XAVIER BECERRA
Attorney General of California
FRANK H. PACOE
Supervising Deputy Attorney General
LESLIE E. BRAST
Deputy Attorney General
State Bar No. 203296
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004
Telephone: (415) 703-5548
Facsimile: (415) 703-5480
Attorneys for Complainant

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

In the Matter of the Accusation Against: **ABBOTT'S COMPOUNDING PHARMACY, JOHN GARCIA AND SHARON GARCIA, OWNERS** **2320 Woolsey Street** **Berkeley, CA 94705** **Pharmacy License No. PHY 45060** **Sterile Compounding License No. LSC 99002** **and** **Elliot Chun-Pong Kwok** **7309 Longmont Loop** **Castro Valley, CA 94552** **Pharmacist License No. RPH 30155** Respondent.	Case No. 5884 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about November 28, 2000, the Board issued Pharmacy License No. PHY 45060 to Abbott's Compounding Pharmacy (Respondent Pharmacy). On or about July 1, 2003, the

Board issued Sterile Compounding License No. LSC 99002 to Respondent Pharmacy. Both the Pharmacy and Sterile Compounding Licenses expired on May 24, 2016, and were cancelled on May 25, 2016. On or about May 24, 2016, Respondent Pharmacy was acquired by Wellspring Compounding Pharmacy. Between November 28, 2000 and May 25, 2016, John Garcia (RPH 23671) was the pharmacy's President and 50 percent shareholder, and Sharon Garcia was the Vice President and 50 percent shareholder.

3. On or about May 7, 1976, the Board issued Pharmacist License No. RPH 30155 to Elliot Chun-Pong Kwok (Respondent Kwok). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2018, unless renewed. Respondent Kwok was the Pharmacist in Charge for Respondent Pharmacy from approximately September 9, 2003, until the pharmacy's sale and change of ownership described in paragraph 2, above.

JURISDICTION

4. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

5. Code section 4011 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. Code section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.

7. Code section 4300.1 of the Code provides that the expiration, cancellation, forfeiture, suspension or voluntary surrender of a license "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."

8. Code section 4307(a) states, in pertinent part, 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 manger, 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.

STATUTORY PROVISIONS

9. Code section 4301 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:

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

. . .

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

10. Code section 4113 (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. Code section 4306.5 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.

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

(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

12. Code section 4127.7 states:

A pharmacy shall compound sterile products from one or more nonsterile ingredients in one of the following environments:

(a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.

(b) An ISO class 5 cleanroom.

(c) A barrier isolator that provides an ISO class 5 environment for compounding.

13. Code section 4076 states:

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

. . .

(9) The expiration date of the effectiveness of the drug dispensed.

REGULATORY PROVISIONS

14. California Code of Regulations, title 16, section 1250.4 (5) requires that:

Any pharmacy that compounds sterile injectable products from one or more nonsterile ingredients must compound the medication in one of the following environments:

- 5.1 An ISO class laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
- 5.2 An ISO class 5 cleanroom.
- 5.3 A barrier isolator that provides an ISO class 5 environment for compounding.

15. California Code of Regulations, title 16, section 1714 states, in pertinent part:

(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

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

(d) No pharmacy or pharmacist shall compound a drug preparation that:

. . .

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

. . .

(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:

. . .

(6) Quality reviews required at each step in preparation of the drug. (6) Does not exceed an amount the pharmacy can reasonably and safely compound.

. . .

(h) 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.

17. California Code of Regulations, title 16, section 1735.4 states, in pertinent part:

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

(1) Name of the compounding pharmacy and dispensing pharmacy (if different);

(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;

(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;

(4) The beyond use date for the drug preparation;

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.

(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy.

18. California Code of Regulations, title 16, section 1735.6 (b) states that "[a]ny equipment used to compound drug preparations shall be stored, used, maintained, and cleaned in accordance with manufacturers' specifications."

19. California Code of Regulations, title 16, section 1735.7 (c) states that "[p]harmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation."

20. California Code of Regulations, title 16, section 1751.4 states, in pertinent part:

(a) No sterile drug preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations.

(b) During the compounding of sterile drug preparations, access to the areas designated for compounding must be limited to those individuals who are properly attired.

21. California Code of Regulations, title 16, section 1751.6 (d) states that the "pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile drug preparations."

COST RECOVERY

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

///

///

///

FACTUAL BACKGROUND

23. Respondent Pharmacy, located in Berkeley, California, performed high risk, non-sterile to sterile compounding, low to medium risk sterile to sterile compounding, hazardous chemotherapy compounding, and compounded products for office use by physician prescribers.

24. At all times relevant to the allegations contained herein, Respondent Kwok was the Pharmacist in Charge (PIC) for Respondent Pharmacy.

25. In December 2015, the Board initiated an investigation of Respondent Pharmacy in response to a complaint that the pharmacy risked employee and patient health and safety by operating in a manner inconsistent with Board of Pharmacy law, FDA and US Pharmacopeial Convention (USP) standards for compounding sterile preparations.

26. On December 29 and 30, 2015, and on January 19, 2016, the Board inspected Respondent Pharmacy. The December inspections were conducted in partnership with the FDA. The following violations of California Pharmacy Law were identified and substantiated:

a. The pharmacy was not maintained in a good state of repair. Plexiglass panels attached with Velcro comprised three walls of the clean room and air freely flowed through areas where the Velcro failed to adhere. One wall of the clean room had a hole on the left side of the laminar flow IV hood. The pharmacy had no certification of its powder hoods or balances.

b. Procedures for sterility and pyrogenic testing were not written and followed. Specifically, the pharmacy's master formula for sodium tetradecyl 3% injectable had an incorrect expiration date and did not state performance of quality reviews.

c. Prescription 102058 for Kaote-DVI stated that it was reconstituted on 12/29/15 and expired on 12/30/15, while the package insert indicated that the product expired 3 hours after reconstitution, requiring that the expiration date should have been 3 hours past reconstitution on 12/29/15.

d. Drug products did not bear appropriate expiration dates. The pharmacy assigned an inappropriate 30-day expiration date, handwritten on the product label, for sodium

tetradecyl Lot: 12152015@24. A 90-day expiration date was on the master formula work sheet and the PCCA updated the formula in February 2015 to 14 days.

e. The pharmacy compounded estriol/testosterone ointment but did not state on the product label that the ointment was compounded.

f. Routine calibration of equipment was not performed. A pharmacy employee used the balance prior to calibration and no documentation of the pH meter calibration was ever made available to Board inspectors for review.

g. Pharmacy employees engaged in non-sterile to sterile injectable compounding, weighing, stirring and checking in a non-ISO environment.

h. Opened and unopened boxes of portable cold packs, used to keep prescription medications cool, were stored in an unsanitary condition in the pharmacy's restroom.

i. Protective apparel was not worn as necessary to prevent contamination. Pharmacy employees entered and exited the cleanroom during compounding without being properly gowned and plastic bags containing used gowns were kept in the anteroom.

j. A pharmacy employee compounded a test product in the biological safety cabinet (BSC) IV hood with the blower off and front sash open.

k. Procedures designed to prevent contamination of drug products were not established and followed. A pharmacy employee moved supplies through the pass-through from a non-ISO area into an IS0-7 area without disinfecting them. Only the bottoms of vials were cleaned prior to placement in an IV hood. The same non-sterile, lint-free cloth was used to clean the inside of the IV hood after being sprayed with non-sterile 70% isopropyl alcohol before and after filling the sterile drug product. A pharmacy employee touched clean room cabinet drawer handles and resumed work in the IV hood without disinfecting his gloves. A bottle of expired Peridox RTU (sporicidal agent) was in the clean room and non-sterile 70% isopropyl alcohol was used to clean the clean room floors and walls. Policies and procedures did not state how to clean the stool and caulking gun located in the clean room and used to apply pressure to the syringe to force oil-based products through the sterile filter.

27. On or about January 16, 2016, Respondent Pharmacy issued a voluntarily nationwide recall of all unexpired lots of sterile compounded products due to concerns about sterility assurance. These included injectable medications, sterile solutions, eye drops, and eye ointments distributed to patients, physician offices and clinics, and veterinarians within California. On or about January 25, 2016, Respondent Pharmacy agreed to completely discontinue all sterile compounding activities.

28. On or about May 24, 2016, Respondent Pharmacy was acquired by Wellspring Compounding Pharmacy. Both Respondent's Pharmacy and Sterile Compounding Licenses expired on May 24, 2016, and were cancelled on May 25, 2016.

FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Pharmacy, Fixtures, Equipment)

29. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), for failure to maintain the pharmacy, fixture and/or equipment in a clean and orderly condition, in violation of California Code of Regulations, sections 1714 (c) and 1735.6 (b), as described in paragraph 25 (a), above, and herein incorporated.

SECOND CAUSE FOR DISCIPLINE

(Failure to Assign Proper Expiration Date and State Performance of Quality Reviews)

30. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), for failure to assign proper expiration dates and state performance of quality reviews, in violation of California Code of Regulations, section 1735.2, subdivisions (d)(3) and (e)(6), as described in paragraph 25 (b), above, and herein incorporated.

THIRD CAUSE FOR DISCIPLINE

(Failure to Correctly State Expiration Date on Prescription Label)

31. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), for failure to correctly state the product expiration date on the prescription label, in violation of Code section 4076(a)(9), and California Code of Regulations, section 1735.4, as described in paragraph 25 (c), above, and herein incorporated.

/ / /

FOURTH CAUSE FOR DISCIPLINE

(Failure to Assign Correct Expiration Date)

32. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), for failure to correctly assign a consistent and correct expiration date to a sterile drug product, in violation of Code section 4076(a)(9), and California Code of Regulations, section 1735.2 (h), as described in paragraph 25 (d), above, and herein incorporated.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Properly Label Compounded Product)

33. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), for failure to state on the product label that a compounded drug product was compounded, in violation of Code section 4076 and California Code of Regulations, section 1735.4 (c), as described in paragraph 25 (e), above, and herein incorporated.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Calibrate)

34. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), for failure to ensure that pharmacy staff assigned to compounding duties are knowledgeable about compounding processes and procedures, in violation of California Code of Regulations, section 1735.6 (c), as described above in paragraphs 28 through 32 (f) and herein incorporated.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Ensure Sterile Compounding Procedures)

35. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), for failure to ensure that sterile compounding occur in an appropriate ISO environment, in violation of Code section 4127.7 and California Code of Regulations, section 1250.4(5), as described in paragraph 25 (g), above, and herein incorporated.

///

///

///

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Maintain Sanitary Storage)

36. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), for failure to maintain proper storage to ensure drug safety, in violation of California Code of Regulations, section 1714 (b), as described in paragraph 25 (h), above, and herein incorporated.

NINTH CAUSE FOR DISCIPLINE

(Failure to Guard Against Contamination)

37. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), for failure to ensure gowning and storage requirements are met to prevent contamination of sterile drug preparations, in violation of California Code of Regulations, sections 1751.4 (a) and/or (b), as described in paragraph 25 (i), above, and herein incorporated.

TENTH CAUSE FOR DISCIPLINE

(Failure to Use Equipment/Train Staff as Required)

38. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), for failure to use compounding equipment in accordance with manufacturer specifications and to ensure the competency of pharmacy personnel using equipment to compound sterile drug preparations, in violation of California Code of Regulations, sections 1735.6 (b) and 1751.6 (d), as described in paragraph 25 (j), above, and herein incorporated.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Establish and Follow Cleaning and Disinfecting Procedures)

39. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), for failure to establish and follow procedures designed to prevent contamination of drug products, in violation of California Code of Regulations, section 1735.7 (c), as described in paragraph 25 (k), above, and herein incorporated.

///

///

///

TWELFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

40. Respondent Kwok is subject to disciplinary action for unprofessional conduct under Code sections 4113 (b), 4306.5 and/or 1751.6 (d), as described above in paragraphs 22 through 25, and herein incorporated.

OTHER MATTERS

41. Pursuant to Code section 4307, if discipline is imposed on Pharmacy License Number PHY 45060 issued to Respondent Pharmacy, it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy License Number PHY 45060 is placed on probation, or until reinstatement if Pharmacy License Number PHY 45060 is revoked.

42. Pursuant to Code section 4307, if discipline is imposed on Pharmacy License Number PHY 45060 issued to Respondent Pharmacy while John Garcia and/or Sharon Garcia have been officers and owners and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, John Garcia and/or Sharon Garcia shall be prohibited from serving as manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy License Number PHY 45060 is placed on probation, or until reinstatement if Pharmacy License Number PHY 45060 is revoked.

DISCIPLINE CONSIDERATIONS

43. To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy and/or Respondent Kwok, Complainant alleges that, effective January 8, 2016, in a decision before the Board of Pharmacy entitled *In the Matter of the Citation(s) Against Abbott's Compounding Pharmacy, Inc., and Elliot Chun-Pong Kwok*, Citation No. CI 2012 58440 issued to Respondent Pharmacy, and Citation No. CI 2012 58441 issued to Respondent Kwok, were affirmed and Respondents were each ordered to pay a fine of $5,000.00 for violations of pharmacy regulations governing the compounding of a high-risk sterile drug product. That decision is final and is incorporated by reference as if fully set forth herein.

///

44. To further determine the degree of discipline, if any, to be imposed on Respondent Kwok, Complainant alleges that, effective February 13, 1999, in a prior disciplinary action before the Board of Pharmacy entitled *In the Matter of the Accusation Against Elliot Chun-Pong Kwok*, Case No. 2031, Respondent Kwok's RPH License No. 30155 was revoked, with revocation stayed, and Respondent Kwok was placed on a three-year term of probation based on his 1996 conviction of a crime substantially related to the qualifications, functions and duties of a pharmacist.

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 License No. PHY 45060 issued to Abbott's Compounding Pharmacy (Respondent Pharmacy);

2. Revoking or suspending Sterile Compounding License No. LSC 99002 issued to Respondent Pharmacy;

3. Revoking or suspending Pharmacist License No. RPH 30155 issued to Elliot Chun-Pong Kwok (Respondent Kwok);

4. Prohibiting John Garcia from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy License Number PHY 45060 is placed on probation, or until reinstatement if Pharmacy License Number PHY 45060 is revoked;

5. Prohibiting Sharon Garcia from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy License Number PHY 45060 is placed on probation, or until reinstatement if Pharmacy License Number PHY 45060 is revoked;

6. Ordering Respondent Pharmacy and Respondent Kwok, 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 deemed necessary and proper.

DATED: 7/7/17

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

SF2016201268
41758147.doc