KAMALA D. HARRIS
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General
NICHOLAS TSUKAMAKI
Deputy Attorney General
State Bar No. 253959
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004
Telephone: (415) 703-1188
Facsimile: (415) 703-5480
E-mail: Nicholas.Tsukamaki@doj.ca.gov
Attorneys for Complainant

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

In the Matter of the Accusation Against: **LAUDEN INTEGRATIVE PHARMACY, INC.** **1820 41st Avenue, Suite F** **Capitola, CA 95010** **Original Permit No. PHY 43209** **Sterile Compounding License No. LSC 99162** **and** **MEHRDAD REYHANI** **394 Brooktree Ranch Road** **Aptos, CA 95003** **Pharmacist License No. RPH 45597** Respondents.	Case No. 5963 **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, Department of Consumer Affairs.

2. On or about August 22, 1997, the Board of Pharmacy (Board) issued Original Permit No. PHY 43209 to Lauden Integrative Pharmacy, Inc. (Respondent Lauden). The Original Permit

was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2017, unless renewed.

3. On or about July 28, 2003, the Board issued Sterile Compounding License No. LSC 99162 to Lauden. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2017, unless renewed.

4. On or about August 24, 1992, the Board issued Pharmacist License No. RPH 45597 to Mehrdad Reyhani (Respondent Reyhani). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2018, unless renewed.

JURISDICTION

5. 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.

6. 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.).

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

8. 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

9. Section 4301 of the Code states:

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

. . .

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

. . .

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

. . ."

10. Health and Safety Code section 11164 provides, in pertinent part:

"Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

"(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements . . . .

. . .

"(b)(1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription."

11. Health and Safety Code section 11165, subdivision (d) provides, in pertinent part:

"For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal

Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

. . ."

12. Health and Safety Code section 11200, subdivision (b) states: "No prescription for a Schedule III or IV substance may be refilled more than five times and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply."

REGULATORY PROVISIONS

13. California Code of Regulations, title 16, section 1711 provides, in pertinent part:

"(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

. . .

"(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. . . .

. . .

"(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created."

14. California Code of Regulations, title 16, section 1716 provides, in pertinent part: "Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code."

///

15. California Code of Regulations, title 16, section 1717 provides, in pertinent part:

"(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. . . ."

16. California Code of Regulations, title 16, section 1717.3, subdivision (a) states: "No person shall dispense a controlled substance pursuant to a preprinted multiple check-off prescription blank."

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

"(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:

. . .

"(2) Equipment to be used.

. . .

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

. . ."

18. California Code of Regulations, title 16, section 1735.4 provides, in pertinent part:

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

. . .

"(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. . . ."

19. California Code of Regulations, title 16, section 1751.6 provides, in pertinent part:

"(b) The pharmacist-in-charge shall ensure that all pharmacy personnel engaging in compounding sterile drug preparations have training and demonstrated competence in the safe handling and compounding of sterile drug preparations, including hazardous agents if the pharmacy compounds products with hazardous agents.

"(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

. . .

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

. . .

"(2) Each person engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years."

COSTS

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

FACTUAL BACKGROUND

21. On or about March 9, 2016, two Board Inspectors performed an inspection of Lauden Integrative Pharmacy.

22. During the inspection the Inspectors determined that the pharmacy was verifying compounded products without having completed required staff training.

23. The Inspectors also discovered approximately 58 schedule III and IV controlled substance prescriptions from approximately February 1, 2013 to February 16, 2016 that Respondents had either refilled more than five (5) times or had refilled in quantities exceeding a 120-day supply.

24. The Inspectors discovered approximately five (5) filled controlled substance prescriptions that were on pre-printed, multiple check-off type forms.

25. The Inspectors discovered approximately twenty-seven (27) filled controlled substance prescriptions that had been transmitted by phone and that were not reduced to writing, initialed by the pharmacist, or identified as orally transmitted prescriptions.

26. The Inspectors discovered approximately four (4) filled controlled substance prescriptions that were not written on a proper controlled substance prescription form.

27. The Inspectors discovered a prescription for liquor carbonis detergens 2% in mometasone 0.1% cream. The label for this prescription used the acronym "LCD" rather than spelling out "liquor carbonis detergens." Respondents mistakenly prepared this prescription as an ointment rather than as a cream. At the time of the inspection, a quality assurance record for that medication error was not immediately retrievable.

28. One of the Inspectors reviewed master formulas for alprostadil 100 mcg/ml, alprostadil 500 mcg/ml, and trimix. Those master formulas were missing the equipment to be used during compounding and the quality reviews required at each step in preparation of the drug.

29. The Prescription Drug Monitoring Program, which is part of the Controlled Substance Utilization Review and Evaluation System (CURES), requires weekly reporting of dispensed schedule II-IV controlled substance prescriptions. On six (6) occasions between approximately May 2013 and January 2016, Respondents submitted CURES reports at more than 7 day intervals.

FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Record of Quality Assurance Review)

30. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and/or (o) of the Code and California Code of Regulations, title 16, section 1711, subdivisions (e) and/or (f), in that Respondents made an error in filling a medication and a quality assurance record for that medication error was not immediately retrievable in the pharmacy. The circumstances of Respondents' conduct are set forth above in paragraph 27.

///

SECOND CAUSE FOR DISCIPLINE

(Maintaining Incomplete Master Formulas for Compounded Drugs)

31. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and/or (o) of the Code and California Code of Regulations, title 16, section 1735.2, subdivisions (e)(2) and (e)(6), in that Respondents maintained master formulas for certain compounded drugs that were missing the equipment to be used during compounding and the quality reviews required at each step in preparation of the drugs. The circumstances of Respondents' conduct are set forth above in paragraph 28.

THIRD CAUSE FOR DISCIPLINE

(Deviation from Prescription Requirements)

32. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and/or (o) of the Code and California Code of Regulations, title 16, section 1716, in that Respondents deviated from the requirements of a prescription. The circumstances of Respondents' conduct are set forth above in paragraph 27.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Provide Name of Compounded Drug on Container Label)

33. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and/or (o) of the Code and California Code of Regulations, title 16, section 1735.4, subdivision (a)(2), in that Respondents failed to provide the name of a compounded drug on that drug's container label. The circumstances of Respondents' conduct are set forth above in paragraph 27.

FIFTH CAUSE FOR DISCIPLINE

(Performing CURES Reporting at Longer than Permitted Intervals)

34. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and/or (o) of the Code and Health and Safety Code section 11165, subdivision (d), in that Respondents submitted CURES reports at more than seven (7) day intervals. The circumstances of Respondents' conduct are set forth above in paragraph 29.

///

///

SIXTH CAUSE FOR DISCIPLINE

(Excessive Refills of Controlled Substances)

35. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and/or (o) of the Code and Health and Safety Code section 11200, subdivision (b), in that Respondents refilled certain schedule III and IV controlled substance prescriptions either more than five (5) times or in quantities exceeding a 120-day supply. The circumstances of Respondents' conduct are set forth above in paragraph 23.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Compounding Training)

36. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and/or (o) of the Code and California Code of Regulations, title 16, section 1751.6, subdivisions (b), (c), and/or (e)(2), in that Respondents failed to maintain records of compounding training as required. The circumstances of Respondents' conduct are set forth above in paragraph 22.

EIGHTH CAUSE FOR DISCIPLINE

(Dispensing Controlled Substances Based on Improper Forms)

37. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and/or (o) of the Code and California Code of Regulations, title 16, section 1717.3, subdivision (a), in that Respondents dispensed controlled substances pursuant to preprinted multiple check-off prescription forms. The circumstances of Respondents' conduct are set forth above in paragraph 24.

NINTH CAUSE FOR DISCIPLINE

(Inadequate Documenting of Orally Transmitted Prescriptions)

38. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and/or (o) of the Code, Health and Safety Code section 11164, subdivision (b)(1), and California Code of Regulations, title 16, section 1717, subdivision (c), in that Respondents filled orally transmitted controlled substance prescriptions without reducing the prescriptions to writing, initialing them, and/or identifying them as orally transmitted prescriptions. The circumstances of Respondents' conduct are set forth above in paragraph 25.

TENTH CAUSE FOR DISCIPLINE

(Filling Prescriptions Based on Improper Prescription Forms)

39. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and/or (o) of the Code and Health and Safety Code section 11164, subdivision (a), in that Respondents filled controlled substance prescriptions that were not written on a proper controlled substance prescription form. The circumstances of Respondents' conduct are set forth above in paragraph 26.

DISCIPLINE CONSIDERATIONS

40. To determine the degree of discipline, if any, to be imposed on Respondent Lauden, Complainant alleges that on or about November 9, 2015, in Case No. CI 2011 49844, the Board issued a Modified Citation and Fine to Respondent Lauden based on a violation of section 4126.5, subdivision (a)(4) of the Code (non-compliant sales to a wholesaler). That Citation is now final and is incorporated by reference as if fully set forth herein.

41. To determine the degree of discipline, if any, to be imposed on Respondent Lauden, Complainant further alleges that on or about December 12, 2014, in Case No. CI 2014 62140, the Board issued a Modified Citation to Respondent Lauden based on a violation of section 4169, subdivision (a)(1) of the Code (purchasing from an unlicensed entity). That Citation is now final and is incorporated by reference as if fully set forth herein.

42. To determine the degree of discipline, if any, to be imposed on Respondent Reyhani, Complainant alleges that on or about February 23, 2012, in Case No. CI 2011 51418, the Board issued a Citation and Fine and Order of Abatement to Respondent Reyhani based on a violation of section 4126.5, subdivision (a)(4) of the Code (non-compliant sales to a wholesaler). That Citation is now final and is incorporated by reference as if fully set forth herein.

43. To determine the degree of discipline, if any, to be imposed on Respondent Reyhani, Complainant further alleges that on or about March 28, 2014, in Case No. CI 2013 60628, the Board issued a Citation and Fine to Respondent Reyhani based on a violation of California Code of Regulations, title 16, section 1751.7, subdivision (c) (dispensing sterile injectable drug products that are compounded from more than one non-sterile ingredient before receipt of end

product testing results). That Citation is now final and is incorporated by reference as if fully set forth herein.

44. To determine the degree of discipline, if any, to be imposed on Respondent Reyhani, Complainant further alleges that on or about August 22, 2014, in Case No. CI 2014 62142, the Board issued a Citation and Fine to Respondent Reyhani based on a violation of section 4169, subdivision (a)(1) of the Code (purchasing from an unlicensed entity). That Citation is now final and is incorporated by reference as if fully set forth herein.

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 Permit No. PHY 43209 issued to Lauden Integrative Pharmacy, Inc.;

2. Revoking or suspending Sterile Compounding License No. LSC 99162 issued to Lauden Integrative Pharmacy, Inc.;

3. Revoking or suspending Pharmacist License No. RPH 45597 issued to Mehrdad Reyhani;

4. Ordering Lauden Integrative Pharmacy, Inc. and Mehrdad Reyhani 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,

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

DATED: 1/11/17

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

SF2016201629
41632024.doc