinstated if it is revoked;

6. Ordering Respondent Kohana and Respondent Quinn, jointly and severally, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: May 6, 2020

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

SF2020200575